

# Bioentrepreneurship Development



A Resource Book



BCIL

**Biotech Consortium India Limited**

Anuvrat Bhawan, 5th Floor, 210, Deen Dayal Upadhyaya Marg, New Delhi - 110 002



BCIL

**Biotech Consortium India Limited**

2018

## **Bioentrepreneurship Development: A Resource Book**

### **Prepared by**

Biotech Consortium India Limited (BCIL), New Delhi

Material from this publication may be used for educational purpose

### **Compiled by:**

Ms. Shreya Sanghvi Malik, Deputy Manager

Dr. Shiv Kant Shukla, Deputy General Manager

### **For further information, please contact:**

Biotech Consortium India Limited

5th Floor, Anuvrat Bhawan

210, Deen Dayal Upadhyaya Marg

New Delhi - 110 002

Email: [info.bcil@nic.in](mailto:info.bcil@nic.in)

## Table of Contents

|    |                                            |           |
|----|--------------------------------------------|-----------|
| 1  | Entrepreneurship                           | 1 - 13    |
| 2  | Profiling the Bioentrepreneur              | 14 - 17   |
| 3  | Entrepreneurial Opportunity                | 18 - 30   |
| 4  | Entrepreneurial Planning                   | 31 - 46   |
| 5  | Commercialization Process & Strategy       | 47 - 57   |
| 6  | Management of Intellectual Property Rights | 58 - 77   |
| 7  | Financial Management                       | 78 - 89   |
| 8  | Financial Statements                       | 90 - 99   |
| 9  | Human Resource Management                  | 100 - 108 |
| 10 | Marketing Strategy                         | 109 - 130 |
| 11 | Strategies for Partnering & Collaboration  | 131 - 133 |
| 12 | Negotiation Skills                         | 134 - 140 |
| 13 | Managing Regulatory Requirements           | 141 - 143 |
| 14 | Funding Opportunities & Incentives         | 144 - 161 |
| 15 | Government Initiatives for Startups        | 162 - 173 |
| 16 | Preparing Business Plan                    | 174 - 189 |
|    | <i>References</i>                          | 190 - 191 |

---

# 1. ENTREPRENEURSHIP

---

***“The best way to predict the future is to create it.”***

**– Peter Drucker**

The Indian biotechnology industry is one of the fastest growing knowledge based sectors. India currently ranks amongst the top 12 biotechnology destinations in the world, and is a global leader in the production of drugs and vaccines. For an economy like India, biotechnology is a powerful enabling technology that can revolutionize agriculture, healthcare, industrial processing and environmental sustainability. According to a forecast by the Association of Biotechnology Led Enterprises (ABLE), the Indian biotechnology industry sector has the potential to be \$ 100 billion (Rs. 6 lakh crore) industry in the next decade.

The Indian biotechnology industry can be broadly classified into five categories namely biopharmaceuticals, bioagriculture, bioservices, bioindustry and bioinformatics. There are approximately 800 – 850 large, medium, small and startup companies in the biotechnology and allied sectors. Within the different sectors in biotechnology, there are multiple disciplines which are huge specialties on their own.

- Biopharma – Drugs, vaccines, diagnostics
- Bioindustrial – Biofuels, nutraceuticals, enzymes
- Bioagri – Hybrid crops, biopesticides, biofertilizers
- Bioservices – custom synthesis & manufacturing and contract research
- Bioinformatics – data analytics and software and database services.

India is in an advantageous position to harness the potential of biotechnology due to its unique strengths such as availability of rich bio-resources, technical expertise, skilled manpower, progressive government policies and rapidly expanding access to international markets.

Promotion of the Indian biotechnology sector is high on the policy agenda of the Government of India. Biotechnology has been recognized as one of the key priority sectors under the 'Make in India', 'Skill India' and 'Startup India' initiative of the Government of India, being one of the few sectors on strong growth trajectory to drive sustainable economic growth and generate large scale employment opportunities.

The DBT National Biotechnology Development Strategy 2015 – 2020 provides a strategic roadmap for India's emergence as a global biotechnology innovation and manufacturing hub and to contribute towards enterprise creation, innovation and economic growth. In order to achieve the \$100 billion target of the Indian biotech industry, there is a crucial need to strengthen the existing biotech industries as well as create new biotech industries.

Entrepreneurship based on innovation has immense growth potential. Given this context, encouraging and promoting self-employment as a career option for young people will be of highest importance. Most policymakers and academics agree that entrepreneurship is critical to the development and wellbeing of society. Entrepreneurs drive and shape innovation, thereby speeding up structural changes in the economy. Entrepreneurship is thus a catalyst for economic growth and national competitiveness.

Entrepreneurship was first coined as a term in the eighteenth century but it was not until the second half of this century that the term achieved widespread usage and became a focus of

concentrated academic research. An entrepreneur is an individual who accepts financial risks and undertakes new financial ventures. The word derives from the French "entre" (to enter) and "prendre" (to take), and in a general sense applies to any person starting a new project or trying a new opportunity.

Many societies place great value on the entrepreneur. To encourage their activity, they may be offered access to inexpensive capital, tax exemptions and management advice. An entrepreneur has the greatest chance of success by focusing on a market niche either too small or too new to have been noticed by established businesses. To help new technologies come to market, many universities have established business incubators for entrepreneurs hoping to turn leading edge research into marketable products.

Entrepreneurship has evolved through the centuries and it has been viewed differently according to conditions prevailing in the world economy. The new-age business ventures are more idea-centric and not just product-based. The key to success in business is not just inheritance; it is creation of more wealth and the constant innovation, from the prevailing to the next best practices. An entrepreneur, typically, is inspired to start a business because the entrepreneur perceives a consumer need that is not being adequately filled. This area of need - sometimes called an "opportunity niche" - can usually be expressed as a problem statement.

*An entrepreneur is a person who starts an enterprise. An entrepreneur is someone who perceives opportunity, organises resources needed for exploiting that opportunity and exploits it.*

Characteristics of an entrepreneur include spontaneous creativity, the ability and willingness to make decisions in the absence of solid data, and a generally risk-taking personality. An entrepreneur may be driven by a need to create something new or build something tangible.

Clearly, all businesses have, at some time, been 'startups'. Equally clearly, not all grow to provide employment, profitability and exports; a considerable number do not survive beyond their first year. This caveat aside, it is now widely appreciated that entrepreneurial activity is a fundamentally important driver of innovation, business growth and economic change.

There is an important underlying human story to owning a small business and this provides a focus for this course. Although many people at some time express a desire to 'work for themselves' or to 'be their own boss', only a minority do so. In this workshop we will focus on the business plans, financial management, marketing, behaviours, motivations and business strategies of entrepreneurs in addition to discussions on the core subject of biotechnology.

### **1.1 Process of Entrepreneurship**

Although enterprises are as different and unique as the entrepreneurs who create them, most of them appear to work through a process. The diagram given below describes the process through which most of them create their enterprise.

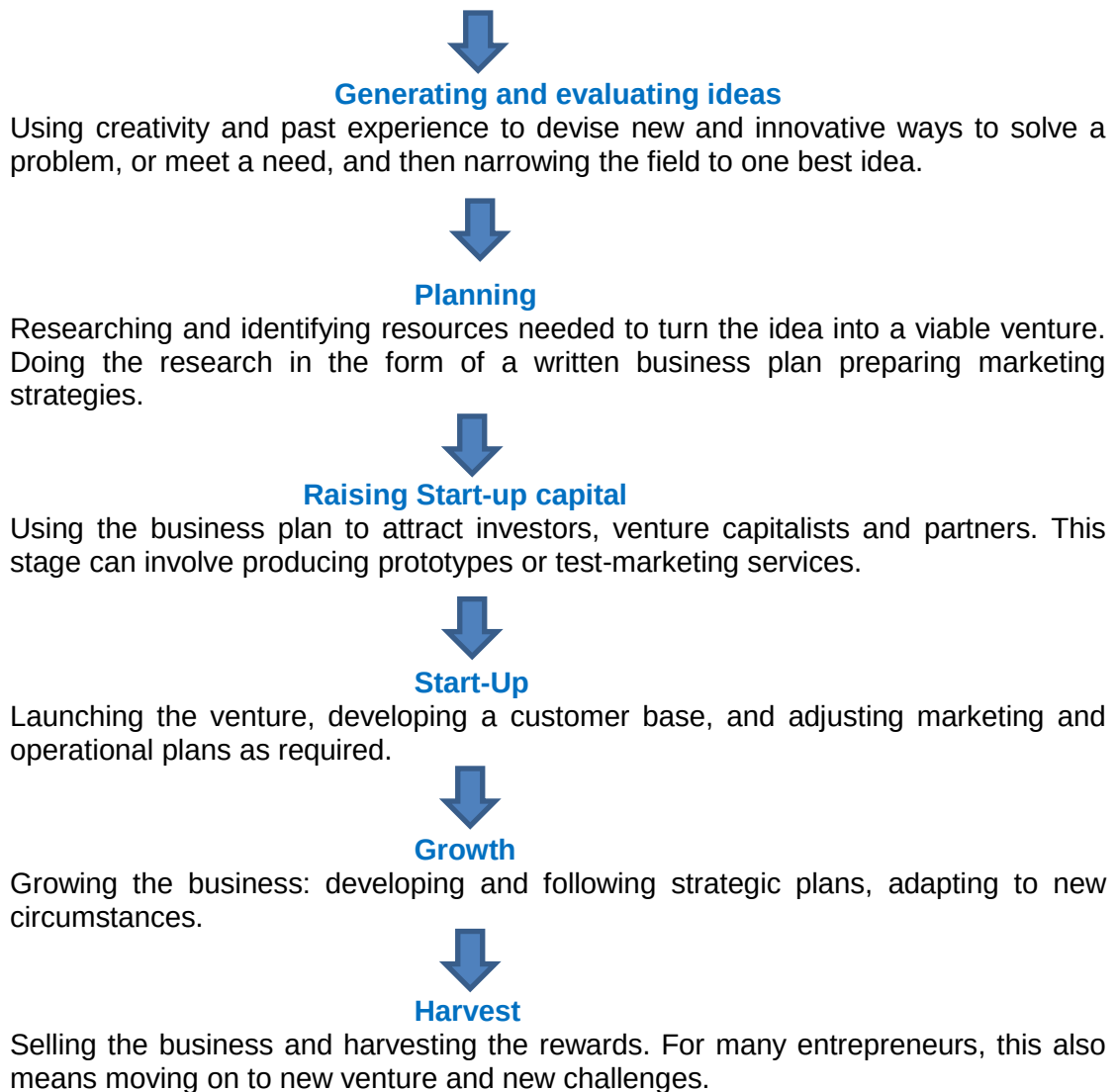
#### **Self-Discovery**

Learning what they enjoy doing; examining their strengths and weaknesses. Examining work experience and relating it to potential opportunities.



#### **Identifying opportunities**

Looking for needs, wants, problems, and challenges that are not yet being met, or dealt effectively.



## 1.2 ***What is Entrepreneurship?***

Entrepreneurship can be described as a process of action an entrepreneur undertakes to establish his enterprise. Entrepreneurship is a creative activity. It is the ability to create and build something from practically nothing. It is a knack of sensing opportunity where others see chaos, contradiction and confusion. Entrepreneurship is the attitude of mind to seek opportunities, take calculated risks and derive benefits by setting up a venture. It comprises of numerous activities involved in conception, creation and running an enterprise.

According to Peter Drucker, Entrepreneurship is defined as 'a systematic innovation, which consists in the purposeful and organised search for changes, and it is the systematic analysis of the opportunities such changes might offer for economic and social innovation.'



The entrepreneurial role encompasses the following responsibilities:

- Perception of market opportunities
- Gaining command over scarce resources
- Purchasing inputs
- Marketing the products
- Dealing with bureaucrats
- Managing human relations within the firm
- Managing customer and supplier relations
- Managing finance
- Managing production
- Acquiring and overseeing assembly of the factory
- Industrial engineering
- Upgrading process and product
- Introducing new production techniques and products.

### **1.3 Competencies of an Entrepreneur**

The entrepreneurial values and attitudes provide the necessary backdrop for acquiring the sense of enterprise. It is however necessary that a budding entrepreneur should have the necessary competencies so that he/she can venture into an enterprise. Competency is a set of defined behaviours that provide a structured guide enabling the identification, evaluation and development of the behaviours in an individual.

Entrepreneurial Competencies are certain basic competencies to be acquired by an entrepreneur. They relate to the type of behaviour exhibited in the performing of various tasks in the discharge of his functions. Some of these competencies are latent in the entrepreneur, which need to be identified, nursed and nurtured. Others are acquired through training and practice. The entrepreneurial competencies can be classified under the following categories:

- **Initiative:** One of the most fundamental competencies required for the entrepreneurs is the ability to take initiative. It is rather the first step in the enterprise. An entrepreneur has to be keen observer of the society, the commercial trends, the product types, the change dynamics and the consumer trends. Once he/she decides to take the initiative, what matters is the speed with which he/she is going to function.
- **Creativity and Innovation:** Competency in creativity and innovation are sometimes basic traits of certain individuals. He/she might not have any new ideas. He/she may use the creative ideas and innovative products and services to meet the challenges of a situation, take advantage of the utility of an idea or a product to create wealth. Example, changes in the packaging of potato chips.
- **Risk Taking and Risk Management:** An entrepreneur ventures into new ideas and new service. He/she treads into areas of uncertainty. There are several elements such as demand supply in the market, resources availability, acceptability of the product design and service which throw a potential challenge to the entrepreneur. In order to attune oneself in the skill of risk taking and management he should practice in several areas of entrepreneurial functions such as entering into new market. For example, when Dhirubhai Ambani faced cash crunch he took the risk of issuing shares in 1977 to the public when they were not that aware about share market.
- **Problem Solving:** Once an entrepreneur is aware that he has ventured on a new area and has taken certain calculated risks, he/she should also be aware

that many problems are bound to come in the path of progress. He/she should understand that there is more than one way of solving problems, look for alternative strategies or resources that would help to solve the problem, generate new ideas, products, services etc. For example: When an entrepreneur faces cash crunch he should look for alternative sources for receiving funds. Ratan Tata shifted the manufacturing plant of Nano cars from Singur to Sanand due to unforeseen complexities.

- **Leadership:** An entrepreneur should also be an effective leader who should be able to guide and motivate his/her entire team. Whenever a company faces problem it is the will power and effective business acumen and communication skills which oversees the success of the corporation.
- **Persistence:** In most cases, the entrepreneurial pursuits are new and need very close attention. Creating a need in the market for the enterprise is one of the main requirements of the entrepreneur. This calls for intense perseverance on the part of the entrepreneur. Roadblocks to success should not deter the entrepreneur. For example: Mixers when introduced did not have many customers but today, we find it to be an essential part of kitchen accessories. When Mahima Mehra brought out her product – Haathi Chaap, she had experimented on various other material before using elephant dung to manufacture handmade paper.
- **Quality Performance:** Since entrepreneurs value outstanding performance, one of the behavioural skills necessary is the sensitivity to and concern for the 'standards' and 'quality of work'. One develops the skill of comparing the quality of the product/services with certain standards, which he/she himself evolves or are set by others. For example: Steve Jobs, the brain behind Apple and I-pod, is known to value quality in all the products introduced by the company.
- **Information Seeking:** Information plays a very crucial role at every stage of enterprise building and management. The quality and extent of information collected and the way these have been used to make various decisions by and large decides the success and failure of any entrepreneurial venture. They can get this information by personally conducting research, using feedback from previous related experience etc.
- **Systematic Planning:** Every entrepreneur has limited resources in terms of time, finance, and manpower. They invest their life's saving and total energy in creating entrepreneurial ventures and cannot afford to lose or waste these. Before putting the whole enterprise into operation, he is required to develop a detailed blueprint.
- **Persuasion and Influencing Others:** One of the important functions of an entrepreneur is to influence the environment comprising of individuals and institutions, for mobilizing resources, obtaining inputs, organising production and selling products and services. They have to practice highlighting the strong points of their products and services in the market explaining the technological competencies of their enterprise to produce quality goods and services.
- **Enterprise Launching Competencies:** Opportunities exist, but not all people respond to them. Large groups in society can perceive only the apparent and traditional openings of earning. Similarly, resources are also available to all members of the society, but very few make efforts to ensure best use of these resources. Entrepreneurs should identify and avail the facilities and resources needed to launch their enterprises.
- **Enterprise Management Competencies:** The enterprise may be small or big but it demands management abilities on the part of its owner or manager. Various management functions such as production, marketing, finance etc., are crucial functions to entrepreneurs. These influence the result directly, and therefore, are necessary determinants for the sustenance of an enterprise.

## **1.4 Types of Entrepreneurs**

Entrepreneurs can be of different types. Some may prefer to go it alone or share the risk in groups with others. They are found in every economic system and every form of economic activity as well as in other social and cultural activities. They are seen from amongst farmers, labourers, fishermen, tribes, artisans, artists, importers, exporters, bankers, professionals, politicians, bureaucrats and so many others. Based on the above features C. Danhof has broadly classified entrepreneurs into four types. These are discussed below.

### **1.4.1 Innovative Entrepreneur:**

In the early phases of economic development, entrepreneurs have initiative to start new ventures and find innovative ways to start an enterprise. Thus, innovative entrepreneurs are those who introduce new products, new methods of production techniques, or discover a new market or a new service or reorganises the enterprise. It is the innovative entrepreneurs who built the modern capitalism. They are commonly found in developed countries. They are aggressive in nature who exhibit cleverness in putting attractive possibilities into practice. Example: Walt Disney who started huge theme parks such as the Disney Land.

### **1.4.2 Imitative Entrepreneur:**

There is a second group, generally referred to as imitative entrepreneurs. They usually copy or adopt suitable innovations made by innovative entrepreneurs. They are adaptive and more flexible. They are organisers of factors of production rather than creators. The imitative entrepreneurs are also revolutionary and important. They contribute to the development of underdeveloped economies. Example: The local mobile companies using the same technology as big companies to manufacture their products.

### **1.4.3 Fabian Entrepreneurs:**

The third type is the Fabian Entrepreneurs. Such entrepreneurs are very shy and lazy. They are very cautious. They do not venture or take risks. They are rigid and fundamental in their approach. Usually, they are second generation entrepreneurs in a family business enterprise. They follow the footsteps of their predecessors. They imitate only when they are sure that failure to do so would result in a loss of the relative position in the enterprise.

### **1.4.4 Drone Entrepreneurs:**

The fourth type is the Drone Entrepreneurs, who refuse to copy or use opportunities that come their way. They are conventional in their approach. They are not ready to make changes in their existing production methods even if they suffer losses. They resist changes. They may be termed as laggards.

## **1.5 Self-Assessment of Qualities, Skills, Resources and Dreams: Identify your personality type before starting a business venture**

An article by Bill Wagner answers the question as to whether personality matters in becoming a successful entrepreneur. Recent studies say yes, successful entrepreneurs share a number of common personality traits, and these traits are the predominant indicators of their success. People, who choose business ventures that are in sync with their true personalities, tend to experience the greatest level of success and fulfilment.

Every personality type, and therefore, every person, has the potential to grow a successful business. One just needs to determine the right opportunity. Self-awareness guides us in understanding what's needed to bridge the gap between who we are and what the opportunity requires. According to him, entrepreneurs can be divided into seven types.

**1.5.1 Trailblazers:** Trailblazers are very competitive, ambitious and goal-oriented, so much so that they tend to be aggressive and sometimes take a steamroller approach. They are restless and energetic, with a strong drive and a sense of urgency, regardless of the task at hand. They tend to have two speeds: fast and faster. Independent, persistent and decisive, they aren't happy unless they are in charge. They are logical, analytical, practical and realistic, they tend to base decisions on facts rather than feelings. They are calculated risk takers. Their business strengths could include the medical, technology, finance, legal and consulting fields. Being strong strategic thinkers, they focus easily on marketing and operations. Their challenge is likely to be working with people, they are usually better leaders than managers and need to surround themselves with others, who can manage the people side of the business. Trailblazers prefer being the driving force of a business. They typically wouldn't buy a franchise or distributorship, but they would start a company that competes with a franchise. They are highly innovative, especially when it comes to taking an idea to the next level.

**1.5.2 Go-getters:** They have a higher-than-average level of both dominance and sociability and are very driven and independent. Go-Getters represent the largest percentage of the founders. Their natural style lends itself to managing and leading both processes and people. They show a great deal of initiative, coupled with a compelling sense of urgency to get things done. Go-Getters are typically good leaders and good managers, excelling at motivating themselves and those around them. The go-getter's business strengths could include doing well in retail, but may prefer being the outside rainmaker. They work well in ambitious and unfamiliar environments. This means they can invest in, buy or start a business that's totally new to you and still make a success of it. They don't need to be an expert in the field to start the business, they are good collaborators and can learn as they go.

**1.5.3 Managers:** They are dominant and independent. In their case, these two characteristics feed each other, so they can appear to be even more dominant or independent than they actually are. They are also very goal-oriented and can be quite analytical, focusing more on processes and outcomes than on people. They have a tendency to look at people as vehicles for helping them accomplish their goals. Consequently, they sometimes disregard or overlook the people part of the equation or unwittingly offend people with their straightforward style of communication. Unlike the two previous entrepreneurial types, Managers have a higher-than-average level of relaxation and know that some projects simply take more time to complete and some goals take longer to achieve than others. They are loyal, sometimes to a fault, as they consider their employees to be an extension of their family. They can deal well with customers, especially repeat customers, so they'll probably be great at growing a business. The manager's business strengths are: Doing things on their own, as great behind-the scene leaders who love working with systems, concepts, ideas and technologies. They excel at competitive selling because they enjoy overcoming rejection and achieving goals despite obstacles. Managers enjoy working by themselves, and managing others can be a challenge, so they need to hire employees who are better than them at listening and working well with others.

**1.5.4 Motivators:** They have a high level of sociability, an above-average level of dominance, and are both driven and independent. This also gives them the ability to work well under pressure and in autonomous situations. It also means that they will be a great consensus builder, a good collaborator and a driver of change. Just like the name suggests, they are the consummate motivator who does well working by, with and through others. The motivator's business strengths: Retail can be their game - or any environment where people are a large part of the equation. They do well in almost any business that involves people, as long as it's a somewhat non-confrontational environment. They can be convincing and avoid most confrontations by creating a strong emotional argument. Motivators do well in the toughest of customer service roles, as they are able to see both sides of the argument. They tend to deal with even the most negative arguments by using the three F's - feel, felt and found - saying, "I understand how you are feeling. In fact, I have felt the same way, but when I learned (inserting their point), what I found was (again, insert your point)". Motivators excel at leadership or sales. They do well in business with partners, or in a business that involves others. Motivators are good at nurturing relationships and often do best in a business that involves keeping clients for the long term. They thrive in a team environment.

**1.5.5 Authoritarians:** They are the backbone of society. Authoritarians are the loyal workers who make the world function. They make their products, service their systems, and always do it right. As an Authoritarian, they may not always be the best founders of an entrepreneurial enterprise, but they can be an excellent distributor, franchisee or owner of an existing business; they can do well when they purchase an ongoing operation. They are detail- and tactic-oriented, and motivated by doing things one- way-the right way. They are very conscientious and cooperative, following rules, procedures and policies carefully. Very thorough with details, they're cautious, deliberate, logical and analytical. They are also relaxed, patient and accommodating by nature, and are a great team player who tends to avoid confrontation. Because they are accommodating, they may dislike prospecting, so they may need to be in a business where customers or clients are driven to them. Most authoritarians need a partner with a stronger natural ability to prospect or network. They can be very successful buying a franchise or business opportunity, as long as the organization is well-supported with advertising and marketing.

**1.5.6 Collaborators:** The primary difference between collaborator and authoritarian is that they have a personality gift called sociability. It's this characteristic that allows them to use their influence to get what they want. It's all about people—they relish the people side of business. They typically benefit from having a partner who is more aggressive about developing new business. Collaborators usually aren't comfortable with cold calling or pitching new ideas; they like to follow prescribed rules and guidelines. Collaborators are good at running customer service-oriented or retail businesses, or any business where being convincing is an important aspect of getting the job done, and done right. From an entrepreneurial perspective, collaborators do well within structured environments where people are an element of success. Collaborators can be great salesmen in a warm selling market because they use their sociability to sell their expertise. 'Warm selling' means they bring the prospect to them, often through a letter or advertisement enticing the prospect to contact them for more information about their product or service. Once

prospects do get in touch, their expertise takes over, and they sell your heart out. On the other hand, cold selling, which generalist personalities typically do well, involves picking up the phone and dialling for dollars, or hitting the streets looking for prospects door to door.

**1.5.7 Diplomats:** They are restless and enjoy working under a certain amount of pressure. They get things done quickly and work well with deadlines. They adjust easily to change and deal well with new situations. They have a high sense of urgency and like variety, and because of their compliance and their need to do things right, they work at their full capacity. They multitask and keep a variety of jobs going at once. Active and energetic, they vigorously attack the parts of their business that they enjoy. They can experience difficulty in delegating details, but do a great job when they can do the work themselves. Diplomats are considered to be the best of the specialist entrepreneurs, as they have both sociability and drive in their personalities. These are two important elements to success. Like most specialists, they are not the greatest rainmaker, but once they have a client or prospect, they do a great job of keeping them. The diplomat's excel in retail or other people-oriented environments. Both outgoing and empathetic, they tend to be well-liked, but they sometimes have a hard time asserting them self and holding others accountable. Therefore, to successfully lead a company, they typically need to hire stronger, more results-oriented personalities, to be sure that deadlines are met, commitments are kept and staff members follow through on duties.

## **1.6 *Advantages and Disadvantages of Entrepreneurship***

To everything in life, there are advantages and disadvantages; entrepreneurship is no exception. As a matter of fact, entrepreneurship involves a lot of risk taking. Yet, it can pay off very well, with rewards such as profits, the opportunity to be your own boss and make your own decisions. Here are some advantages and disadvantages to consider:

### **1.6.1 Advantages –**

- **Excitement:** Due to its high capacity for risk, there is a lot of adventure for example, Steve Jobs left his position in Apple Inc., and started Pixar, which later turned out to be a successful venture.
- **Originality:** Some feel that they can offer a new service or product that no one else has offered before, i.e., I-pod and I-pad
- **Independence:** Some wish to be their own boss and make all the important decisions themselves.
- **Desired Salary:** They are not being paid what they are worth and would rather work on their own and earn the money they should be earning for their efforts.
- **Freedom:** Entrepreneurs can work on any idea which they feel will eventually turn out to be a successful venture, for instance, Richard Branson's idea of space mission.

### **1.6.2 Disadvantages –**

- **Unstable Income:** Starting your own business means that you must be willing to give up the security of a regular pay check.
- **Fewer Benefits:** There will undoubtedly be fewer benefits, especially when considering that your business will be just starting off.

- Work schedule: The work schedule of an entrepreneur is never predictable; an emergency can come up in a matter of a second and late hours may become the norm.
- Administration: All the decisions of the business must be made on his/her own; there is no one ranked higher on the chain of command in such a business, and the fear of a wrong decision can have its own effect.
- Incompetent staff: Most of the time, the entrepreneurs will find themselves working with employees who "don't know the ropes" as well as they do, due to lack of experience.

### 1.7 Entrepreneurial Motivation

Men and women who have a perception of self-efficacy and are yet to feel interested in or motivated by the idea of being on their own comprise a potential, future source of entrepreneurship. What motivates a person is a question easier asked than answered. Mr. Narayan Reddy was driven by the desire to utilise his discovery of the molecule as a business opportunity. In terms of Maslow's need hierarchy theory, one may say that Mr. Narayan Reddy was driven by the need for self-actualisation. Since entrepreneurial situation is characterised by personal accomplishment in competitive situations and involving higher standards of excellence, one often across reference to 'need for achievement' as the primary driver of entrepreneurial behaviour.

#### SEEDS OF VIRCHOW

*Until 1981, Narayan Reddy, M.Sc. Organic Chemistry, had been working for a pharmaceutical company where he had developed a molecule. He was contemplating commercial utilisation of that molecule by setting up a small-scale unit – much smaller than what he actually started. Actually, he met two medicos, who had just returned from a Gulf country and were looking for some productive avenue for investment of their savings, Reddy's idea appealed to them. Thus, the willing entrepreneurs met– where there is a will there is a way– and the seeds for the venture were sown. After a detailed study of the technical, economic, commercial and financial feasibility of the idea of manufacturing a bulk drug from the molecule, 'Virchow Laboratories' was started in 1982 as a SSI with an initial investment of Rs. 28 lakhs – Rs. 8 lakh in the form of equal contribution by the three promoters and Rs. 20 lakh funding from the Andhra Pradesh State Finance Corporation (APSFC). Project implementation was even more challenging as he set out to acquire land, construct factory, purchase equipment, negotiate with suppliers, potential customers and obtain environmental, drug control and other clearances. Initially, it was he who acted as the pivot of the enterprise wheel. In the course of time, a strong managerial team was put in place and thanks to persistent emphasis on good management practices, Virchow emerged as the world's largest and the best producer of the basic drug from the chosen molecule.*

**1.7.1 Need for Achievement:** It implies a desire to accomplish something difficult; to master, manipulate, or organise physical objects, human beings or ideas; to do this as rapidly and as independently as possible; to overcome obstacles and attain a high standard; to excel one's self, to rival and surpass others; to increase self-regard by successful exercise of talent. Yes, entrepreneurship provides you with the best opportunity for making the best use of your talents as in employment of the 9-5 routine, pressure to adhere to rules and regulations, preference for compliance of boss's instructions over the use of personal creativity and innovativeness stifles your progress and self-development. You can create a work environment that suits your abilities and interests.

**1.7.2 Need for Power:** This is the concern for influencing people or the behaviour of others for moving in the chosen direction and attaining the envisioned objectives. In common perception, politicians, social & religious leaders Chief Executive Officers (CEOs), Government Bureaucrats/Civil Servants typify the

need for power. Such a perception seems more based on the belief that the source of power lies in the “position” a person occupies in organisational/societal context. In the same vein, business ownership too may imply a need for power. Moreover, you would appreciate that the process of founding a business, one has to win the commitment of capital providers, suppliers of equipment and materials, the employees and that of the customers. Power may not be used to further one’s self-interests alone, it may be also be used to touch the lives of others, to make a difference. Entrepreneurs driven by this socialised face of the need for power. They found organisations that are a source of sustenance and self-respect for many.

**1.7.3 Need for Affiliation:** Often you must have heard your parents saying that whatever they do they do it for their children. If a man thinks about interpersonal relationships, he has a concern for affiliation. It implies, among other things a tendency of the people to conform to the wishes and norms of those whom they value. Apparently, social activists, environmentalists, teachers, and doctors and nurses may seem as predominantly driven by these needs. Entrepreneurs are believed to be low on affiliation, as they are and expected to be, innovative, trendsetters and tradition breakers. However, it is not necessary that affiliation should only interfere with achievement. In certain cultures, family comprises the bedrock on which the successful careers are built. One works, as if, not for personal gratification but for family. Desire to carry on the tradition of business in the family and the community to which one belongs, may be interpreted as reflecting need for affiliation as well. In the countries with the colonial past, such as ours, the first generation of entrepreneurs in Independent India was driven by patriotic fervor and the desire to rebuild the economy left stagnated by the alien rulers. One can certainly trace some elements of affiliation motivation in such instances.

**1.7.4 Need for Autonomy:** It is a desire for independence and being responsible and accountable to oneself rather than some external authority for performance. It is the desire for an opportunity for the fullest expression of one’s abilities. In the context of entrepreneurship, it is usually interpreted as the determination not to work for someone else. In most job situations, employees are given little freedom to exercise their discretion in taking decisions and choosing a course of action so much so that absence of it drives them into starting their own ventures.

### **What does Entrepreneurial Motivation mean for Entrepreneurship Development?**

It means that for promoting entrepreneurship it is important to kindle and arouse the right motivation. In the absence of motivation, even able men and women may not take to entrepreneurship. Persons having abilities search for the avenues for their expression and hence are drawn to entrepreneurship. Persons eager to be on their own may strive hard to acquire the necessary competencies to realise their dreams. How truly one has said that entrepreneurs are the dreamers who do!

In explaining and developing entrepreneurial motivation, it is important to learn that different individuals are motivated differently, and that one may be trying to satisfy more than one need through one’s pursuit. This is an important observation as economic theory very simply says that the objective of the firm or that of the entrepreneur is profit maximisation.

## **Experience Sharing: A saga of the world's fastest DNA, RNA stain**

Both Dr Fathima Benazir (38) and Mr Alex Paul (38) were schoolmates and best childhood buddies. She was a postdoctoral research fellow at Indian Institute of Science (IISc), Bangalore, and was keenly looking out for opportunities abroad. She approached Mr Alex Paul and sent him her portfolio.

### **The Unexpected Spark**

Intrigued by her profile and research accomplishments, Mr Paul persuaded her to apply her research to solve problems in different areas of Life Sciences.

"I always wanted to be a passionate scientist rather than an entrepreneur," says Dr Fathima, Co-founder & CEO, Azooka Life Sciences.

After several discussions and advice from her IISc mentors including Prof H S Savithri, Department of Biochemistry; Prof M R N Murthy, Molecular Biophysics Unit; and Dr C V Natraj, Advisor, Society for Innovation and Development (SID) IISc, she teamed up with co-founder Mr Alex and started Azooka Life Sciences in 2015. The name 'Azooka' is derived from the Spanish word Azúcar, which means sugar in Brazil.

### **Significance of Nucleic Acid Stain**

The Bangalore-based start-up is said to be the discoverer of a patent-pending nucleic acid gel stain developed from a plant source used as a food additive.

The fluorescent dye named 'tinto rang' is a nucleic acid dye available for applications in Biological Sciences and Genomics.

Nucleic acid stains are a vital part of DNA-based disease detection compared blood-based disease diagnostics. These stains are vital chemicals used in identifying diseases in human, animal and crop diseases. In fact, Nucleic Acid-based Testing (NAT) is a USFDA (United States Food and Drug Administration) approved and globally accepted methodology for non-invasive and rapid disease detection.

NAT is said to be a precise and painless molecular testing technique. It is commonly available in the Americas, Europe, Malaysia and Thailand. "However this is not prevalent in India due to the high-cost of the assays and devices used in nucleic acid testing," Mr. Paul comments.

On an average, the NAT can cost anywhere between Rs 5,000 to Rs 15,000, and can go up to Rs 25,000, given that only expensive hospitals in cities provide the facility.

"The conventional methods are inferior compared to NAT. It takes longer time, and the

results can be negative because of longer incubation periods. Certainly nucleic acid tests are very specific, faster, accurate and way of the future," Dr Fathima voices.

India's problem is that it has to import nucleic acid stains - mainly from the US or Germany. As a result, there is a payment of 40 to 50 percent import duty including transportation. Most nucleic acid stains are biohazards, toxic, carcinogenic, and mutagenic, and demands careful handling and disposal post experimentation. Nucleic acid stains are used on a daily basis in disease detection and DNA forensics, so disposing carcinogenic and hazardous substances is a major challenge.

### **World's Safest Dye**

Right now, there are around 30 nucleic acid stains in the world that bind to DNA and RNA. They are widely used in DNA and RNA extraction, visualization and extensively in DNA Forensics, sequencing and genomic studies. Azooka claims its fluorescent dye as the world's safest and fastest DNA and RNA stain. It was conceived out of Dr Fathima's PhD research, and was launched in March 2016, after 3 long years of hard work and research.

"Our nucleic acid stain is purely an Indian product, and our customers can save big on import duties. Our stain is the first nucleic acid stain to be reported in India and APAC," adds Mr Paul.

The stain is said to be the safest and fastest DNA stain available in the market. "Our dye is faster than the market leading stains like Ethidium Bromide which takes 10 to 40 minutes to stain. Our dye consumes only 30 seconds," Mr Paul points.

The start-up is planning a worldwide product launch by the end of 2016. "Our commercial wing Bhoot Enterprises will fulfil the product manufacturing, distribution, marketing, and sales in India. There are some regulatory and IP challenges in taking our products to market, but we are working under the guidance of SID..." Mr Paul reveals.

Comparing NAT and ELISA (Enzyme-Linked Immunosorbent Assay), a test that detects and measures antibodies in the blood, the latter's test timeline can vary anywhere between 3 to 6 months.

Azooka would focus on developing fluorescent dyes that can be used in multicolor labeling experiments such as FISH (Fluorescence in situ hybridization), FACS (fluorescence-activated cell sorting), chromosomal imaging, cell imaging, sequencing and other

pharmacogenomics studies. "We are incubated for social impact, and we have a big mission.

Our research is cutting-edge, but we didn't find the right market in India because molecular diagnostics is still nascent in the country. SID played an important role and recognized our innovation," she adds.

Currently Azooka is seed funded and incubated at SID, IISc. The start-up operates only on research and innovation grants.

"We want to purely be an IP- and R&D-based company by creating IPs and values. It is a big mistake to approach VCs immediately after conceiving your ideas. Once you discuss your ideas with VCs and if they are not convinced, you lose your ideas," he cautions. He emphasizes that once venture capitalists (VC) enter a start-up's picture, the focus of research changes.

Mr Paul conceptualized most of the company's products, including the market research and the direction the start-up would take in the future. Prior to this, he was the director of product management and marketing at Zoho Corporation.

### **Chasing Challenges**

DNA-based diagnoses is not so popular in India unlike it is in the US, Europe or Australia. "Educating the market about what we do is a challenge. Finding the right talent is another daunting task," Mr Paul shares.

Since India does not have proper molecular diagnostic system in place, many times HIV-infected blood, for example, was given to kids. In such circumstances, Azooka's dye is said to play a crucial role in detecting such diabolical elements in samples.

### **Funding Dramas**

Azooka's initial attempts to win grants proved tougher. "We were told to sell-off our technology and get settled for life. We were already running out of cash, and had a zero bank balance. But we didn't give up. We wanted to bring and build our innovative technology - the country's first nucleic acid stain -- right here in India," Dr Fathima states. While seeking funding, the start-up's final proposal was rejected by the committee since they claimed their technology as 'no novelty' status.

"The committee is comprises of teachers and academicians who have very less knowledge about markets and entrepreneurship. Thus winning a grant is a challenge. The right system is not in place, and we had to pay a steep price," Mr Paul stresses.

Azooka's products are targeted at blood banks, disease detection kit manufacturers, DNA-based diagnostic labs, DNA Forensics, academic institutions, universities, research labs, and companies in the pharmacogenomics space, seed companies in crop breeding and crop improvement, and medical device vendors.

"We are also looking forward for Patent Cooperation Treaty (PCT) to protect our molecule for 30 months all across the world in 160 countries," Mr Paul comments.

At IISc, Azooka has over 20 customers already. "We want to first win the home ground before a global launch. We also want to partner with kit vendors and molecular diagnostics device manufacturers," Dr Fathima opines.

The start-up expressed interest in working with Roche Diagnostics, Danaher Corporation, Thermo Fisher Scientific, Qiagen and Bio-Rad among others

---

## 2. PROFILING THE BIOENTREPRENEUR

---



I want to be remembered as someone who put India on the scientific map of the world in terms of large innovation. I want to be remembered for making a difference to global healthcare. And I want to be remembered as someone who did make a difference to social economic development in India.

— Kiran Mazumdar-Shaw —

### 2.1 Characteristics of Biotechnology Industry

- Medium to very long product development lead times;
- Capital-intensive;
- Highly regulated;
- Extensive skill sets and technical knowledge required;
- One of the most research-intensive industries in the world;
- Mostly ethical clearance is essential, especially for any animal/ human testing;
- Intellectual property protection is an essential element of success for most biotechnology companies;
- Strong linkages and strategic alliances established with universities; institutions and other biotechnology companies;
- Capital raising is essential and consumes a significant amount of time and resources throughout an organization's life cycle.

### 2.2 Entrepreneurship in the context of Biotechnology

In the context of biotechnology, the bioentrepreneur operates in a knowledge-based and science-based industry, where competitive advantage is achieved through the effective management of intellectual property emanating from good science. The bioentrepreneur is often a scientist/researcher-turned-entrepreneur who wishes to see their research successes put into practice through commercialization.

In many industries, technological developments have increased the diffusion of innovations through improved speed and quality of communication, improving market knowledge of both producers and consumers. However, the main issue is that for biotechnology, due to high capital costs, technology diffusion will be slow without significant levels of investment. This investment tends to come either from large, established pharmaceutical companies (Big Pharma) or from public and private investors. As opposed to the IT industry where \$2–3 million would be required to get software designed, developed and on to the market within a six to 12-month period; in biotechnology, 'a typical drug takes 15 years and hundreds of crores to bring to market'.

Furthermore, there is a very distinct difference between basic/blue sky research, which is problem-solving research for the benefit of health, largely undertaken by public organizations such as universities, government agencies and research

institutes, and incremental/applied research and development which private sector firms are more likely to be involved in.

It is argued that the difference between entrepreneurship in biotechnology and other industries is not in the essential ingredients (which are largely the same), but in their proportions (which will vary). This is illustrated by comparison between the biotechnology and IT industries, the most prominent of the high-technology industries. The table below outlines a comparison between Biotechnology and IT showing how the proportions may differ. It is important to make this distinction between bioentrepreneurship and entrepreneurship in other industries, as exemplified by the IT example.

*Differentiating features of IT and biotechnology*

| Features                               | Information Technology (IT)                                                                                                                                 | Biotechnology                                                                                                                                    |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Product life cycles                    | Very short – often 6–12 months                                                                                                                              | Medium to long                                                                                                                                   |
| Technological requirements             | While a university degree is available, most IT skills are learnt by doing                                                                                  | In developing new products, extensive skills sets and technical knowledge are required. PhDs are common                                          |
| Resource requirements                  | Limited to labour costs, hardware, software and overheads                                                                                                   | This is a capital-intensive industry with extensive sunk costs                                                                                   |
| Capital raising                        | Most start-ups proceed to initial product launch without backing                                                                                            | Capital raising is essential and occupies much of the resources and energy of the bioentrepreneur                                                |
| R&D cycle                              | Quite short – particularly where virtual teams collaborate<br>Moore's Law                                                                                   | These vary – for incremental developments they can be one to two years – for discovery developments they can be 20–30 years                      |
| Regulatory requirements                | The market moves so rapidly that regulation does not keep up. Corporate governance is largely internal                                                      | Extensive regulation which severely impacts on the product development process – this is a highly regulated industry                             |
| Ethics                                 | Ethical issues do not predominate in this industry. Codes exist but are often voluntary                                                                     | Ethical clearance is essential for any animal or human testing. Ethics in biotechnology is a public issue                                        |
| Extent of R&D                          | Linked to the R&D cycle. R&D on individual products is not extensive but many products can be concurrently developed                                        | The trial process – animal, chemical and field trials provide evidence that this is a long intensive process                                     |
| Linkages                               | Collaboration is often between companies and individuals. Smaller firms innovate and then look to sell either their product or the business to larger firms | Linkages usually include institutions such as universities, CSIRO or multinationals. Small firms innovate and are often acquired by larger firms |
| Product development and product launch | Product development continues well after product launch (much to our annoyance)                                                                             | Due to ethical and regulatory issues product development must be completed prior to launch                                                       |
| Intellectual property                  | Few patents, some trademarks, design copyright most prevalent. Intellectual property control difficult to maintain                                          | Patents most prevalent, some trademarks. IP control is essential to the success of most companies. It is also a substantial financial burden     |

### **2.3 What is Bioentrepreneurship?**

Bioentrepreneurship is a relatively recent term outside the USA. The USA is often considered to be the motherland of biotechnology, though many believe that given Watson and Crick's contribution to the science underpinning biotechnology, the UK deserves that status.

Nevertheless what is less disputed is the birthplace of bioentrepreneurship. The USA is certainly the place where the bioentrepreneur has operated for over three decades. Before the IT giants of Microsoft, Sun, and Cisco were a twinkle in Steve Burrell's eye, Genetech and Amgen were making headway expanding through their own research programmes, competing and in critical cases collaborating with the major established pharmaceutical companies known as Big Pharma. These first biotechnology companies were populated by scientists, assisted by merchant bankers and other entrepreneurial investors.

They established strong IP positions protected by the patent system that has so successfully ensured success for Big Pharma, through which they could establish licensing and other deals with the likes of Eli Lilly, Pfizer, the newly created Sanofi-Aventis, Merck, GSK, Roche, Monsanto and DuPont to name but a few.

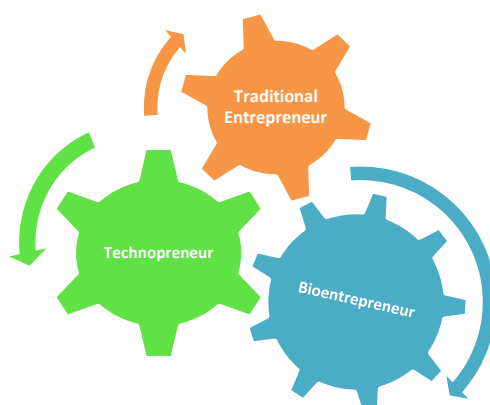
**Bioentrepreneurship can be described as creation of wealth derived from the application of the biosciences to the business context.**

Bioentrepreneurs look for commercial value in every aspect of technology that they utilize. Innovativeness is vital to the creation of a biotechnology venture while credibility remains the backbone of the bioentrepreneur's character. The challenges of financing from venture capitalists prove to be a constant struggle for the bioentrepreneur. Similarly, risk-taking comes from dealing with the uncertainties of R&D, a rapidly evolving marketplace and the nebulous field of intellectual property.

## **2.4 Profiling the Bioentrepreneur**

In arriving at a profile of the bioentrepreneur, having just gained a feel for the industry in which they operate, we must first define the broader concept of the technopreneur. The technopreneur is a breed of entrepreneur that has emerged in the last two decades as a part of the global era of knowledge economies and new technologies.

Technopreneurs recognize the value of technology and invent new ways of using it to change their industries. They also make much use of computers, the Internet and other modern advancements in developing the business venture and its operations. Their skill sets are therefore predominantly technical rather than business oriented. Profiles of technopreneurs illustrate certain similar attributes to traditional entrepreneurs such as innovation, opportunity identification and capture, risk-taking and perseverance. Bioentrepreneurship is essentially a subset of technopreneurship; that is, technopreneurs that have begun their ventures in the biotechnology industry.



### **2.4.1 Education Qualifications**

Bioentrepreneurs as individuals seem to sit at the highest end of the educational spectrum. The vast majority of biotechnology businesses are started up by holders of science degrees, MBAs, PhDs and various other tertiary qualifications. Their ages tend to be much older at the initiation stage

of the enterprise as compared with the traditional entrepreneurs. This is mainly due to the length of time spent in university, as well as the time required to develop the idea into a viable product. It also appears that the majority of these entrepreneurs begin with education directed towards the sciences and therefore have an in-depth knowledge on their very complex products. Intellectual capital and subsequently property therefore commonly resides in the very heads of bioentrepreneurs, and can be the source of a biotech firm's competitive advantage. This phenomenon is not often described in traditional entrepreneurship.

#### **2.4.2 Technical Skills**

Technical skills get the bioentrepreneur established in their venture. However, technical skills alone will not offer sustainable competitiveness, as exploiting opportunities relies heavily on traditional entrepreneurial skills. So the question remains. How does the bioentrepreneur or the entrepreneurial biotech company build this knowledge base of business strategic skills? Largely, it has been through experiential learning rather than through the codified knowledge developed through university courses, although the trend toward the biotech PhD, augmenting their qualifications with an MBA is becoming apparent.

#### **2.4.3 Experiential Learning**

One of the problems with experiential learning is that experiences by their nature are limited. Most bioentrepreneurs commence this stage of their career late, having been successful in their scientific field first and after having completed the PhD. Their range of business experiences is often limited to one or two companies. This limited access to distributive knowledge can be problematic to building an entrepreneurial knowledge base not only in individual biotech companies, but for the industry as a whole. Such a dilemma is exacerbated by the barriers to potential entrepreneurs, particularly those from other industries, to entering the industry in a competitive manner, given the strong requirement for technical knowledge, as well as market knowledge. Limited experiential learning experiences do not support robust strategic judgement, particularly in an industry where change can be considered a constant rather than a variable. The extent to which this has contributed to the high (and growing) failure rate of small biotech firms or whether this is an inevitable consequence of a long, complex and very expensive R&D pipeline is almost impossible to delineate. On the positive side, failure is a critical ingredient in the experiential learning process. The more failed entrepreneurs who come back to try again, the more robust the entrepreneurial knowledge base will be come in the industry.

With regard to the bioentrepreneur's environment, Genentech provides an interesting example. In the creation of a venture that explored the uses of gene splicing, Swanson had to convince renowned scientists to join this experimental company whilst trying to acquire venture capital in a new, remote area of business. Despite the reluctance of pharmaceutical companies to provide any financial support, Swanson went on to create a speculative market boom that inspired 'confidence' in the industry. Genentech's first major success was in licensing recombinant human insulin to Eli Lilly. However the success of the bioentrepreneur and their company cannot be assured by the possession of the correct characteristics. The entrepreneurship must be combined with the desire and ability to innovate.

***Innovation and entrepreneurship go hand in glove.  
It remains unclear which is the hand and which is the glove.***

---

## 3. ENTREPRENEURIAL OPPORTUNITY

---

*“Enthusiasm is the sparkle in your eyes, the swing in your gait, the grip of your hand and the irresistible surge of will and energy to execute your ideas”*

*- Henry Ford*

Peter F. Drucker defined entrepreneur as one who always searches for an opportunity. The basic test of a successful entrepreneur is the identification of business opportunity in the environment and initiating steps to produce and sell goods and services to make the best use of that opportunity.

### 3.1 What is Entrepreneurial Opportunity?

There are a lot of opportunities in the world of business, which everyone might not be able to spot. An entrepreneur should be able to spot it. Entrepreneurial opportunity can be described as an economic idea which can be implemented to create a business enterprise and earn profits.

Before selecting an opportunity, the entrepreneur has to ensure two things-

- There is a good market for the product he is going to produce
- The rate of return on the investment is attractive to be accepted by him.

Only when the entrepreneur is able to fulfil these two criteria, he/she can be successful. Quite often, a question arises - Can all ideas be converted into opportunities? Mostly entrepreneurs conceive an idea and start their business without even analysing the market which often leads to satisfying their own ego, and the result is that they launch a product that has very few customers.

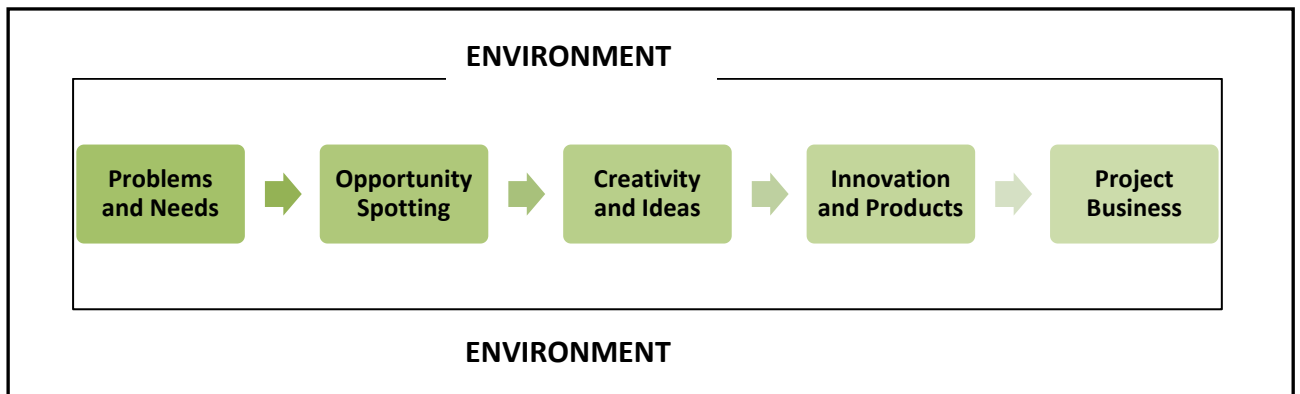
#### 3.1.1 Elements of Entrepreneurial Opportunity

An entrepreneurial opportunity may be described as an attractive economic idea which could be implemented to create a business, earn profits and ensure further growth. It has five elements which are as follows:

- Assured market scope
- An attractive and acceptable rate of return on investment
- Practicability of the idea
- Competence of the entrepreneur to encash it
- Potential of future growth.

#### 3.1.2 Exploring Opportunities in the Environment

A prospective entrepreneur has to find an opportunity which would be suitable for him/her in terms of customers to be served and profits expected. An opportunity may be derived from the needs and problems of the society.



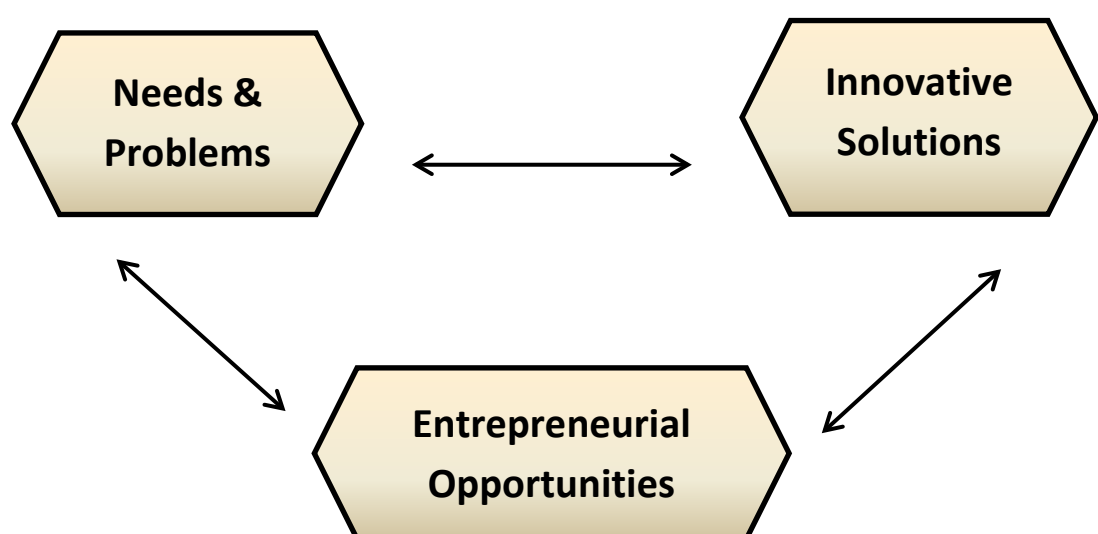
This above diagram shows the following stages:

- i) Opportunity spotting by analysing the needs and problems that exist in the environment
- ii) Evaluating the ideas received from different sources to find a creative solution
- iii) Identifying a product or service through innovation
- iv) Setting up a project and nurturing it to success.

Sensing entrepreneurial opportunities is thus a process of converting an idea into an opportunity and then into an enterprise. We can see clearly that the first stage is to spot the needs by looking into the needs and problems that exist.

### 3.1.3 *Perceiving and Sensing Opportunities*

The entrepreneurs perceive opportunities, synthesize the available information and analyse emerging patterns that escape the attention of other people. They are people with vision, capable of persuading others such as customers, partners, employees and suppliers to see the opportunity, share and support it.



### **3.1.4 Factors involved in Sensing Opportunities**

To sense an entrepreneurial opportunity, an entrepreneur employs his/her sharpened skills of observation, analysis and synthesis to identify an opening. The most important factors involved in the process are:

#### **3.1.4.1 Ability to Perceive and Preserve Basic Ideas**

Spotting an idea often triggers the process of sensing an opportunity. The following are the various sources which lead to the emergence of basic ideas:

- **Problems:** When a problem exists, an idea leads to a solution to resolve that problem; it emerges as a business opportunity.
- **Change:** A change in social, legal, technological aspects etc. leads to new opportunities to start a business.
- **Inventions:** New products or services leads to new business opportunities.
- **Competition:** Competition often results in emergence of new and better ideas that result in new business opportunities.
- **Innovation:** Creating new things of value as well as new and creative processes that add value to the existing products or services. For example, computers to tablets.

#### **3.1.4.2 Ability to harness different sources of Information**

Various sources like magazines, journals, books, seminars, trade shows, family members, customers, friends etc. help in getting information that results in evolution of basic ideas. Bring together various sources of information and knowledge, and analyze it to the best possible extent. The analysis helps in the identification of the right opportunity to start a new business.

#### **3.1.4.3 Vision and Creativity**

Creativity in innovating a solution and vision: The entrepreneur should be able to creatively identify an idea to generate a valuable solution to a problem. Once the solution is identified their vision to convert the solution into business opportunity helps them to move forward, overcoming all the obstacles. They constantly

- Overcome adversity
- Exercise control over the business
- Make a significant difference.

### **3.2 Environment Scanning**

Business environment may be defined as all those conditions and forces external to a business unit under which it operates. Entrepreneurship does not emerge and grow spontaneously. Rather, it is dependent upon several economic, social, political, legal and other factors.

#### **3.2.1 What is Environment Scanning?**

It is a careful monitoring of an organization's internal and external environment for detecting early signs of opportunities and threats that may influence its current and future plans.

### **3.2.2 Why do we need to scan our Environment?**

In a rapidly changing environment, one rule of thumb applies: If you don't adapt, you don't endure. This is the core idea behind environmental scanning. Definitions of the term refers to the means by which organizations gather information on changing conditions and incorporate those observations into a process where necessary changes are made. The right information, combined with the right adaptations, can determine an organization's future viability. If an entrepreneur is not aware of the environment surrounding his/her business, he/she is sure to fail.

### **3.2.3 Importance of Environment**

Sensitivity to environmental factors is crucial for an entrepreneur. If a company is able to adapt to its environment, it would succeed in the long run. For example, Sony is failing to understand the changing trends in mobile phones and therefore losing its market share. The benefits of understanding the relevant environment of business are:

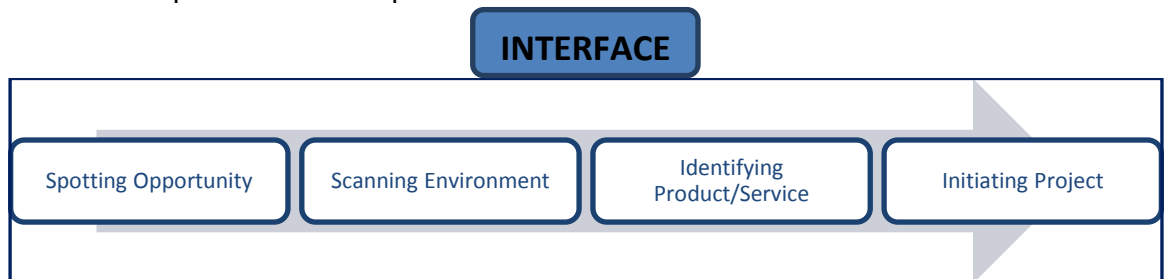
- **Identification of opportunities to get first mover advantage:**  
By keeping in touch with the changes in the external environment, an enterprise can identify opportunities and find strategies to capitalise on the opportunities at the earliest. For example, Volvo, the Swedish brand, has 74% share in the luxury bus segment as it had entered India earlier.
- **Formulation of strategies and policies:**  
It helps in identifying threats and opportunities in the market. These can serve as the basis of formulation of strategies to counter threats and capitalise on opportunities in the market.
- **Tapping useful resources:**  
If the company has a thorough knowledge of the external environment, it can tap raw materials, technology and even financial resources from the market at economical prices, at the right time.
- **Better performance:**  
Proper understanding of the various elements of the external environment is necessary to take timely action to deal with threats and avail opportunities for the purpose of improvement in the performance of the firm.
- **Sensitisation of entrepreneurs to cope up with rapid changes:**  
A keen watch on the trends in the environment would help sensitise the entrepreneur to changing technology, competition, government policies and changing needs of the customers. For example, trends in clothing.
- **Image building:**  
If a company is sensitive to the external environment, it will come out with new products and services to meet the requirements of the customers. This would build the image or reputation of the firm in the eyes of the general public. For example, call-radio taxis with additional features like GPS systems, online booking etc.

### 3.2.4 Analysis of Environment

Environment analysis is the process of monitoring the economic and non-economic environment, to determine the opportunities and threats to an organisation. Such an analysis involves data collection, information processing and forecasting to provide a rational basis for developing goals and strategies for business survival and growth. Information for environmental scanning can be collected from several sources. These include—

- Verbal information from customers, wholesalers, retailers, distributors, consultants, etc.
- Records of companies
- Government publications
- Publications by various financial institutions
- Formal studies conducted by strategic planners.

The data, so obtained, is processed and analysed with the help of quantitative and qualitative techniques.

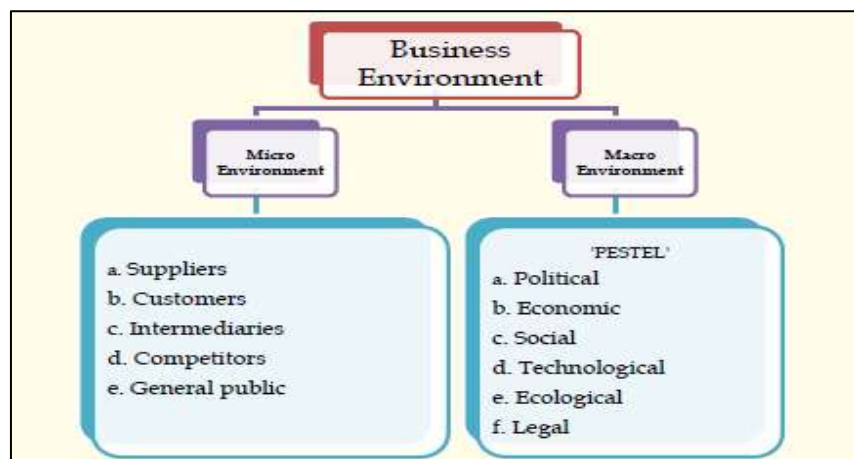


The above flow chart shows that an opportunity received by the entrepreneur should be tested against important environmental parameters to arrive at a sound business choice. This interface is an evaluative process leading to a judgement. Is it a viable idea? Does it make sound business sense? If yes, the entrepreneur can proceed to the next stage of product or service identification.

### 3.2.5 Environmental Factors

Entrepreneurship environment refers to the various forces within which various small, medium and large enterprises operate. These factors exert influence upon each other and do not operate in isolation.

Business environment consists of two levels, i.e., micro environment and macro environment.



### **3.3 Problem Identification**

A *problem* is a roadblock in a situation, something that sets up a conflict and forces you to find a solution. When an entrepreneur identifies such a road block, he/she is said to have identified the problem. The objectives of problem identification are as follows:

- It should clearly state the problem
- Identify target group facing the problem
- Find the market acceptability of the solution to the problem.

Problem identification helps the entrepreneur to:

- Bring out new products in the market
- Understand the problems and needs of the market
- Be creative
- Increase employment generation
- Increase national income (of the country).

### **3.4 Idea Generation**

It is the process of creating, developing, and communicating ideas which are abstract, concrete, or visual. It includes the process of constructing through the idea, innovating the concept, developing the process, and bringing the concept to reality.

Business ideas are all around you. Some business ideas come from a careful analysis of market trends and consumer needs; others come from serendipity. If you are interested in starting a business, but don't know what product or service you might sell, exploring the ways of getting business ideas will help you choose.

By following different ways for generating ideas an entrepreneur collects a number of ideas. The process of generation of ideas can be streamlined by developing an awareness for different "idea fields". This will help the entrepreneur in enlarging the scope of thinking, at the same time structuring the ideas according to convenient frames of reference. Idea Fields can be described as: 'Convenient frames of reference for streamlining the process of generation of ideas'.

### **3.5 Innovative Efforts**

We have seen that innovation is an important and key component of the talents and abilities needed for an entrepreneur. Apart from applying innovation to spot and harness opportunities, it can also be applied to develop new products and services.

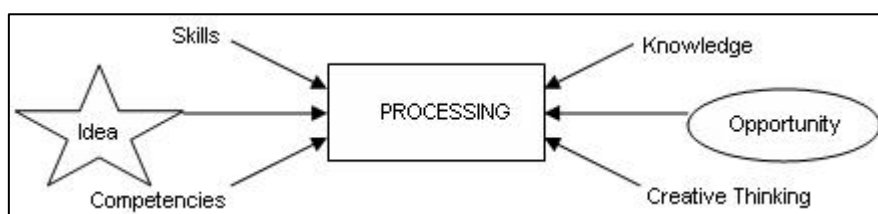
There are basically five ways in which innovative ideas can be generated:

- i) Develop a new product or service.
- ii) Improve an existing product or service
- iii) Find a new process or resource for manufacturing a product.
- iv) Find new markets for existing products or services.
- v) Find a new use of an existing product or service.

A very useful concept to bear in mind is that, most often innovative products and services are born as results of problem solving. Someone found that while tightening screws, overtightening often resulted in damage to the fixtures. Here was a problem and the solution came in the form of a self-adjusting screwdriver which prevented over tightening. Similarly when doctors found monitoring of dosage of medicine to be administered to patients on a regular basis through traditional methods using a syringe cumbersome, a pharmaceutical firm developed a new process of implanting the required medicine in the patient for constant discharge of regulated and required dosage in to the blood stream.

### 3.6 Transformation of Ideas into Opportunities

While the initial spotting of ideas (i.e., basic idea) is of a random nature, the development of ideas after scanning the environment (i.e., post scanning) idea is a more purposeful activity. Thus the former is an experiential process while the latter is a strategic process. All basic ideas have to undergo a vigorous process of examination, evaluation, analysis and synthesis to identify viable opportunities. This process of a basic idea becoming an opportunity is shown in the diagram below:



### 3.7 Idea and Opportunity Assessment

In a sense, generating ideas is relatively an easy exercise, especially if it is done in groups. However, this process can also become a wild goose chase because all ideas need not necessarily become sound business opportunities. We have to assess it in terms of the potentiality of the opportunity. The steps involved in this type of investigation are discussed below:

#### 3.7.1 Product Identification

An idea should lead the entrepreneur to a definite product/service which he can sell. So the first step is to obtain a concept of the product or service suggested by one idea. We should also see whether this product is already available in the market or not. If it is, then we should identify the reason for introducing the same product or service in the market. For example, innovating a new pendrive especially for teachers which will have a built in antivirus and which can be worn like a watch so it minimises the problem of losing the pendrive.

#### 3.7.2 Application and Use

Ideas should be examined for their real life use and application. If it already exists in the market, we will have to find out its present use, then we may think of modifying it for better use. In the above mentioned example, we can clearly see that even though there are many companies manufacturing pendrives, the latest will be in consonance with the upcoming trends.

#### 3.7.3 Level of Operation

This is a crucial test for product/service identification. Depending on the use of the product/service the entrepreneur will produce it in a cottage industry or a small scale– industry or a large–scale industry.

#### 3.7.4 Cost

What is the per unit cost of the product at particular level of operation? Whether this cost is comparable with that of other competitive products? These are some of the questions that have to be answered. This will ultimately decide the sale price.

### **3.7.5 Competition**

Any product or service will face market competition at some stage. So market competition should be assessed through a study of the trends in demand and supply.

### **3.7.6 Technical Complexity**

What type of technology is required to produce the product? Whether training and application of such technology will be locally available or will it have to be supported from other places? What would be the position of supply of plant and machinery for such a technology? These are important issues that have to be resolved.

### **3.7.7 Annual Turnover and Profit Margin**

Ideas should also have to be examined on the basis of expected annual turnover. This will also indicate the market share of the product or service. Once the entrepreneur has assessed the opportunities on this basis he/she should go ahead and assess the market also.

## **3.8 Market Assessment**

Selection of a product or service will depend upon many factors. While assessing the market, an entrepreneur has to prepare details on the following lines:

### **3.8.1 Demand**

The demand assessment will be based on the size of market being targeted, i.e., local markets, market at state level or national/international market. It will also involve a study of the target groups of consumers, their preferences, tastes and other related variables.

### **3.8.2 Supply and Nature of Competition**

While assessing market, supply position is also studied by entrepreneurs. By supply position what is meant is the complete picture of quantities of the product made available in the market by all the existing players. It should take into account future supplies from possible entrants in the field.

### **3.8.3 Cost and Price of Product**

It is important to determine the cost of the product and its comparison with available products in the market. Cost variable of competitors in terms of transportation delays, wastage, storage etc., have to be studied to spot cost advantage. This will influence the delivery mechanism of the identified product or service.

### **3.8.4 Project Innovation and Change**

Market assessment will require a study of prevailing innovations and changes being carried out by existing entrepreneurs. Technological advancements in the field have to be analysed because they may change the quality and influence the cost and price ultimately.

## **3.9 Trend Spotting**

It means identification of new trends. This will help the entrepreneur to understand the market and produce goods or provide services in sync with the market trends.

But how do we spot trends? One of the keys to business success is to anticipate what the market will want or need before the entrepreneurs are aware of it themselves. Since its unlikely for an entrepreneur to see into the future, the best way

to do this is to become a trend-spotter. Professional trend-spotters charge big money for reports and industry trend updates. But there are some entrepreneurs who spot these trends themselves. There are so many ways to spot trends.

### 3.10 Creativity

Creativity is important to entrepreneurs because it is the first stage in the process of innovation, providing the stimulus for opportunity discovery and new venture creation. As new entrants, entrepreneurs often justify themselves upon the same dimensions as creativity: novelty, usefulness, and appropriateness. Arguably, one of the first tasks demanded of an entrepreneur is to manifest creative ability through the conceiving of new product-market opportunities and unique value propositions. From these initial acts of creativity, entrepreneurs must build effective organizations that can repeatedly bring ideas to commercially valuable forms in order to survive and grow.

The process of creativity involves five steps: 1. Idea germination, 2. Preparation, 3. Incubation, 4. Illumination and 5. Verification.

#### The Creative Process:



**3.10.1 Idea germination:** This is the seeding stage of a new idea. It is the stage where the entrepreneur recognises that an opportunity exists. The idea germination takes place according to interest, curiosity of the entrepreneur according to which opportunity is explored and exploited to its best potential. Creative idea germinates besides the interest, the need of a specific problem or area of study.

**3.10.2 Preparation:** On the basis of the idea, interest and curiosity the need is adjudged by the entrepreneur and he starts looking for the answer to implement the idea. If the idea is to launch a new product or service then market research is conducted. That happens because the seed of curiosity has taken form of an idea, the entrepreneurs foresee the future of the product.

**3.10.3 Incubation:** This is the subconscious assimilation of information. This is the transition period. The entrepreneur starts thinking about the idea and implementation in his sub-conscious mind.

**3.10.4 Illumination:** In this period of illumination the idea re-surfaces in realistic way and entrepreneur comes out with viable plan to give practical shape by collecting raw-material, arranging funds, policy-making for the implementation of idea.

**3.10.5 Verification:** Also called the validation or testing stage. This is where the idea is verified to prove that it has value. This is the most difficult phase of creativity as obstacles begin to appear. This is the developing stage in which knowledge is developed into application.

**3.10.6 Innovation:** It is the process of entrepreneurship which involves the translation of a useful idea into an application which has commercial value. It takes persistent effort to work out analytically the details of the enterprise or service, to develop marketing strategies, to organize finances and strategize operations.

**Elements in the Innovation Process:**



- **Analytical planning:** Carefully identifying the product or service features, design as well as the resources that will be needed.
- **Resource organization:** Obtaining the required resources, materials, technology, human or capital resources.
- **Implementation:** Applying the resources in order to accomplish the plans and delivering results.
- **Commercial application:** The provision of value to customers, reward employees, and satisfy the stake holders.

The entrepreneur should look into various factors before deciding on the opportunity. Even if the opportunity looks promising, an entrepreneur should look into the environmental factors before choosing the best opportunity.

### **3.11 Misconceptions about Generating Ideas for Entrepreneurial Opportunities**

Even though research tells us newer and smaller firms are less likely to engage in formal or structured environmental research, the fact is that generating and evaluating business ideas is an important step in the entrepreneurial process. Some of you have may have fairly specific ideas about potential entrepreneurial ventures; others may know only in broad sense in what entrepreneurial direction they did like to go; and the rest may not have any clue whatsoever! No matter what the stage may be of entrepreneurial idea readiness it is important to generate and evaluate potential business ideas. Entrepreneurship journals, books and available literature are filled with stories of Entrepreneurs striking it rich because they had a great idea. These, however, tend to give a false impression about great workable ideas.

These misconceptions about great idea are:

#### **3.11.1 Great ideas just appear out of nowhere**

The reality is that the best idea generators tend to do so in a structured systematic way. They don't wait for the things to happen but instead approach idea generation as the top priority activity by devoting sufficient period of time to it.

#### **3.11.2 There are no illogical ideas**

The reality is that, many ideas may not be very good, though to prevent others from feeling that their contribution is not valued; the belief is that, all ideas should be approached as worthy. Sometimes, the most powerful ideas come from what at first glance seemed illogical.

### **3.11.3 The customer will tell you what to do if you will only listen**

The best source of ideas is the people who will purchase your products. The only problem with this belief is that, although customers can help identify unmet needs, they require more involvements in making a great idea workable than simply listening to the customers.

### **3.11.4 We can generate all the ideas we will ever need if we sit down at a meeting**

Generating great ideas should not be restricted to a meeting. Great ideas are best shaped through an ongoing dialogue, not relegated to a specific place and time.

### **3.11.5 Great ideas are not the problem; implementing them is**

The reality is that, problems with implementation arise from not screening carefully enough, the ideas that are generated. If this were done, a lot of frustration could be minimized as ill-thought-out ideas could be screened out before even being implemented.

## ***Experience Sharing: Enabling global clinical trials in India***

*After graduating in Biomedical Engineering from the University of Sheffield (UK) in 2011, Mr Anant Agarwal (27) returned to India with a broken knee. Little did he know that his broken knee would lead him along the path to his ultimate destiny - the birth of his Kolkata-based start-up Indoriv Clinical.*

*After recovering from his physical ailment for a year, Mr Agarwal found an internship as a clinical research coordinator in Kolkata in 2012. He enjoyed his position and space, and explored it furthermore ardently.*

*Mr Agarwal received positive feedback and good reviews for his initial projects and started receiving projects from other pharma companies and CROs.*

*He also bagged a major stem cell project from a popular CRO. He tackled it fully as a one-man army. He was also fortunate enough to find credible mentors and valuable guidance from doctors and healthcare professionals around him.*

*It was then he decided to convert all of his learnings into an entrepreneurial venture, which he also long dreamt of during his student days in the UK.*

*Indoriv Clinical is now a four-year-old clinical research consultancy located in West Bengal.*

*"It's funny that when I started, I didn't have a plan at all," laughs Mr Agarwal. "I just went with it. Clinical research is a complex field to be in, since it has many diversifications. Back then I was just 22, and was still learning about the industry. I had very limited knowledge of clinical research project management and that's what I was doing. So I decided to stick to clinical project management at ground level and develop a clinical research consultancy."*

### ***Implementing Innovations***

*When a pharma company or a CRO comes out with a new drug, device, or a cosmetic product, they require clinical data to prove its safety and efficacy for commercializing.*

*All this is monitored under India's Drugs and Cosmetics Act which makes Indoriv's role pivotal in the ecosystem of clinical research.*

*"Indoriv is essentially a clinical data generation start-up. Our work is responsible in determining whether or not a drug is safe to be released in the market. Our main target is to organize clinical research in India to improve speed and quality of a clinical trial and making sure that a patient's right is protected. We leverage our expertise to manage this on the ground. We tie up with doctors and registered hospitals to manage human clinical trials.*

*"Every country in the world is becoming compliance-based and all medical products are being thoroughly tested before they are released in the market. Every medical innovation has to go through this process. So in short we are the implementers of medical innovation," explains Mr Agarwal.*

*Apart from management services, the start-up has also started its own diagnostic laboratory which is now providing centralized pathology solutions and medical archival.*

*Mr Agarwal says, "We have also started clinical trial medical supply, and have now come up with our very own digitization platform - MPET -- which is aimed at digitizing clinical research in India."*

*He expects MPET to be a turning point for his company since it is a different form of clinical research business in itself which will help several pharmaceutical companies worldwide.*

### **Trial Turmoil and Challenges**

The clinical research industry in India is still going through several regulatory changes. In fact 2013, all clinical trials were stopped in India, where the Ethics Committee of all hospitals were registered before proceeding for clinical trials.

Mr Agarwal points, "Lack of awareness and training among doctors, healthcare professionals and hospitals is a challenge. Even though this situation has improved, there is still a huge scope for better training and awareness. Another challenge is the existing vague regulatory laws, and the slow rate of clinical trials approval from the drug controller general of India."

However, he feels that the regulatory bodies have become faster and the laws are now becoming clearer.

"Clinical Research is a booming Industry to be in and more importantly has a huge potential for entrepreneurs in this field," he adds.

So far, locally, the start-up never required funding. "During the initial stages, my company did not require very heavy funding. Today I have the projects, and the confidence that my work could be scaled up to huge potential which is why we are currently looking to raise funds actively," he explains.

Indoriv's infrastructure including technology hardware and medical equipments were acquired through retained earnings.

"Fortunately, we had enough work to work through our cash flow for salaries and other costs. However, to expand in India it is important to acquire funding for cash flow and marketing requirements," he voices.

IndorivClinical's client list boasts of top 10 pharma and CROs including Biocon, Sun Pharmaceuticals, Syngene, Dr Reddy's, Alkem Pharmaceuticals, Clianza Research, Lambda Therapeutic Research, ManipalAcunova, Veeda Clinical Research, Karmic Life Sciences and ZydusCadila.

### **Exit Strategy**

Indoriv's growth strategy is based on two parallels, reveals Mr Agarwal.

First, it intends to expand its work and services pan India specifically in tier-2 cities where the majority of the population lives.

"Our work requires a large pool of patient population enabling speeding up of clinical trials process. This requires investment in terms of working cash flow and marketing. We already have the work and projects. We are ready to expand," says Mr Agarwal.

The second parallel is its upcoming software MPET, which aims to digitize clinical research at its source.

He voices, "This will help in capturing data which is missed out manually, and integrate seamlessly with medical databases worldwide. This will improve quality compliance and will also allow global trials to increase in India. Currently, only 2 to 3 percent of all global clinical trials happen in India, which has a disease burden of 18 percent. This would require development and marketing investments. Our exit strategy is either IPO or M&A."

### **Ambitious Revenues**

For Indoriv, this is its fourth year in business, and it has achieved its target revenue of Rs 1 crore without any investment in the company.

"We are aiming to quadruple this revenue in the next two years based on the contracts and clients we have, and also the projects we have signed up. If relevant funding is obtained for MPET, we would potentially be targeting a revenue of around Rs 30 to 40 crore in the next 5 years," Mr Agarwal comments.

Given the nature of collaborative work, the start-up's collaborators include several leading hospitals from both Government and private sectors, diagnostic centres (including radiology), doctors, healthcare professionals and pharmacies.

He has couple of suggestions to the Government. "We need clarity of guidelines, a smarter and flexible framework for operations. The Government can also look at digitization of Adverse Events (AE) and Serious Adverse Events (SAE), and drug monitoring procedures to streamline the whole process. We also need local research centres for faster processing of documents and monitoring," he recommends.

### **Healthcare Penetration**

Educated in the UK, he feels that the regulatory framework and structure is very clear and precise in the West.

"Talent is awarded. An investor and entrepreneur need to work together to create a big company. The support given to an entrepreneur there is much better than that in India," he continues. "In India, investment is usually given to companies who have already proved their models. The risk-taking capacity here is relatively lower. Most businesses would not be given investment in their ideation stage. This trend is changing slowly and should gain more traction in the coming years. However, we also need to be cautious about the start-up bubble."

He views 3D Bioprinting and Telemedicine as good areas for start-ups to venture.

"What the healthcare industry in India needs right now is penetration of Medtech in all areas of healthcare, which will not only improve the

quality of healthcare but also help healthcare penetration to tier-2 cities and rural areas of India," he notes.

### **Potential and Scalability**

Healthcare and clinical research overall is seen to produce huge margins and amazing scalability potential with good exit options.

"However, healthcare in general takes time to build. Venture capitalists and shareholders might need to be patient for a while. Once the initial framework is over, it has a potential to grow several times their investment," Mr Agarwal justifies.

He points that Mumbai and Delhi are becoming new start-up destinations.

"Start-ups emerge with the collaboration of ideas and the support, and funds to back them up. Delhi and Mumbai have all these essential elements. This is also supported by the penetration of technology in these cities, and the purchasing power of the people to use those start-ups' product and services," he observes.

He states that crowdfunding could be a great way of raising funds for a start-up.

"This is very popular abroad. I am not sure if this is regulated in India, but it could be a great method of raising funds," Mr Anant suggests, a lover of music and movies.

### **Compliance! Compliance!**

The clinical research industry is all about protocol, compliance and discipline, MrAnand shares.

"My first auditor in clinical research told me something that I still follow as a golden rule even today. He said, 'You are allowed to make mistakes in clinical research; you are not allowed to hide them.' Thus our work cannot be done under false pretense. Therefore, apart from discipline and compliance it is very

important to be good at documentation and being transparent in operations wherever healthcare is involved," he opines.

He thinks that losing patience is one of the biggest mistakes entrepreneurs commit while running their dream.

"The younger generation has amazing ideas today. However everything takes time to settle down and establish itself. When you start something it is important to stick to your idea and keep reinventing and renovating to make it right. You might just end up having a completely different business than what you started with. Start-ups by its very nature is something new whose market credibility has not been proved. A lot of people want to become overnight sensations," he reasons.

He has also learnt the hard way in making right hiring decisions. "The right team can take you either to top or put you under the ground," he highlights.

### **Start-up Basics**

As a start-up entrepreneur, Mr Anant adds that communication and transparency are two very important elements in work.

"It is important to keep talking to people -- regularly and constantly. Trust-building takes time. A lot of people begin a start-up for the sake of erecting a start-up. What you want to achieve should be clearer even if the methods keep changing with time," he expresses.

"Don't settle for less!" he advises young start-up entrepreneurs.

"Since most start-ups lack the confidence, they usually end up making the wrong decisions and settle for less -- which I have personally done for a very long time. It important to assess your worth versus what you are charging for your services.... Keep at it. Believe in your idea and don't lose patience. You will end up managing your work brilliantly," he signs-off.

---

## 4. ENTREPRENEURIAL PLANNING

---

***“Logic will get you from A to B. Imagination will take you everywhere”  
– Albert Einstein***

Setting-up a business is not an easy task. An enterprise is a separate and distinct unit, institutionally arranged to conduct any type of business activity. It needs to combine the necessary things such as materials, tools, equipment, working space and bring together all of them in a systematic and effective manner to accomplish the entrepreneur's desired objective. Thus, every business entity needs to select an appropriate legal structure or framework to work in. This legal structure determines the extent of ownership and responsibility of proprietor(s). Appropriate form of organisation strongly influences the enterprise's success and future prospects. Once selected, changing the 'form' is quite a complex, time consuming and costly affair.

### 4.1 Definition of MSME Enterprises

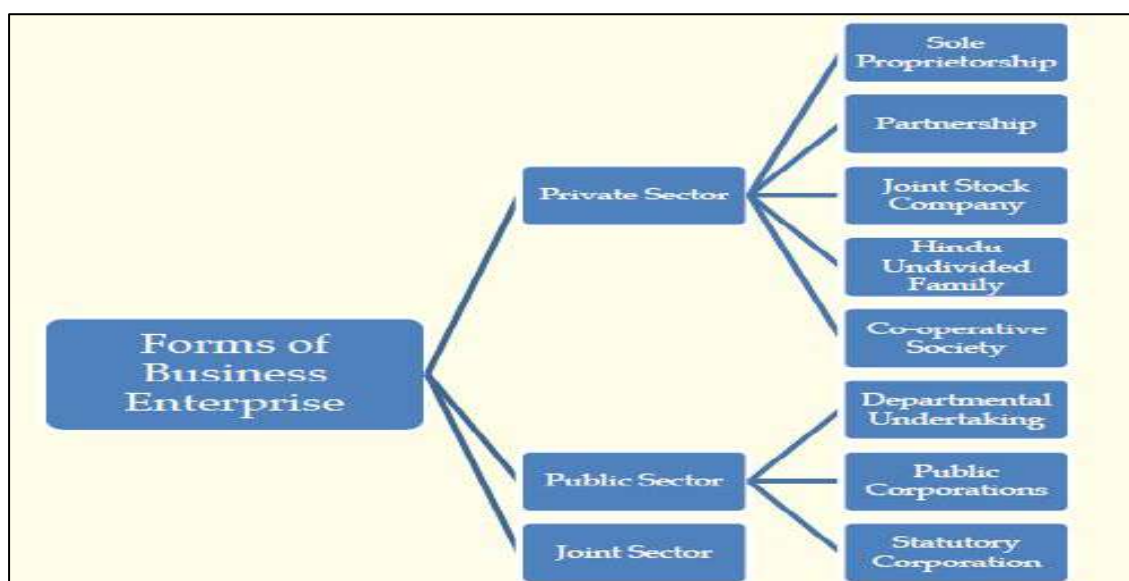
In accordance with the provisions of Micro, Small & Medium Enterprises Development (MSMED) Act, 2006 and its amendment of 2018, the Micro, Small and Medium Enterprises (MSME) are classified on the basis of their annual turnover:

| <i>Classification<br/>(Post<br/>Amendment)</i> | <i>Annual Turnover</i>                                |
|------------------------------------------------|-------------------------------------------------------|
| Micro Enterprises                              | Less than or equal to Rs. 5 crore                     |
| Small Enterprises                              | More than Rs. 5 crore but not exceeding Rs. 75 crore  |
| Medium Enterprises                             | More than Rs 75 crore but not exceeding Rs. 250 crore |

### 4.2 Types of Enterprises

From the point of view of ownership and management, business enterprises may be broadly classified under three categories.

- Private sector enterprises
- Public sector enterprises
- Joint sector



#### **4.2.1 Private Sector Enterprises**

The enterprises which are owned, controlled, and managed by private individuals, with the main objective of earning profit comes under this category. Private individuals thus could start a venture as:

- Sole-proprietorship
- Partnership
- Joint Hindu family business
- Co-operative
- Company

#### **4.2.2 Public Sector Enterprises**

When business enterprises are owned, controlled and operated by public authorities, with welfare as primary and profit as secondary goals, they are called as public sector enterprises. Either the whole or most of the investment in these undertakings is done by the Government(s). These enterprises have the following forms of organisation:

- Departmental undertaking
- Public corporations
- Government companies.

#### **4.2.3 Joint Sector Enterprises**

Joint sector is a form of partnership between the private sector and the government where management is generally in the hands of private sector, with enough representation on Board of Directors by the Government too. Resources are mostly borne equally. Thus, one of the first decisions that an entrepreneur will have to make for his new venture is how the business should be structured. We know all businesses must adopt some legal configuration that defines the:

- Control,
- Personal liability,
- Rights and liabilities of participants in the business's ownership
- Life span
- Financial structure.

This decision of ownership and management will have long-term implications. So an entrepreneur may consult experts and professionals and seek help to select the form of ownership that is right for him/her. In making a choice, an entrepreneur will want to take into account the following:

- Vision regarding the size and nature of the business.
- The level of control the entrepreneur wishes to have.
- The level of "structure" entrepreneur is willing to deal with.
- The business vulnerability to lawsuits.
- Tax implications of the different organizational structures.
- Expected profit (or loss) of the business.

From the entrepreneur's point of view the most commonly opted out forms for starting anew venture are:

- Sole proprietorship
- Partnership
- Company

As entrepreneurs are strongly motivated by monetary gains and independence, these three forms fulfil the basic requirement of entrepreneurs well, making them the most desirable structure to commence a venture.

### **4.3 Overview of the Five Basic Legal Forms of Organization**

#### **4.3.1 Sole proprietorship**

Historically, it appears that business first started with this form of organization. One of the oldest, simplest and most commonly used forms of business organization which is owned, financed, controlled and managed by only one person is called as sole proprietorship, single entrepreneurship or Individual proprietorship.

##### **Suitability of sole proprietorship form of business**

The success or failure of an enterprise depends upon the intelligence, competence and sensible decision making capacity of the entrepreneur. Before opting for sole proprietorship, an entrepreneur should carefully compare and evaluate pros and cons of this form. Basically, this type of form is suitable when:

1. Capital requirement is limited
2. Confidentiality / secrecy is important
3. Market is local
4. Goods are of artistic nature or demands customized approach
5. Quick decision-making is necessary
6. Size of the venture is small.

##### **Sole proprietorship registration procedure**

A sole proprietorship does not need to be registered (**so yes, 'registration of a sole proprietorship' is a wrong thing to say**) and is therefore an inexpensive manner of commencing business. However, in order to start a sole proprietorship an entrepreneur requires certain industry specific licenses. A few general factors are:

- Business name: Sole proprietors are under no obligations to select a trade name for their business. However, they are free to do so if they desire to.
- Others: PAN Card no. of the sole proprietor, bank account no. in the name of sole proprietorship business, Shops & Establishment License, Employee Provident Fund Registration or Importer Exporter Code (if in export-import business) as and where applicable, have to be complied with.
- Payment of taxes: A sole trader has to ensure his/her business meets the state and federal taxation requirements. Due to the fact that legally, a sole tradership and a sole trader are a single entity, the sole trader bears the taxes of the business.

#### **4.3.2 Partnership**

Partnership form of organisation has developed due to the inherent limitations of sole proprietorship i.e.

- Limited capital
- Limited managerial ability
- Limited continuity.

In this era of specialization, expansion and diversification, expecting one man to combat them all is not possible. Business acumen and wealth seldom meet in one person. This, desirable combination probably led to the emergence of Partnership form of business. A partnership is an association of two or more persons to carry on, as co-owners of a business and to share its profits and losses. Thus, two or more persons may form a partnership by making a written or oral agreement to carry a business jointly and share its proceeds.

### **Suitability**

The use of better sophisticated production techniques has necessitated more investments. Complex nature of businesses needs expert managerial hands. Thus, partnership form of a business is an ideal choice for starting a new venture, if the entrepreneur's–

- Capital and managerial requirements are higher as compared to that of sole proprietorship;
- Enterprise falls in the category of either being a small or a medium scale enterprise;
- Direct contact with the customers is essential.

### **Drafting of partnership deed**

Partnership is an agreement between persons to carry on a business, entered into either orally or in writing. It is always desirable to have a written agreement so as to avoid misunderstandings and unnecessary litigations in future. When the agreement is in written form, it is called a '*Partnership Deed*'. It must be duly signed by the partners, stamped and registered. Any alteration in one partnership deed can be made with the mutual consent of all the partners. Although it is left to the choice of the partners of the firm to decide themselves as to what should be mentioned in their partnership deed, yet a partnership deed generally contains the following:

- Name of the firm.
- Nature of the business.
- Name of partners.
- Place of the business.
- Amount of capital to be contributed by each partner.
- Profit sharing ratio between the partners.
- Loans and advances from the partners and the rate of interest thereon.
- Drawings allowed to the partners and the rate of interest thereon.
- Amount of salary and commission, if any, payable to the partners.
- Duties, powers and obligations of partners.
- Maintenance of accounts and arrangement for their audit.
- Mode of valuation of goodwill in the event of admission, retirement and death of a partner.
- Settlement of accounts in the case of dissolution of the firm.
- Arbitration of case of disputes among the partners.
- Arrangements in case a partner becomes insolvent.

### **Registration procedure**

A partnership firm can be registered whether at the time of its formation or even subsequently. Entrepreneur needs to file an application with the Registrar of Firms of the area in which his/her business is located.

#### **Step: 1**

Application for partnership registration should include the following information:

- Name of the firm
- Name of the place where business is carried on
- Names of any other place where business is carried on
- Date of partners joining the firm
- Full name and permanent address of partners.
- Duration of the firm

#### **Step: 2**

Every partner needs to verify and sign the application. Ensure that the following documents and prescribed fees are enclosed with the registration application.

- Application for registration in the prescribed form-I.
- Duly filled specimen of affidavit
- Certified copy of the partnership deed
- Proof of ownership of the place of business or the rental/lease agreement thereof.

It may be noted here that, the name of the partnership firm should not "contain any words which may express or imply the approval or patronage of the government except where the government has given its written consent for the use of such words as part of the firm's name". Once the Registrar of Firms is satisfied that the application procedure has been duly complied with, he/she shall record an entry of the statement in the Registrar of Firms and issue a Certificate of Registration.

### **4.3.3 Joint Stock Company**

Resources and the life span of both sole proprietorship and partnership form of organisation stands limited with liabilities being unlimited. To comply with these growing needs, the demand was on rise for:

- 1) Capital
- 2) Managerial talent and skills
- 3) Limited liability

Thus, joint stock company as a modern form of business organisation emerged to meet the requirements of large sized business.

## **4.4 Company:**

An entrepreneur, under the 'Company' form of organisation has a further choice to incorporate an enterprise either as:

- a) Private company
- b) Public company
- c) One Person Company (Companies Act 2013)

A company has a separate legal entity (separate legal person). Shareholders of the firm contribute capital to the company in the form of equity shares. Companies are governed by the Companies Act, 2013.

#### 4.4.1 Salient Features:

- **Types of Companies** : Public Limited or Private limited or One Person Company
- **Capital requirements:** Minimum capital requirement is Rs. 500,000 in case of public companies and Rs. 100,000 in case of private companies. In case of one-person company, paid up share capital of the company should be less than Rs. 50 lacs and average annual turnover in 3 immediate preceding financial years should be less than Rs. 2 crores. Shares and Preference Shares can be issued by Indian Companies. Although all equity shares have voting rights, the law allows issuance of equity shares with differential rights with respect to voting, dividend sharing, etc.
- Minimum Number of Subscribers, Shareholders and Directors Required.

|                                                     | Public   | One Person Company | Private |
|-----------------------------------------------------|----------|--------------------|---------|
| Minimum numbers of subscribers/shareholders/members | 7        | 1                  | 2       |
| Maximum number of subscribers/shareholders/members  | No limit | 1                  | 200     |
| Minimum number of directors                         | 3        | 1                  | 2       |

- **Equity Restrictions:** There are no debt/equity restrictions under the Company Law. However, limits are prescribed for acceptance of deposits by companies.
- **Value of Shares:** The shares of a company whether preference or equity must have a nominal/par value.
- **Management of the Company:** Company is managed by the Board of Directors who may delegate powers, except where any transaction requires approval of Board of Directors under the Companies Act, to any director or managing director.
- **Requirements as to appointment of a Company Secretary:** The law provides for compulsory appointment of a full time Company Secretary, where the paid up capital of a company exceeds the prescribed limit, (presently Rs 50 million). Where the paid up capital is Rs 1 million up to 50 million a compliance certificate from a practicing company secretary is required every year.
- **Procedure for registration and incorporation:** The promoters of the company have to apply to the Registrar of Companies for availability of the proposed name of the company. After obtaining approval, the Memorandum and Articles of Association of the proposed company are filed with the Registrar of Companies for registration. On registration, a Certificate of Incorporation is issued which is conclusive evidence of the company having been incorporated.
- **Commencement of Business:** A Certificate to commence business is required in case of a public limited company whereas in the case of a private limited company business can be started immediately after incorporation.
- **Costs associated with Incorporation:** The costs associated with incorporation of a company relate to drafting and printing of the Memorandum and Articles of Association, stamp duty, registration and filing fees, in addition to professional fees of advisors who assist in the process.

- **Time taken for Incorporation of a Company** With the introduction of mandatory e-filing procedures, it usually takes 2-4 weeks to incorporate a company in India.
- **Restriction on distribution:** A company can distribute its profits as dividend after transferring certain percentage of its profits to the general reserve (subject to certain conditions). However, capital profits are not allowed to be distributed.
- **Records to be maintained**  
Companies registered in India are governed by the Companies Act, 2013 and are required to maintain statutory books as prescribed under the Act. There is no provision as to the form of the books of accounts. However, it is incumbent on the companies to maintain accounts on accrual basis and the books of account must be retained for a minimum of eight years.
- **Preparation of financial statements**  
Financial statements are normally prepared once in a year under the Companies Act. However, a listed company is also required to publish quarterly results and half yearly results after review by auditors. For tax purposes, financial statements as at 31st March each year must be prepared.
- **Contents of financial statements**  
Financial statements of a company are prepared in the form prescribed under the Companies Act.
- **Audit of financial statements**  
Every company in India, irrespective of its size, must have its financial statements audited, by a member of 'The Institute of Chartered Accountants of India'. Companies or other entities, which have exceeded the prescribed limit of turnover (presently Rs 1 crore if engaged in business and Rs 50 laks if engaged in profession), also have to get their accounts audited under the Income tax Act.
- **Inspection of Records**  
The books of accounts and other records are open to inspection by any director, Registrar of Companies and other government agencies such as excise, sales tax etc.
- **Accounting year**  
The accounting year of an organization must end on 31st March every year for income tax purposes.
- **Language in which business records are required to be maintained**  
There is no prescribed language for maintenance of books and business records. It can be maintained in any Indian language. Companies generally maintain their accounts in English.

#### 4.4.2 Income tax

Income tax is chargeable on taxable income computed in accordance with the provisions of the Income-tax Act, 1961 (the Act). All taxpayers are required to follow a uniform accounting year from April 01 to March 31.

Income earned during the financial year is assessed to income-tax in the next year, called the **assessment year**.

There are certain permissible deductions in computing the taxable income and there are certain disallowances in respect of expenditure incurred by the company. In arriving at taxable income, outlays on revenue account, incurred

wholly and exclusively for business purposes are deductible. Certain expenses are specifically disallowed or the quantum of deduction is restricted. These include:

- Interest, royalties, technical service fees or any other chargeable amounts paid outside India or in India to non-residents without the withholding of applicable tax. However, such expenditure is deductible in the year in which the tax is paid/ deducted at source;
- Interest, contractual payments, rent, royalty, professional/technical service fees, etc paid to a person resident in India without withholding of applicable tax. However, such expenditure is deductible in the year in which the tax is paid/ deducted at source;
- Income-tax/ wealth tax paid;
- Provisions for taxes, duties, interest on loans from public financial institutions or on term loans from a scheduled bank and certain statutory contributions to funds on behalf of employees, not actually paid.
- Security transaction tax paid, if investments are kept for capital gain purposes.

Depreciation is normally calculated using the declining balance method at varying rates. All similar type of assets eligible for the same rate of depreciation are clubbed together in a block and depreciation is charged on the value of the block. Depreciation is available for a full year, irrespective of the actual period of use of the asset. However, in the year of acquisition of the asset, depreciation is allowed at half the normal rates, if the asset is used for less than 180 days in that year. No depreciation is available in the year of sale of the asset. Depreciation on intangible assets such as know-how, patents, copyrights, trademarks, licences, franchises or other similar business or commercial rights, is also available.

The rates of depreciation for different blocks of assets are as follows:

Buildings - 5 –10%  
Furniture and fittings - 10%  
General plant and machinery - 15%  
Intangible assets - 25%  
Computers - 60%

The following are some of the other important deductions that are available to arrive at the taxable income:

- Certain preliminary expenses over a five-year period commencing from the year, in which the business commences;
- Capital expenditure on scientific research related to the business of the taxpayer; 125% of the amounts paid to approved scientific research associations; and 200% of the amount of expenditure incurred on in-house research and development facilities.
- Tax deductions are available in respect of profits derived from manufacturing items / goods or services, including computer software and information technology (IT) enabled services, from units in specified locations, industrial undertakings or enterprises engaged in infrastructure development, specific projects etc. or with specific registrations such as Industrial Parks, free trade zone (FTZ) or software technology park (STP) or export processing zone (EPZ) or special economic zone (SEZ); and units that are registered as hundred % export oriented undertakings (100% EOU).

- Business losses, other than from speculation business, are permitted to be set off against income from any other source (except income from employment i.e. salary income) in the same year. Business losses not so set off are permitted to be carried forward for set off against business profits arising in subsequent eight years. Unabsorbed depreciation is permitted to be carried forward for an unlimited period.

Corporate tax rate is also applicable to partnership firms. The corporate tax rates for the financial year 2017-18 are as follows:

- **Domestic Company**
  - o 30% or 25% (if turnover is less than Rs. 50 Crore)
  - o Surcharge of 7% where income exceeds Rs. 1 Crore; and surcharge of 10% if income exceeds Rs. 10 Crores.
  - o 3% less is also payable.
- **Minimum alternate tax (MAT) for the AY 18-19**  
MAT is payable by a company at 18.5 % plus applicable surcharge and education cess on the “book profits” computed as specified where the income-tax liability determined under the normal tax provisions is lower than tax on “book profits”. Tax credit for MAT is allowed against tax liability in subsequent ten years, where tax becomes payable under normal provisions of the Act.
- **Dividend distribution tax for the AY 2018-19**  
Dividends distributed by an Indian company are not taxable in the hands of the shareholders. The Company distributing the dividends is liable to pay a dividend distribution tax of 15%.
- **Withholding tax – Tax deducted at source**  
The Indian tax law casts an obligation on each taxpayer to withhold tax (tax deducted at source) on specified payments, among others on the following:
  - o Salaries;
  - o Interest;
  - o Rent;
  - o Commission or brokerage;
  - o Payments to contractors;
  - o Professional / technical fees / Royalty; and
  - o Payments to non-residents.
- **Personal Income tax for Assessment Year 2018-19**
  - 0 – 2,50,000 – Nil
  - 2,50,001 - 5,00,000 - 5.15% (including education cess @ 3%)
  - 5,00,001 - 10,00,000 - 20.6% (including education cess @ 3%)
  - 10,00,001 and above - 30.9% (including education cess @ 3%)
  - Maximum amount not chargeable for senior citizen above 60 years is Rs. 3,00,000 and for senior citizen above 80 year is Rs. 5,00,000.
- **Capital Gains Tax**  
Tax on capital transaction is levied in the form of capital gains tax on transfer of a capital asset. Short term capital gains are charged at normal rates applicable for personal or corporate taxation. Long term capital gains are taxed @ 20% (plus applicable surcharge and

education cess @ 3%). However, a long term capital gain arising from transfer of listed securities, on which Security Transaction Tax has been paid, is exempt from tax whereas short term capital gain arising from transfer of above securities is charged to tax @ 15% (plus applicable surcharge and education cess as 3%).

- **Gift tax**

Gift made after September 30, 1998 are not chargeable to Gift Tax. However, aggregate amount of gifts from unrelated persons received on or after April 01, 2006, above the threshold limit of Rs.50,000 will be taxed as income. Gifts received from blood relation, lineal ascendants / descendants and gifts received on certain occasions like marriage, inheritance, etc are exempt.

#### **4.4.3 Indirect Taxation: Goods and Services Tax (GST)**

GST is an indirect tax levied on the supply of goods and services. GST Law has replaced many indirect tax laws that previously existed in India. GST is 'one indirect tax' for the entire country. GST was passed by the Parliament on 29th March 2017, and came into effect on 1st July 2017. In particular, GST has replaced the following indirect taxes at the central and state levels:

- At Central level
  - o Central Excise Duty
  - o Service Tax
  - o Additional Excise Duties
  - o CVD (levied on imports in lieu of Excise duty)
  - o SAD (levied on imports in lieu of VAT)
  - o Excise Duty levied on Medicinal and Toiletries preparations
  - o Surcharges and Cesses
  - o Central Sales Tax
- At State level
  - o VAT/Sales tax
  - o Entertainment tax (unless it is levied by the local bodies)
  - o Luxury Tax
  - o Taxes on lottery, betting and gambling
  - o Entry tax not in lieu of Octroi
  - o Cesses and Surcharges

The concept of GST can be understood with the following example:

A product with a base price of ₹ 100, after levying excise duty @ 12% of value of the product is priced at ₹ 112. On sale of such goods, VAT is levied @ 12.5% and value to the ultimate consumer is ₹ 126. In the GST system, on a base price of ₹ 100 Central GST (CGST) and State GST (SGST) both will be charged, say @ 8% each, and then the value to the ultimate consumer becomes ₹ 116. Therefore, in the GST regime, the industry can better compete in the global environment.

GST primarily removes the cascading effect on the sale of goods and services. Removal of cascading effect directly impacts the cost of goods and services. GST is also technologically driven. The activities such as registration, return filing, application for refund and response to notice needs to be done online on the GST Portal at <https://www.gst.gov.in/>.

- Other taxes  
The other taxes that are levied are expenditure tax, interest tax, stamp duty and research & development cess.

#### **4.4.4 One Person Company- A Concept for New Age Business Ownership**

The revolutionary new concept of 'One Person Company' (OPC) has been introduced by the Companies Act, 2013. This concept of OPC was first recommended by the expert committee of Dr. JJ Irani in 2005. OPC provides a whole new bracket of opportunities for those who look forward to start their own ventures with a structure of organized business. OPC will give the young businessman all benefits of a private limited company which categorically means they will have access to credits, bank loans, limited liability, legal protection for business, access to market etc all in the name of a separate legal entity.

Though the concept of OPC is new in India but it is a very successful form of business in UK and several European countries since a very long time now.

- **The concept with special features**  
One Person Company is defined in Sub- Section 62 of Section 2 of The Companies Act, 2013, which reads as follows:

*'One Person Company means a company which has only one member'*

It shall also be important to note that Section 3 classifies OPC as a Private Company for all the legal purposes with only one member. All the provisions related to the private company are applicable to an OPC, unless otherwise expressly excluded.

The only exception provided by the Act to an OPC is that according to the rules only "NATURALLY-BORN" Indian who is also a resident of India is eligible to incorporate an OPC. Meaning thereby, the advantages of an OPC can only be obtained by those INDIANS who are naturally born and also a resident of India. At the same, it shall also be worth mentioning that a person cannot form more than 5 OPC's.

- **OPC and its Formation**  
An OPC is incorporated as a private limited company, where there is only one member and prohibition in regard to invitation to the public for subscription of the securities of the company.

The Salient features of an OPC include the following:

- o An OPC can be formed under any of below categories :
  - o Company limited by guarantee.
  - o Company limited by shares
- o An OPC limited by shares shall comply with following requirements:
  - o Shall have minimum [paid up capital of INR 1 Lac
  - o Restricts the right to transfer its shares
  - o Prohibits any invitations to public to subscribe for the securities of the company.
- o An OPC is required to give a legal identity by specifying a name under which the activities of the business could be carried on. The words 'One Person Company' should be mentioned below the name of the company, wherever the name is affixed, used or engraved.

- o The member of an OPC has to nominate a nominee with the nominee's written consent, and file it with the Registrar of Companies (RoC). This nominee in the event of death or in event of any other incapacity, shall become a member of an OPC. The member of an OPC at any time can change the name of the nominee providing a notice to the RoC in such manner as prescribed. On account of Death of a member, the nominee is automatically entitled for all shares and liabilities of OPC.
- ***Exemptions available to one person company – legal provisions***  
An OPC has certain privileges and exemptions which are not available to private companies. Such exemptions are enlisted for your ready reference:
  - o Signatures on Annual Returns – Section 92 of the Companies Act, 2013

It is provided in section 92 of The Companies Act, 2013, that the annual returns in the case of One Person Company shall be signed by the company secretary or where there is no company secretary, then by the director of the company.

- o Holding Annual General Meetings – Section 122 of the Companies Act, 2013  
Section 122(1) of The Companies Act, 2013, provides that the provisions of S.98, S.100 to S.111(both inclusive) are not applicable to One Person Company. Therefore, provisions relating to General Meetings, Extra Ordinary General Meeting and Notice Convening to General Meeting are not applicable to One Person Company. However, for fulfilling the purposes of S.114 of the Companies Act, 2013, where any business is required to be transacted at an Annual General Meeting, or other General Meeting of the company by means of an ordinary or special resolution, it shall be sufficient if the resolution is communicated by the member of the company and entered in the minutes book which is required to be maintained U/s 118 and signed and dated by the member and such date shall be deemed to be the date of meeting under the purposes of Companies Act, 2013.
- o Board Meetings and Directors – Section 149, 152 & 173 of the Act  
One Person Company needs to have one director. It can have maximum of 15 directors which can also be increased by passing a special resolution as in case of any other company. For the purposes of holding board meetings, in case of a OPC which has only One director, it shall be sufficient compliance if all resolutions required to be passed by such a company at a board meeting are entered in a minute book – signed and dated by the member and such date shall be deemed to have the date of the board meeting for all the purposes under Companies Act, 2013.
- o Signatures on Financial Statements - Section 134 and 137 of the Act.  
The OPC shall file with the RoC a copy of financial statements duly adopted by its members along with all the documents which are required to be attached to such financial statement, within 180 days from the closure of the financial year along with cash flow statements. The financial statement shall be signed by only one

director and the annual return shall be signed by the company secretary and the director, and in case if there is no company secretary then only by the director.

- o Contracts by One Person Company – Section 193 of the Act. The new Companies Act, 2013 gives special attention to the contracts which will be entered by One Person Company.

If the company fails to comply with the provisions as to providing the information to the RoC then it shall be liable for punishment of fine which will be not less than twenty thousand rupees and extend to one lakh rupees and the imprisonment for a term which may extend upto 6 months.

- ***How is an OPC Different from Sole Proprietorship***

The concept of OPC allows a single person to run a company limited by shares, and Sole proprietorship means an entity where it is run and owned by one individual and where there is no distinction between the owner and the business. The distinction between both the structures is as follows:

- o Limited Liability - Fundamentally the basic difference between a sole proprietorship and an OPC is the way and manner in which the liability is treated in an OPC. OPC is different from sole proprietorship because it is a completely separate entity and that is the distinction between the promoter and the company. The liability of the shareholder will be limited to the unpaid subscription money in his name. On the other hand the liability in a sole proprietorship, the person/owner is alone liable for the claims which will be made against the business.
- o Tax Bracket - Though the concept of an OPC has been incorporated in the Companies Act, 2013 but the concept of same does not exist in tax laws as yet, as a result an OPC can be put in the same bracket of taxation as other private companies. According to Income TA, 1961 a private limited company is under the bracket of 30% on total income with an additional surcharge of 5% if the income exceeds 10 million with an addition to 3% of education cess.
- o Succession - In an OPC there is a nominee designated by the member. The nominee which will be a Natural Born citizen of India and who resides in India. The nominee shall in the event of death of the member become a member of the company and will be responsible for the running of the company. But in the case of sole proprietorship this can only happen through an execution of WILL which may or may not be challenged in the court of law.
- o Compliances - A One Person Company has to file annual returns etc just like a normal company and would also need to get its accounts audited in the same manner. On the other hand a sole proprietorship would only need to get audited under the provisions of Section 44 AB of the Income Tax Act, 1961 once its turnover crosses the certain threshold.

- ***Impact of OPC in Indian Entrepreneurship***

Though the concept of an OPC is still very new in Indian entrepreneurship and thus very revolutionary, it will take time for such a new concept to be incorporated with complete efficiency, but as and when the time will pass, an OPC will have a sparkling future and it will be embraced as a most successful business concept. The reason behind it is the incorporation of same is less paper work, one person can form a company without any additional shareholder, and if the member is willing to add shareholders, all he needs to do is to modify the Memorandum of Association and file it before Roc. Small entrepreneurs will grow in Indian entrepreneurship, be it weaver, traders, artisans, small to mid-level entrepreneurs, OPC is a bright future for them to grow and to get recognition globally.

Foreign Investors will be dealing with one member to establish a corporate relationship and not with a score of shareholders/directors where there are more chances for disparity in Ideas, concepts etc for a business to grow. Any foreign company who wishes to establish in India through an Investment, through a merger or through a Joint venture will have to just lock the deal with the member of an OPC, and the venture will be expected to start sooner with more effective results. In upcoming years the impact of an OPC will be remarkable and it is a promising future for Indian Entrepreneurship.

Expectedly, there will be good Foreign Investments, Joint Ventures, and Mergers etc. An OPC is doing well in European Countries, In United States, Australia the same is resulting in strengthening the economy of the countries. In India when the expert committee of Dr. JJ Irani proposed the concept of an OPC, it was solely aimed for the structured organized business, with a different legal entity altogether and to organize the private sector of the entrepreneurship, which indeed is expected to be done, alongwith a significant growth in Indian Economy benefiting the country on the Global Level.

## Experience Sharing: Consure Medical

Though his first start-up failed in 2004, Mr Nishith Chasmawala's relentless entrepreneurial pursuit today is helping millions of patients worldwide through his new start-up, Consure Medical, which develops novel critical care products. Its first product is a novel device to manage fecal incontinence.

The genesis of the New Delhi-based start-up was at the Standord-India Biodesign Fellowship, a program designed to train next-gen medical technology innovators in India.

It was at this program both the founders, Mr Nishith Chasmawala and Mr Amit Sharma met together, who are now Consure's CEO and Director of Products respectively.

### Novel Portfolio

Consure Medical was started in 2012. Both the founders were veterans of the medical device industry and have launched novel class II and III devices in the US, EU and Japan.

The start-up is developing and commercializing a novel portfolio of critical care devices that work across a continuum of care settings.

Its first product - Qora SMK - provides a novel means to manage fecal incontinence in non-ambulatory patients.

Worldwide more than 100 million patients are incontinent each year, and rely on either an absorbent pad (adult diaper) or a fecal drainage device.

The use of pads manifests dermatitis, maceration, increases the length of stay, and has direct impact on healthcare costs. Though drainage devices contain fecal exudate in a bag, and hence avoid complications of pads, they have a very narrow indication of use and manifests complications like necrosis and sphincter dysfunction.

With the Qora technology, Consure reimaged management of fecal incontinence by developing a novel drainage catheter that can be used with varying stool consistencies or rectal tone on patients across a continuum of care facilities.

More importantly, this technology can be used by a minimally trained person at costs that are comparable or lower than the cost of using a diaper.

The patented Qora SMK has been cleared by the USFDA (US Food & Drug Administration), making Consure one of the few medical device companies in India that has its core patents granted in key geographies and regulatory clearances in place.

Similar to the latent need of incontinence, Consure today has 4 products in its

development pipeline, and is targeting commercial launch of these additional products by the fourth-quarter in 2016.

Before starting Consure, Mr Nishith was in charge of the core-technology development team at Kyphon (USA), which was acquired by Medtronic in 2007 for \$4.2 billion. He had a great passion to wanting to directly impact the healthcare ecosystem in India, and was exploring ways to come back to India.

Mr Amit, prior to joining him, was a founder of a design and development start-up. He was looking out for a more refined focus to create a lasting impact.

Purely from a design perspective, he saw an inherent conflict of interest in a consulting model because, at the cost of amazing product design, clients always gravitated towards a 'fit' within their existing portfolio and business model. He wanted to start a medical device company that was not encumbered by legacy products and addressed latent clinical needs by imbibing brilliant design methodology and user experience.

Mr Nishith holds a BS in Plastics Engineering from UMASS Lowell (University of Massachusetts), USA; Mr Amit holds a BS in Mechanical Engineering from Indraprastha University, and a MS in Design from Indian Institute of Technology (IIT) Delhi.

### Mapping Trends

While exploring entrepreneurial opportunities, the founders repeatedly saw three macro trends that increased their curiosity and led to a deeper analysis.

"We saw that medical devices are designed, developed and commercialized in silos and nobody had any qualms about it... Due to increased awareness, accountability via regulations, budgetary constraints and smart policies being implemented via Affordable Care Act (Obama Care), we saw that care facilities were getting more cost-conscious when making purchasing decisions," explains Mr Nishith.

Clinical safety, efficacy and regulatory clearances were obligatory requirements for medical device companies. To be commercially successful, companies needed to demonstrate a clear health-economic value proposition of their technologies versus existing standards of care.

He continues, "We saw a unique opportunity in developing products for the clinical setting with the least amount of resources and then try to stretch its feasibility all the way up to ICU or

trauma care. Again, breaking the silo model to focus on continuum of care and reduce costs." Mr Nishith notes that to overcome legacy health challenges, innovators in India are leading a silent transformation in delivery of health services and access to affordable healthcare.

"These models, though at a nascent stage, are a beacon of the shifting healthcare paradigm that other economies can emulate. By virtue of being in India, and with a deep focus on the Indian healthcare market, we saw a unique opportunity to disrupt distribution models to eradicate corruption, expand access to healthcare and alleviate overall health economic costs," observes Mr Nishith. "Mind-mapping of these macro trends and identifying latent clinical needs in different care settings was the genesis of Consure Medical."

### **Lessons From The Past**

The founders had learnt a lot from their previous start-ups.

"For 2 years Consure was in stealth mode and relied solely on grants and subsidies from government and corporates. During this time, the company focused on one product, completed its development, contract manufacturing and First in Human (FIH) safety study before approaching any investors. Besides capital, the main challenges were lack of local subject matter expertise and lack of a medical device ecosystem," says Mr Nishith. During initial stages, both the founders bootstrapped the company forgoing salary for almost 2 years, and relied on grants and friends in the industry to get to a significant clinical milestone.

The Series A investment was led by India Innovation Fund, Indian Angel Network, India Venture Partners and Mr Shrikumar Suryanarayan (Chairman and Co-founder, Sea6 Energy, & former President of R&D at Biocon).

Immediately post Series A, the company also secured two international grants enabling the company to extend its runway and aim for a bigger milestone.

Mr Nishith comments, "We are very fortunate to have supportive and patient investors with a long-term focus. Our investors have perfected the art of staying involved and helping out in a very non-intrusive manner. We believe there is always more capital that is chasing fewer good deals in general. Healthcare is considered to a

very robust industry from an investment perspective, which augurs well for entrepreneurs that want to create value and make lasting impact to healthcare."

Consure has achieved major regulatory and intellectual property milestones in half the timeline of a typical Silicon Valley medtech start-up with about one-tenth the financing over the last three years.

### **IPO-Ready By 2019**

At the moment, Consure is targeting intensivist, critical care nurses and CEOs of hospitals. "We make sophisticated devices that are very consumer-centric in design, but still require a prescription for use. We are also in conversations with large distributors and strategic partners to expand commercialization in different geographies," points Mr Nishith.

Being an advanced development stage and early commercial stage company, it is executing a customized commercial strategy in India, USA and Japan.

"We have our hands full with India, the US and Japan. Outside of these markets, we will expand along with a strategic partner or a distributor. We are working with index sites and key opinion leaders in India and the US," Mr Nishith reveals.

The start-up hopes to be IPO-ready by 2019.

He says that New Delhi is a favorable destination for medical devices start-ups.

"Gurgaon has the highest concentration of large medical device companies. It also has lots of big hospitals in and around Delhi. There is reasonably strong manufacturing base in Faridabad, Gurgaon, Chandigarh and Baddi in Himachal Pradesh," he states. "Personally for a global medical device company like ours - I like the airport and flight options of Delhi. Probably the best in the country with Mumbai being the second in terms of connectivity."

Mr Nishith feels that most medical device entrepreneurs are not interested in entrepreneurship.

"They are extremely motivated to solve a clinical problem or commercialize a novel technology, which is usually related to a deep emotional attachment. Often times, being an intrapreneur or collaborating with another company has higher odds of commercial success, than starting up on your own," he ends.

---

## 5. COMMERCIALIZATION PROCESS & STRATEGY

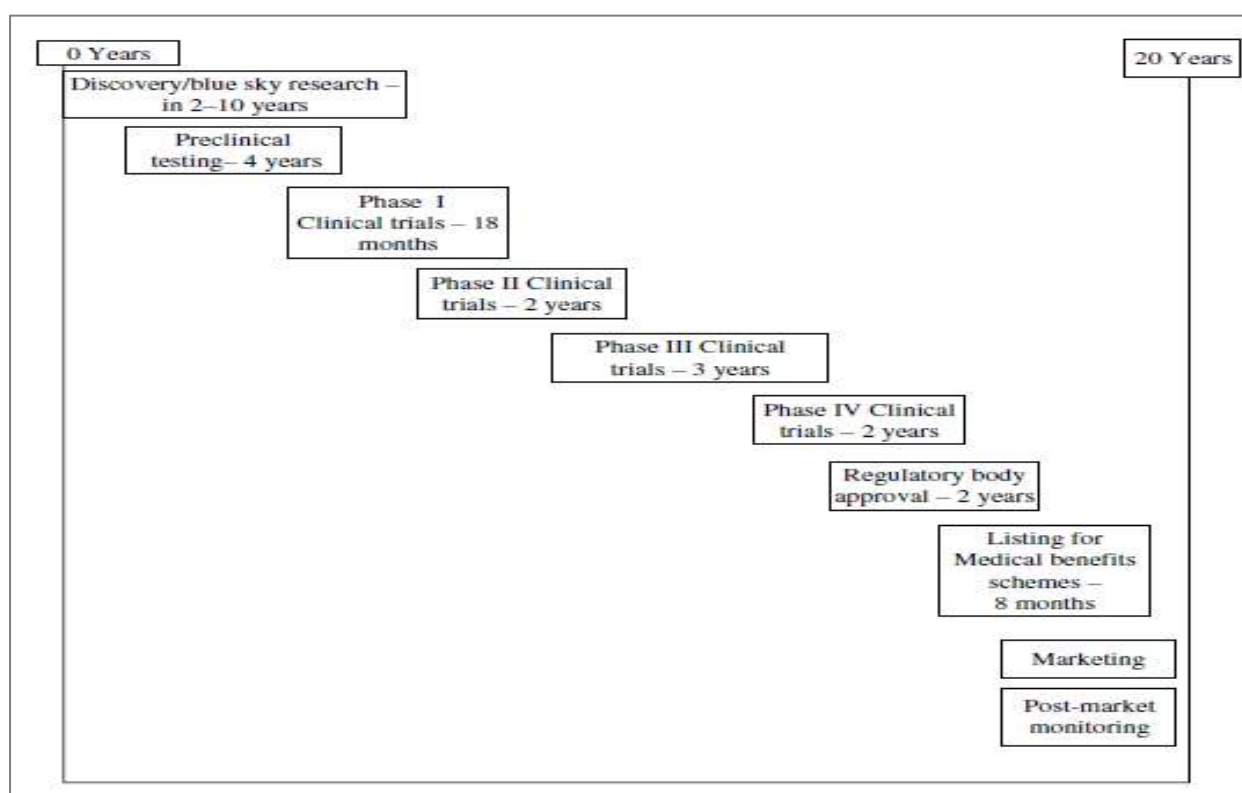
---

***“Commercialization is broadly defined as the process of taking an idea to a successful outcome in the market, whether it is a product, service, process or organisational system”***

Biotechnology companies, in general, face a far more extended R&D pipeline than many other high-tech industries. In the IT industry, typically \$2–3 million would be required to get software designed, developed and on to the market within a six to twelve-month period. However, in biotechnology, a typical drug takes 15–20 years and \$200–900 million to bring to market, with no guarantee of success. Investor criticism of biotechnology as a poor investment performer due to long lead times compared with IT.

The breakthroughs of Cohen and Boyer in recombinant DNA, seen to be the point of inflection for the biotechnology industry, only occurred in 1973. It is therefore unrealistic to expect massive changes in product development lead times within such a short period.

Stages of development are better indicated through the R&D pipeline giving a clear indication through the stages of R&D, from discovery research, to applied research including patenting, then through pre-clinical (including toxicity testing usually involving pharmacokinetics) and the three to four clinical trials stages prior to regulatory approval and market launch. The entire R&D cycle can take 10 to 20 years, and cost hundreds of crores of rupees, if successful.



The R&D pipeline also provides the small biotech firm with a basis for judging their exit strategy from the product as well as the overall product strategy, which is essentially the IP strategy – that is, when to license, whether to outsource trials, whether to manufacture, whether to remain a research-based company, and ultimately whether to allow the company

to be acquired by a larger player who can move the product more effectively through the pipeline. However for a founder of a small biotechnology firm, which has a research focus, it is always tempting to sell off the company with its IP and use the proceeds to fund further research in a related area, hence returning to one's comfort zone.

***The strategies for successful commercialization are founded on the three key factors of success:***

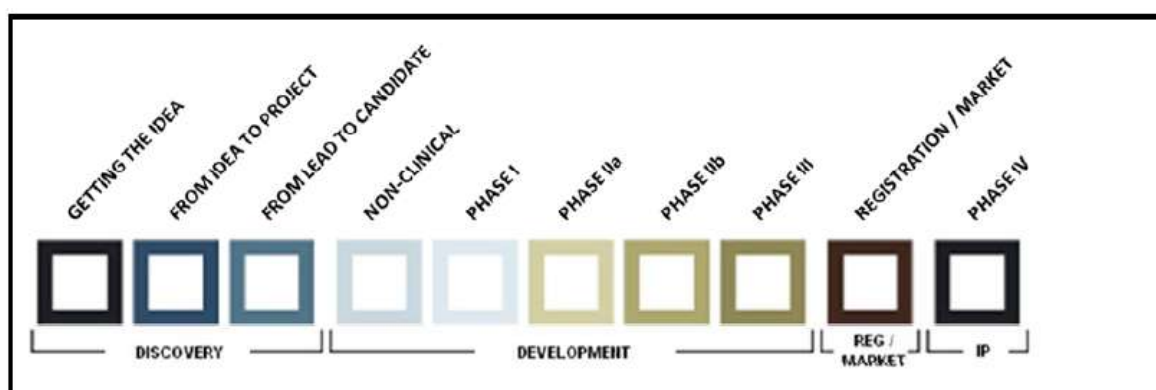
***ENTREPRENEURSHIP, INNOVATION AND COLLABORATION***

## 5.1 Biotechnology Product Value Chain

A firm's **investment strategy** outlines “what”, “when” and “how” it will interact with its **value chain** to create value for shareholders. These decisions are embodied in its **business model**.

What is a “value chain”?

Michael Porter introduced the concept of the value chain in his book *Competitive Advantage*, using the term to describe all the activities a firm performs and how those activities interact. He said a firm's value chain is embedded in a larger stream of activities, called the value system. This figure shows a typical value chain for the development of a drug.



Often, in the process of biotech drug development, firms will take up one or a number of the activities required to take a product from discovery to market.

The value chain is composed of a matrix of supply chain relationships along the drug discovery process. Only a small handful of biotech companies are engaged in the full value chain, from research and development through to marketing. The vast majority of biotech firms exploit a small or specialised niche.

The *pharmaceutical* value chain is characterized by two quite different focuses.

- The first is the business of scientific innovation – discovering a lead drug candidate then taking it through various stages of screening and preclinical testing, and eventually phase I and II human trials. A phase II trial is usually aimed at achieving a clinical proof of concept.
- The second focus is on commercialisation, which involves gathering information required by regulators and customers and communicating it to them. These activities occur during phase III clinical trials, the regulatory approval processes, marketing and selling, and any phase IV post-marketing studies.

Whilst the value chain outlines the major stages involved in getting a drug from concept to market, it does not indicate how multiple parties may interact with the value chain around any one (or multiple) stage. The vast majority of biotech firms either contract or collaborate for access to a wide variety of skills and complementary assets (such as manufacturing, sales and marketing infrastructure and distribution) that are vital to the development and commercialisation of their own innovation, or they provide know-how and services that other firms are reliant on.

## **5.2 Strategy for Commercialization**

The commercialisation strategy of a biotech involves the decisions it makes about “what”, “when” and “how” it will interact with its value chain.

- **“What”** describes the final product or service that the firm offers. For a pharmaceutical company this includes the formulation, presentation and therapeutic indications for a drug.
- **“When”** describes the point in the value chain that a firm decides to earn a return on its innovation. For example a firm may decide to sell or license a drug candidate soon after its discovery, or after preclinical testing or after phase I, II or III clinical trials.
- **“How”** refers to the revenue model through which value flows back to the company. Examples of revenue transaction mechanisms include direct physical product sales, licensing of technology for royalty payments, sale of technology and outright sale of the entire firm. All these strategic choices are summarised in a firm’s business model.

Arguably each firm should aim to insert their product, service or intellectual property into the value chain at the point that will maximize value creation for its shareholders. Full integration is not an option for most biotech firms due to a limitation in financial and human resources. So a commercialisation strategy needs to evaluate the costs, rewards and risks of participating further down the value chain, or enabling the firm to control more of the product development, manufacturing and marketing activities. To do this it is helpful to have a good understanding of what factors drive a company to commercialise (earn a return) in the “market for ideas” vs. the “market for products”.

## **5.3 Market for Ideas v/s Market for Products**

Financial returns on an innovation may be earned through the “product market” or the “market for ideas.” The product market we are all familiar with – it describes the way in which we buy and sell physical products (medicines or diagnostic kits, for example) or services (laboratory tests or surgery).

The market for ideas, on the other hand, is a notional market in which innovations are sold or licensed before they are a final product (or service). In essence the innovation is still an idea, or intellectual property – it is a collection of intangibles. Choosing between these two options is a key element in commercialization strategy. The innovator can try and take a product to market themselves (including manufacturing, marketing and distribution) or they can sell the idea to another firm – one with the appropriate infrastructure to launch the innovation.

- In the first instance, the innovator will use or pioneer its own value chain, meaning the firm integrates internally or contracts for the value-added activities.
- In the second, the innovator will use an already-existent value chain. The majority of biotech firms commercialize their innovations in the market for ideas -after all, manufacturing, marketing and distribution all bring additional costs-but there are times when this may not be the best strategy.

## 5.4 How do we know which is Best Option?

Intellectual property protection and access to complementary assets (regulatory knowledge, manufacturing ability, sales and distribution teams) both play a part. Strong intellectual property protection and a lack of in-house complementary assets usually means a company commercialises in the market for ideas – selling or licensing to a party with the skills and infrastructure to bring it to market. This is typical for small biotech firms.

However, when a firm does not have strong intellectual property protection, then it's at risk of having a larger partner appropriate (steal) its ideas, or take a much greater share of the value than the smaller firm thinks is fair. In this case, that firm might be better off keeping its intellectual property protected as a trade secret, which means it takes the innovation to market itself. If resource constraints means self-commercialization is not possible, then a small firm will need to rely on the reputation of the larger company to not be taken advantage of. If this occurs, it's best to use a trusted intermediary (such as a prominent venture capitalist or licensing lawyer) to act as a go between in negotiations that will not include full disclosure of the trade secrets until after deal completion.

A second situation is when there is no existing full value chain for a product, and the biotech start-up is forced to pioneer the development of new complementary assets.

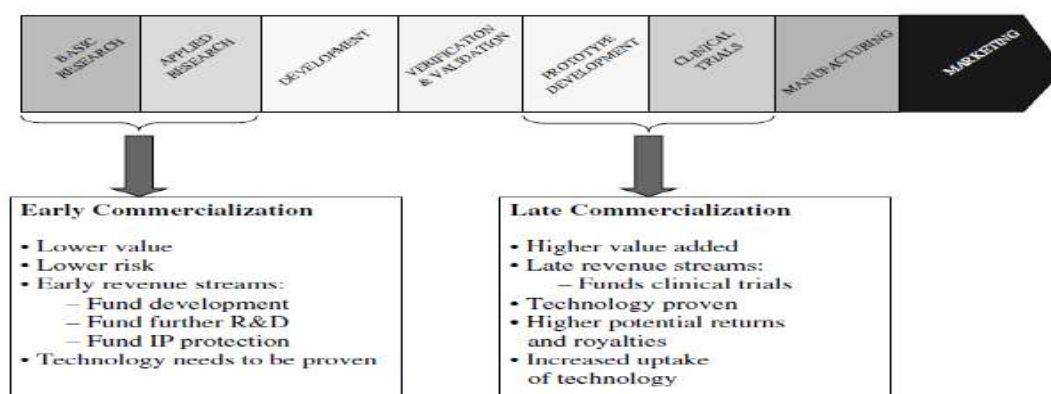
Sometimes an evaluation of the risks and rewards of using an existing value chain vs. building one will show the latter to be more rewarding, though building one requires access to sufficient capital. Products targeted at high-paying and/or highly centralised or niche market opportunities may lead to the development of downstream infrastructure for manufacturing, sales and marketing and distribution, even though existing channels could be used (e.g. orphan drugs, products sold to specialists or hospitals).

Once a startup has made the decision to commercialise in the market for ideas, the next questions are “when” and “how” to plug into the value chain. Cooperation might occur via research partnerships, arms-length licensing agreements or cozy joint ventures among other alternatives. Further, a company might find help at many points along the value chain, from discovery to preclinical testing or clinical testing to marketing.

## 5.5 Decision-making for Commercialization

Commercialization of research and knowledge requires a number of decisions to be made. This chart summarizes at a high level the common commercialization options practised by technology managers. A second major decision is to identify the point at which the technology or IP is harvested along the value chain. Greater value is gained as the technology or IP is progressed along the value chain.

*Funding innovation in biotechnology companies*



For simplicity, the value chain described here relates only to the development and commercialisation phase of the life cycle. The value chain is an essential concept in biotech commercialisation strategy because it is composed of a matrix of supply chain relationships along the drug discovery process, with only a small handful of biotech companies engaged in the full value chain from research and development through to marketing.

The vast majority of biotech firms exploit a small or specialised niche in the chain. The nature of the value chain is likely to evolve over the course of the product life cycle – through the stages of development, commercialisation, maximum profitability and generic substitution. This added dimension significantly increases the complexity of the value chain concept.

## **5.6 Technological Innovation vis-à-vis Business Models**

Looking at pharmaceutical development, there is a broad range of technologies and projects that span these factors, suggesting that different business models may be appropriate for various technological innovations. In *Science Business*, by Gary Pisano (2006) the author provides a useful examination of four broad classes of technological innovation and the common business models associated with them:

### **5.6.1 Novel research methods and tools (such as high-throughput screening, combinatorial chemistry, bioinformatics)**

Several business models are available to these companies, including simply licensing the use of the technique or tool to other drug companies that would then use them in their own discovery process. A second model would be to sell drug discovery services, while a third strategy would be to vertically integrate forward into drug R&D and develop proprietary molecules.

### **5.6.2 Identification of novel mechanisms of action or targets (angiogenesis, RNAi)**

Innovation here is concerned with the identification of new disease targets or mechanisms of action implicated in diseases. The market for ideas is not fully efficient in this situation. It is unlikely that intellectual property can be completely secured on a mechanism or class of targets. Often a lot of prior art exists and the intellectual property is based heavily on the kind of knowledge that cannot easily be transferred from one company to another, so it is unlikely that a firm in this innovation category can simply license its innovation. It is therefore more likely to pursue a drug discovery and development strategy. But how far down the drug development value chain should it integrate? This depends on the characteristics of the drug and the market. If it is a small-molecule drug candidate targeting a well-established therapeutic market (hypertension, for example, or diabetes or depression) the rationale for full vertical integration is weak, assuming the innovator is able to secure IP protection on the molecule. A licensee would likely have the necessary complementary assets and capabilities required to take the drug candidate down the development pathway to market.

### **5.6.3 Novel compound types/novel treatment modality and novel markets**

Biotechnology is bringing us new types of therapeutic molecules, such as rDNA, stem cells, monoclonal antibodies and new treatment modalities. Novel market opportunities are also being developed such as those for orphan disease for personalised medicine.

These types of innovations can be difficult to license due to lack of knowledge and capability on the part of would-be partners. Also, importantly, they typically require significant investments in downstream assets (development,

manufacturing, distribution). Full vertical integration may be the logical strategy for these types of innovation. Collaborations have been seen with these opportunities, but the risks are high, disputes common and collaboration may be a second-best strategy. While vertical integration reduces the risks of operating in an inefficient market for ideas, it raises other risks. The level of capital required is huge, and may preclude R&D portfolio diversification.

- 5.6.4** Identification of novel treatment modalities and therapeutic markets (gene therapy, xenotransplants, or drugs for rare genetic diseases).

## **5.7 Process of Commercialization**

### **5.7.1 Stage One – Identifying Options**

The Stage One involves identifying all options available to a firm in commercialising an innovation. A framework is given below to guide biotech entrepreneurs in considering their options in the following six strategic commercialisation parameters.

- 'what' to commercialise?
- 'when' to plug into the value chain?
- 'how' to transact with the value chain?
- 'with whom' to transact?
- 'who' are desired as shareholders?
- 'where' will the company operate?

More than likely, a few preferred combinations of options will emerge.

### **5.7.2 Stage Two – Evaluating Options**

What is important at this stage of the model is that a firm develops a systematic approach to evaluating their options. The critical paths, costs and anticipated rewards for these option combinations should be modelled in detail. The company should challenge its assumptions and comfort zones and to consider alternative options to those they readily identify with.

When choosing the options that the firm will invest in, the firm should also consider the opportunity cost of keeping open other, less preferred options. If the opportunity cost is low, then keeping such options open (and not losing sight of them) will allow the company to be more flexible in adapting its commercialisation strategy to changes in its internal and external environments during the long commercialisation journey.

### **5.7.3 Stage Three – Amplifying Value and Reducing Uncertainty**

At the Stage Three, the company selects a portfolio of options and makes the necessary investments. The first step in amplifying value/reducing risk is to map out the critical path for each chosen combination of options.

Clear go/no-go criteria should be developed for each critical action. This sets up the decision-making in stage three where options are exercised or terminated.

### **5.7.4 Stage Four – Exercising or Terminating Options**

In Stage Four, options are either exercised or terminated in accordance with go/no go criteria established in stage two. Establishing these criteria up-front will aid in preventing a psychological bias against disengaging from options with inherent sunk costs. Stage Four is tactical rather than strategic in nature.

## **5.8 Commercialization Options: Pathways & Strategies to Market**

Commercialization includes knowledge diffusion, consulting services and contract research rather than just the linear transfer of technology or intellectual property (IP). The options for commercialization to market are listed below.

### **5.8.1 Spin-off**

Spinning off the technology or IP into a start-up allows focus on commercializing the IP. Advantages include access to government assistance programmes or pre-seed funds. Disadvantages include requirement for a significant capital outlay and resources, risk associated with medium to long time-to-market (especially biotechnology/pharmaceutical projects) and the inherent risk in establishing a new venture.

### **5.8.2 Traditional out-licensing of technology or IP**

Licensing involves the transfer of rights to make, use or manufacture patented IP. It is a low-risk alternative to the spin-off option requiring low capital outlay. However, returns are also comparatively low depending on the progress of the technology along the value chain. When the technology has progressed to prototype stage or clinical trials then a higher royalty rate can be obtained. Negotiations usually involve an upfront licence fee with annual royalties usually payable per quarter. They can be subject to milestones set by the licensee and agreed by the licensor. A minimum annual fee is set for royalty payments. If royalty payments are lower than the minimum annual fee then the difference is payable by the licensee. Licensing involves transferring the rights to the technology/IP on an exclusive or non-exclusive basis. Licenses also define fields of use, geographic areas, economic limits and production and distribution limits. A licence agreement stipulates the licensing arrangements including the licensing fees and royalty payments.

### **5.8.3 Trade sale**

The rights to a technology or IP are transferred 100 per cent exclusively to a client in exchange for a single payment or a series of progress payments. This approach allows IP to be divested or transferred to an entity that perceives greater value in the IP or is readily able to exploit the IP. This allows the IP provider to redirect the payments to fund the further development of higher-value technology or IP. The only disadvantage with this approach is the loss of total control over the IP and the emotional attachment that may still exist.

### **5.8.4 Internal development**

Technology or IP is further developed internally either as a technology platform, converted to a product or as a hybrid where the technology platform is used to further develop products or applications. This approach adds value to the technology/IP as it is further progressed along the value chain. This approach implies that the organization has the resources and capability to progress the technology or IP across the full spectrum of the value chain; from discovery, through development and finally launched to market. The internal development option is limited to organizations that have established capability to achieve this, including research, development and prototyping, clinical trials and regulatory approval, manufacturing, and sales and marketing. Examples of biotechnology organizations that possess this capability include, Genentech, Amgen and Abbott Laboratories.

### 5.8.5 IP bundling/packaging

Grouping of technologies or different IP with synergistic or complementary characteristics where the sum of the technologies is far greater in value than the individuals.

### 5.8.6 Incubation

The technology/IP is incubated within another institute, organization or cooperative research centre where the technology is further developed. The advantage of this is using resources within the other organization to further develop this technology. The disadvantage of this approach is clarifying the ownership of existing IP, further development of the IP and any new IP that is generated. This approach may involve joint ownership by all parties where the ownership is clearly articulated in an agreement by prior arrangement. The agreement may also specify joint equity based on the contribution by all parties involved.

### 5.8.7 Collaboration/Partnership/Joint venture

This is similar to the incubation option, however, specific partners or collaborators may be used at various stages of the development of the IP. Collaborations are usually established at an early stage while a joint venture may be formed at a latter stage when the technology or product is more defined.

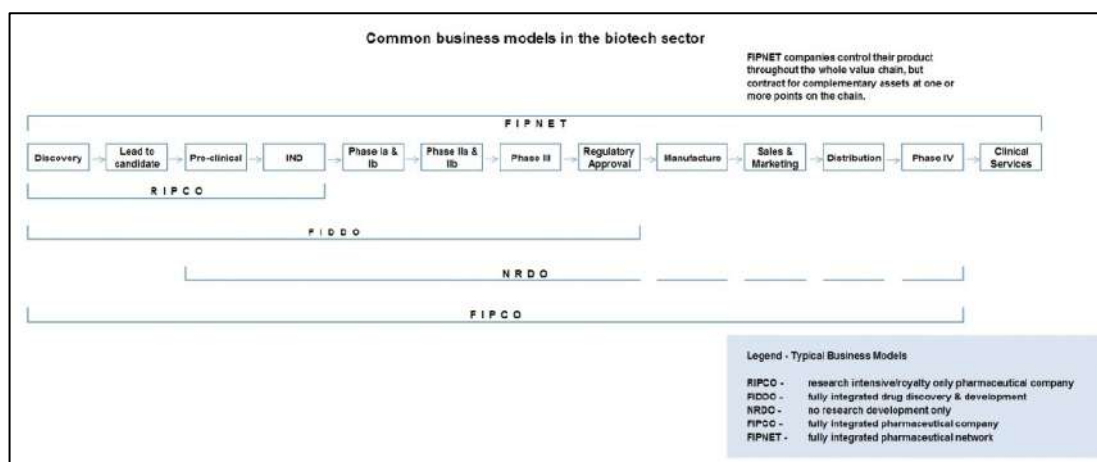
### 5.8.8 Stepping-stone approach

A strategy for commercializing the technology/IP is mapped along the various stages of the value chain and may involve a combination of internal development, licensing and collaborations. This type of approach is quite complex and may involve through licensing across the different stages of the value chain.

### 5.8.9 Simple contract

IP or know-how is simply transferred and applied to an organization via a simple contractual arrangement. This may be based on a single or multiple fee structure payable upfront, progressively or as a progress payment after the transfer has successfully occurred. This may also involve royalty payments but is not common. Many contract R&D, product development, manufacturing, marketing and distribution agreements are executed using this option.

## 5.9 Business Models in Biotechnology Commercialization



The above image summarizes some of the common business models in the biotechnology sector – showing which parts of the value chain the firms participate in and discussing very briefly the usual types of transaction mechanisms they use.

#### **5.9.1 Research Intensive Pharmaceutical Companies (RIPCO)**

With limited financial resources, the vast majority of biotech firms start out life as RIPCOs. They focus on the earlier stages in the value chain, such as discovery and preclinical development. The RIPCO model covers platform and tool-based companies seeking to commercialise drug targets, services and technologies that can be sold or licensed to other companies. At some point in the product development process, a RIPCO will plug into the value chain by contracting with one or more alliance partners who have the resources and/or capabilities to move the product development project further along the value chain. A RIPCO may not necessarily earn revenues the moment they plug into the value chain, as revenues may be contingent on achievements being made by the alliance partner as work progresses.

#### **5.9.2 Fully Integrated Drug Discovery and Development Organization (FIDDO)**

In the FIDDO model, platform companies extend their existing capabilities in order to take an innovation further along the product development process. The expectation is to enter an alliance or licensing agreement on more favourable terms than can be achievable under the RIPCO model.

#### **5.9.3 No Research, Development Only (NRDO)**

We also have NRDO model, whereby a company in-licenses product from others that is already in preclinical or clinical testing. An example is The Medicines Company; that firm does not engage in drug discovery.

#### **5.9.4 Fully Integrated Pharmaceutical/ Biopharmaceutical Company (FIPCO/FIBCO)**

With the FIPCO/FIBCO model, the strategy is to build and fully integrate most parts of the drug discovery and development chain. Given the large amount of capital required, few biotech firms attain this model, although many dream of it.

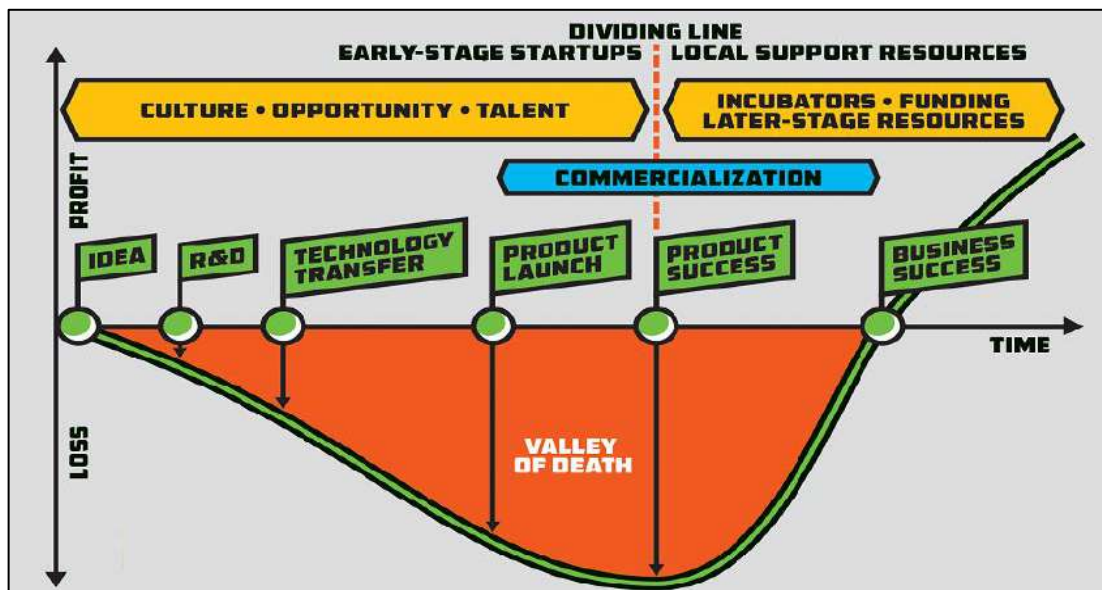
#### **5.9.5 Fully Integrated Pharmaceutical Network (FIPNET) or VIPCO (Virtually Integrated Pharmaceutical Company Organisation)**

More recent concepts are the FIPNET business model, whereby companies may outsource/contract extensively for services at any point(s) in the value chain, providing access to complementary assets outside the firm. This allows a company to maintain control of the product development process and defer the point at which they plug into the value chain.

Hybrid business models are sometimes used, particularly by platform or tool-based companies that enjoy stable revenues from licensing or sales, which allows for attracting investors or using their own income stream to develop products.

The ultimate goal for many biotech companies is still to pursue a traditional FIPCO structure controlling the value chain for their product offering. This may be a strategy driven by the promise of long-term return to investors and possibly naïve to the cumulative risks along the way. In any case, this seems to have become very difficult to do for biotech firms, due to the significant costs involved in bringing a product through the entire drug development and marketing chain. Therefore, the basic options seem to be to either find a niche in the value chain or control a relatively narrow slice of the market.

## 5.10 Avoid 'Valley of Death'



- ***The Valley of Death traps many commercialization initiatives***

All too often, promising technology development projects languish for years in limbo after they move beyond the initial research stage. There is even a name for this: the Valley of Death, which projects need to cross before attracting startup funding, or development partners. These projects are too far along to get funding from “research” sources, but are unable to negotiate partnership or licensing arrangements with large companies, or attract investors, because they are perceived as “too early”.

Some believe that the Valley of Death is an unavoidable feature of the landscape, or that it exists because of flaws in the way investors think. We think of it as more analogous to a sand trap in golf. It certainly exists, and falling into it is bad. However it can be avoided all together with careful planning and good execution. Even if you fall into it, you can get out if you know how.

- ***To cross the Valley of Death one must “BRIDGE” two cultures***

Moving a technology project past the Valley of Death is at its heart about building a bridge between two very different world views. A project languishes in the Valley of Death when this bridge is not in place.

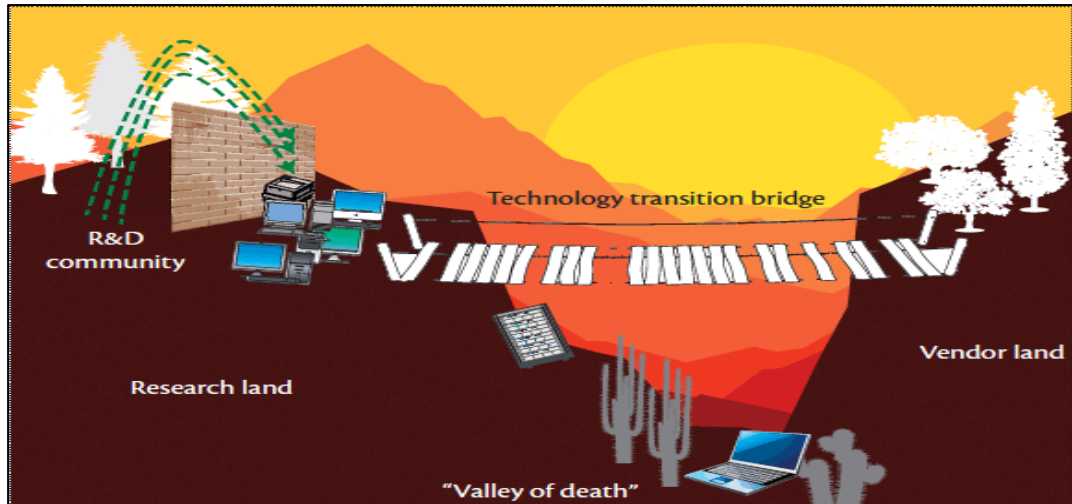
- o On one side are the technologists who developed the project to the point where it appears “promising”, and with “commercial potential”. Frequently they see the objective as commercializing the technology.
- o On the other side are managers within companies that are potential development partners or licensees, and investors who might wish to invest in the future of the project. For this group, the objective is to build a business, and realize an investment return.

- ***Creating the “BRIDGE” is often neglected***

We frequently see projects, or new ventures, where the team trying to commercialize the technology has not articulated the potential business in all its details. Sometimes they don’t feel the need to do this, thinking that it is really the “partner’s” job. Sometimes they just do not know how. And sometimes, they simply lack bandwidth to think through the myriad of complex issues that need to be resolved.

On the other hand, potential partners and investors rarely see it as their job to figure out what the business is going to look like, and their response is often “Hm, ... looks interesting.... but it's too early”. Meaning, “the technology looks interesting, but until we understand what the business would look like we can't decide whether or not it sounds like an attractive business proposition”.

- ***‘BRIDGING’ the Gap: Describe the Business for Investors***



The bridge between these two world views is a clearly articulated description of the business that can be created if the project moves forward.

---

## 6. MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS

---

***“An invasion of armies can be resisted, but not an idea whose time has come”  
— Victor Hugo***

Intellectual property (IP) protection is critical to fostering innovation in the society. If ideas are not protected, companies and individuals would not be able to enjoy the benefits of their inventions, thereby focusing less on further R&D. Similarly, authors and artists would not be receiving the due respect and reward for their creations, which would ultimately lead to less cultural vigor in the society.

On one hand IPR provisions provide a safe harbor to these original creators and inventors to protect their work and enjoy the right to exclusivity. On the other hand, it encourages further innovation and creativity, thereby leading to an intellectual as well as economic development of a society.

Regardless of the product manufactured or service provided by an individual or an organization, it is likely that there is involvement of IP in some form or the other. Hence one must strategically consider the steps involved in protecting, managing and enforcing his intellectual property rights, to get the best commercial results from its ownership.

Intellectual Property Rights (IPRs) arise out of intangible creations (ideas, works of art, etc) and are given to a creator by a Government of a country. IPRs are territorial rights that are restricted to the country of protection. These are monopoly rights vested with a creator/ inventor/ author and prevent others from using, making or selling the creation.

There are different types of IPRs that have been specified worldwide for the protection of innovative ideas and its forms. The IPRs of prime importance are:

- Patents
- Trademarks
- Copyrights
- Industrial Designs
- Geographical Indications
- Integrated Circuits
- Plant Varieties & Farmers Rights
- Trade Secrets.

To begin with, the creator must understand and identify the different forms of Intellectual Property protection which can be provided to protect his work. While some of the features will come under the ambit of Patents, some aspects may be copyrightable, while the remaining can be registered as a Design. The first step lies in identifying the most appropriate and relevant forms of IP.

Another important factor which one must keep in mind is jurisdiction. IP protection is territorial in nature. For example, if a trademark is registered in India, it will be protected in India only. However, there are certain methods of extending the protection to foreign countries, as discussed under topics related to ‘Madrid Protocol Trademark Applications’, ‘Patent Cooperation Treaty Applications’. The decision to protect a work in several countries has to be taken strategically after considering several issues like finance, market demand, availability of the product, infringement risks etc.

Due diligence forms an essential step in protecting intellectual assets. At the outset, it is strongly recommended to use NDAs to prevent disclosure of confidential information. At the same time, certain analytics tools like Priority or Novelty Search, Freedom-to-Operate Search, Infringement Search; Trademark Availability search reduces the risk of unnecessary legal hassles.

Registration is the most essential step in safeguarding an intellectual asset. However, it becomes futile without proper management and commercialization. As we have already discussed, it is necessary to organize all the intellectual assets in a systematic order to keep track of current status of IP applications, renewal dates or any other required formality, failing which may lead to rejection of IP protection. In this regard, building an IP portfolio becomes necessary.

A good IP portfolio increases the value of the company. Rapid increase in IP portfolio implies the necessity of a dedicated in house IP team. It is also essential to continuously encourage and promote generation of more IP, for example, by providing incentives to employees at an organization. Another activity which boosts proper management of intellectual assets is conducting IP Audits at regular intervals.

## 6.1 PATENTS

*“The patent system added the fuel of interest to the fire of genius.”*

— Abraham Lincoln

A Patent is a right granted by the Government of a country to the inventor for a limited period of time. Under the Indian patent legislation, the subject of a patent is a new invention. Invention means a new product or process involving an inventive step that is eligible for industrial application. To be patentable, an invention has to fulfill the three criteria of novelty, non-obviousness and industrial application. Novelty means that the invention has either not come in public domain or it does not form part of the state of the art.

Self-disclosure or commercialization by the inventor before the filing of the patent application leads to loss of novelty. A patent granted under the Patents Act, 1970 (Patent Amendment Act, 2005) confers upon the patentee the exclusive right to prevent third parties, which does not have his/her consent, from the act of making, using, offering for sale, selling or importing, selling or importing for those purposes that product or the product through that process in India.

As per the current Indian Patent Law, the term of every patent is 20 years from the date of filing of the application.

These features of the Patent Law and the criteria for patentability are by and large the same in other countries with variations in respect of only procedures for filing patent applications and rules and regulations relating to patentability and grant of patent.

### **Public disclosure and patent filing**

*Dr. Ria Sen has developed a new system for diagnosing cancer cells and identifying the location of the tumour. Although Dr. Sen is interested in commercializing some of her research, she would like to ensure that doing so would not prevent other researchers from having access to her findings. She publishes the findings in Science journal. After a year, she thinks of filing a patent application and she contacts a patent attorney. The attorney advises her that now it won't be possible to obtain a patent even if she files a patent application as her own publication would serve as document in public domain.*

The invention must have use or any application in the industry. The invention further should be a subject matter that can be patentable before the respective jurisdiction's Patent Office. Not everything which is new, non-obvious and useful can be patented. In USA new plant forms, software, business methods can be patented, but not in India.

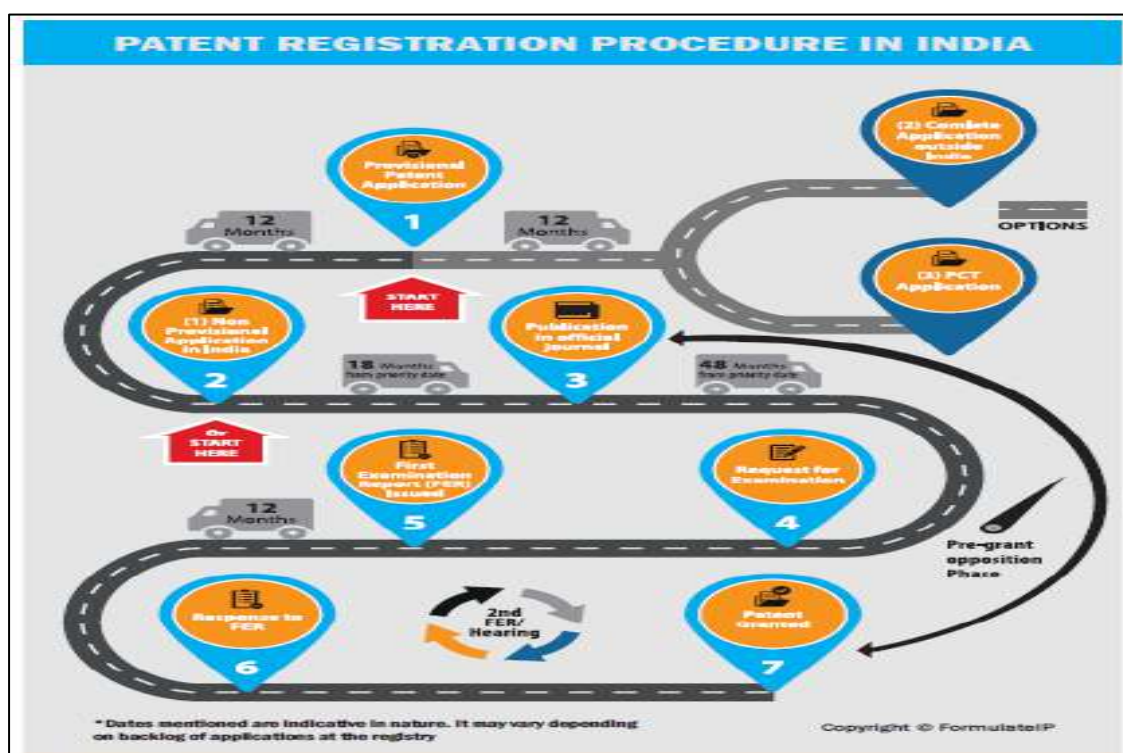
However, there are certain common things which are not patentable anywhere in the world.

For example:

- Laws of nature.
- An abstract idea. For example, you have a brilliant idea on how to eradicate poverty perpetually. Your idea may have the potential to bring about a revolution in society, but the idea cannot be patented, since the idea by itself does not involve anything that is tangible.
- Any literary, musical or artistic work.
- Inventions relating to atomic weapons, etc.
- Mere arrangement of re-arrangement of known elements, for example: umbrella with a torch and a clock
- Traditional Knowledge.

### 6.1.1 Patent Registration Procedure in India

Step1: It is always recommended to conduct Prior Art Search to check whether your invention is novel or not. Subject to the outcome of the Search, an applicant may proceed to filing the Patent Application. An application for a patent can be filed by the true and first inventor and also by the assignee or legal representative of the inventor, as the case may be.



Step 2: You may file the Patent Application along with Provisional Specification or a Complete Specification at any of the four offices mentioned below: a. Mumbai Patent Office: Maharashtra, Gujarat, Madhya Pradesh, Goa, Chattisgarh, Union territories of Daman, Diu, Dadra and Nagar Haveli; b. New Delhi Patent Office: Haryana, Himachal Pradesh, Jammu and

Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal, Delhi and the Union Territory of Chandigarh; c. Chennai Patent Office: Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and Union Territories of Pondicherry and Lakshadweep; and d. Kolkata Patent Office: Rest of India On successful application, the Patent Office will issue an application number using which you can track the status of your application.

- Step 3: 18 months from the date of filing or Priority Date (whichever is earlier), the Patent Application is published in the official Patents Journal, published every week by the Patents Office on its website. On publication, the patent specification including drawings and deposits are available in the public domain. The rights of the applicant under the Patents Act, starts from the date of publication, but can only be enforced after the patent has been granted.
- Step 4: An Application with a formal request for examination along with the official fee has to be filed within 48 months from the date of filing the application or Priority Date (whichever is earlier). The Patent Application is then allotted to a patent examiner who is an expert in the technical domain of the concerned patent. Presently there are four examination groups based on the broad area of technical specialization in the Patent Office. These are namely, (i) Chemistry and allied subjects, (ii) Biotechnology, Microbiology and allied subjects, (iii) Electrical, Electronics and related subject and (iv) Mechanical and other subjects.
- Step 5: The application is examined on both procedural as well as patentability grounds. Within 1-3 months a First Examination Report (FER) is issued.
- Step 6: The patent applicant is required to comply with the objections and amend his application as mentioned in the FER within the next 6 months. If all the objections are overcome a patent is granted for 20 years. If the objections are not rectified as required or not complied within the prescribed time frame, the patent application could get rejected. It is important to note that a patent is granted only when the application has not been successfully opposed by any third party.
- Step 7: Once the patent is issued, you need to maintain the patent by paying an annual renewal fee from third year onward till the life of the patent before Indian Patent Office. It is mandatory to commercialize your patent within 36 months from grant of patent for which you need to submit a status of working of the patent periodically. In case you do not submit the working of patent as stipulated by the Patents Office, then your patent can be revoked by the Patent Office. A patent can be refused by the Patents Office either during the examination stage, or objected to at pre or post grant stage. With regards to examination of a patent application, if the patent does not meet the patentability criteria then it can be rejected for which you can respond to the FER (First Examination Report) as well as make a request for a personal hearing in the Patents Office. With regards to pre or post opposition which can be for various reasons such as the invention being in public domain or the invention being stolen, you again need to satisfactorily respond to the objections raised. In case you are not satisfied with the decision of the patent office, you can file an appeal with the Intellectual Property Appellate Board (IPAB) against the decision of the patent office which has the power to revoke or amend their decision within the prescribed timeline.

The schedule of fees payable for patent filing to the Indian Patent Office is available at [www.ipindia.nic.in/form-and-fees.htm](http://www.ipindia.nic.in/form-and-fees.htm).

NPA = Non-provisional patent application  
PPA = Provisional patent application

| PATENTS                                                                                 |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| DOs                                                                                     | DON'Ts                                                                      |
| Make sure your invention is patentable, i.e. it's new, non obvious and has utility      | Do not wait for the invention to get completed and then file an application |
| Conduct a Prior Art Search to check whether similar inventions exist                    | Do not forget to check whether you are infringing a third party patent      |
| Decide where you will file the application strategically as patent laws are not uniform | Do not disclose your invention carelessly before filing an application      |
| Mention 'Patent Pending' on your invention once an application has been filed           | Don't forget to file NPA within 12 months if you have filed a PPA           |

## 6.2 Trademarks

A trade or service mark (a word, name, device, symbol or any combination) is adopted by an organization to identify its goods or services and distinguish them from those of the others. Trademark ownership is usually acquired through use of a term or word or symbol to identify the origin of the goods or services. It is a mark capable of being represented graphically.

It distinguishes the goods or services of one person from those of others and may include shape of the goods, their packaging and combination of colours. A registered trade mark or a mark used indicate a connection in the course of trade between the goods or services and some person having the right as proprietor or by way of permitted user, to use the mark.

### Example of Trademark



**Did you know taglines and phrases can also be protected as a trademark?**

An example of a tagline: "We bring good things to life." **GE's tagline**

## 6.3 Copyrights

Copyright means an exclusive right to do or authorize the doing of any of the acts listed below in respect of works in which copyright subsists. Copyright subsists in literary (including computer programme), dramatic or musical work, in an artistic work; in a cinematograph film and in a sound recording.

Doing or authorizing the doing of any of the acts in respect of the above works broadly include reproduction, issuing of copies to public, making any cinematographic film or sound recording, translation, adaptation, selling or giving or

even making offers to sell etc. on commercial rental any copy of the computer programme or making a copy of the film. Doing any of such acts, as stipulated in the Copyright Act, 1957 amounts to infringement of the copyright of the owner.

In other words, copyright subsists in "original works of authorship" which have been fixed in any tangible medium of expression from which they can be perceived, reproduced, or otherwise communicated, either directly or with the help of a machine or any other device.

***Did you know copyright is a right which is created with the creation of the work and can be protected by putting a c in a circle © followed by the year. However for its enforcement, copyright needs to be registered.***

It may however be pointed out that unlike patent which protects the idea, copyright covers the "expression" in a particular work, computer program, musical work, video or motion picture, sound recording, sculpture, photograph and so on in which the "expression" is embodied, illustrated, or explained, but does not protect the "idea".

#### **6.4 Industrial Designs**

Industrial design rights are intellectual property rights that make exclusive the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or composition of pattern or color, or combination of pattern and color in three dimensional forms containing aesthetic value. An industrial design can be a two- or three-dimensional pattern used to produce a product, an industrial commodity or a handicraft. The Design Act, 2000 defines a "design" to mean only features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article, two dimensional or three dimensional or both, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article, appeal to and are judged solely by the eye. The copyright on a design accrues to the proprietor of the design only when registered in accordance with the provisions of the Act.

***Did you know industrial design also plays a role in branding of the company?***

*A particular design of the product such as coke's bottle is recognized by the customer as a product belonging to coke.*

#### **6.5 Geographical Indications**

As per the Geographical Indications Act of Goods (Regulation And Protection) Act, 1999, "Geographical Indication", in relation to goods, means an indication which identifies such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of country or a region or locality in that territory, where a given quality, reputations or other characteristics of such goods is essentially attributable to its Geographical origin and, where such goods are manufactured goods, one of the activities of either the production or processing or preparation of the goods concerned takes place in such territory, region or locality, as the case may be.

***Did you know India has these geographical indications other than Darjeeling Tea?***

- ***Chanderisaree*** (Guna, Madhya Pradesh);
- ***Kota Doria*** (Kota, Rajasthan);
- ***Kancheepuram silk*** (Tamil Nadu);
- ***Solapur terry towel*** (Maharashtra);
- ***Mysore silk*** (Karnataka);
- ***Kullu shawl*** (Himachal Pradesh);
- ***Madurai Sungudi*** (Tamil Nadu);
- ***Kangra tea*** (Himachal Pradesh);
- ***Coorg Orange*** (Karnataka) Bidriware (Karnataka);
- ***Channapatna toys & dolls*** (Karnataka).

Any name which is not the name of the country, region or locality of that country shall also be considered as the Geographical Indication if it relates to a specific Geographical area and is used upon in relation to particular goods originating from that country, region or locality, as the case may be.

## 6.6 **INTEGRATED CIRCUITS**

'Layout- design' has been defined in the Semiconductor Integrated Circuits Layout Design Act, 2000 mean a layout of transistors, and other circuitry elements and includes lead wires connecting such elements and expressed in any manner in a semiconductor integrated circuit.

A lay out design which is not original, or which has been commercially exploited anywhere in India or in a convention country, or which is not inherently distinctive or which is not inherently capable of being distinguished from any other registered designs, shall not be registered as a layout-design.

## 6.7 **PLANT VARIETIES AND FARMERS RIGHTS**

Instead of Patent, India chose *sui generis* system for protection of plant varieties integrating the rights of breeders, farmers and village communities, and by making provision for equitable sharing of benefits. The Act offers flexibility with regard to protected genera/species, level and period of protection. It covers all categories of plants, except micro-organisms. The objectives of the Protection of Plant Varieties and Farmers Rights Act, 2001 act are:

- To provide for an effective system for protection of plant varieties.
- To confer rights to farmers and plant breeders and to provide for their protection.
- To stimulate investment for research and development in the field, both in public and private sector.
- To facilitate growth of the seed industry and to ensure availability of high quality seeds and planting materials of improved varieties to farmers.

## 6.8 **TRADE SECRETS**

Trade secret (a concept that may be applied to almost any secret which is used in business) is used to protect valuable proprietary information and is a commonly used form of protection for software. It gives the owner of the trade secret a competitive edge over the others. The protection provided by trade secret remains legally valid as long as the trade secret is maintained. It is necessary to bind individuals (those who have access to the secret) by contractual agreements called nondisclosure or confidentiality agreements. This way protection can be maintained while a trade secret is being used.

*A **trade secret** is a secret till it is kept **confidential** and is not divulged to anyone. In order to keep trade secret **confidential** one needs to inform the other party with whom the information is being shared that it is confidential.*  
***Contractual obligations** through **employee agreements** and **non-disclosure agreements** can be ensured for its protection.*

## 6.9 **Other Aspects**

### 6.9.1 **International Perspective on Patents**

Although the criteria of patentability viz. novelty, inventive step and industrial application remain same across the globe, there are exceptions with respect to the scope of protection. Across the globe there are different laws governing the patentability of biotechnological and life science inventions. In US there

are two modes of protection for plant varieties, one is plant patent and other is the protection of plant variety. Microorganisms, modified organisms, processes to modify or processes using such organism are also patentable in US. Also software can be patent protected in US. In comparison to US, Europe has limited the scope of protection by excluding certain inventions just like India, in accordance with the guidelines laid out in the World Trade Organization's Agreement on Trade Related Intellectual Property. Articles 52 and 53(b) of European patent convention define what can and what cannot be patented. Biotechnological inventions are basically patentable, but with the following exceptions:

- Methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body
- Plant and animal varieties
- Essentially biological processes for the production of plants and animals.

In US and Europe, secondary application/use of a known substance is patentable; while in India, it is not patentable. The protection of secondary use of a known substance in Europe is done through the Swiss claims.

### **6.9.2 IP Analytics**

In recent decades there has been rapid development in the technology sector which has resulted in the shortening of life cycles of the products. In order to have a competitive edge in the market, companies are trying hard to consistently develop new products. More emphasis is being laid on the R&D departments. However, although more attention on innovation is yielding considerable results, many companies are unaware of how to use the outputs strategically. Business planning and technology planning are two entirely different areas. The key is to link them in such a manner that technology analysis can pave the way for business development.

This is when IP Analytics comes into the picture.

An in-depth statistical analysis of this information with respect to IP activity in a specific field of technology is often termed as IP Analytics. By having access to such patent data, a better and thorough understanding of the 'big picture' is possible which will help you to take strategic and informed decisions. From such an analysis it may be possible to discover current patterns and trends in the industry which otherwise would have been difficult to come across. Various IP Analytics Tools are discussed as follows:

- **Prior Art Search:** A prior art search involves searching different patent and non-patent databases to identify identical or similar inventions that are patented/published or available in the public domain.
- **Novelty Search:** A novelty search is the second step where the novel features of your invention as against the existing prior art are identified. The purpose is to establish the points of novelty which make the proposed invention new or novel.
- **Freedom to Operate Search (FTO):** It is usually conducted as a due diligence effort to identify the potential patent barriers to commercialization of any product/process in a certain jurisdiction. The purpose of this search is to make sure that the proposed invention is not infringing any patented materials in the country where it is being filed and free from any potential risk to operate in that jurisdiction.

- **White Space Analysis:** It is a methodology which identifies absence of patents/innovations in a particular product or technology area and thus acts as a primary driver of innovation decision making. The said search is one of the pre-trial activities conducted by a third party against a particular patent.
- **Invalidation Search:** This kind of search is conducted only with the purpose of invalidating another patented invention of a third party patent which is in conflict with your invention.
- **Mapping/Landscaping:** It is a compilation of patent information by creating a visual representation to encourage faster and easier understanding. Using bibliographic data it is easy to identify which technical fields particular applicants are active in, and how their filing patterns and IP portfolios change over time. It is also possible to find out which countries lead in which fields. For example, if a person wishes to study the patents filed for pharmaceutical products by a particular company, he may compile all the relevant information in an organized structure which is known as a Patent map or a landscape

### 6.9.3 IPR Protection: Start from the Idea Stage

People tend to think that IP protection is required only once the final product is ready to be launched in the market. But this is a common misconception. IPR provisions can be effectively used and enforced from the Idea stage. IPR associated with the product lifecycle can be categorized into the following stages:

#### A. Idea Stage

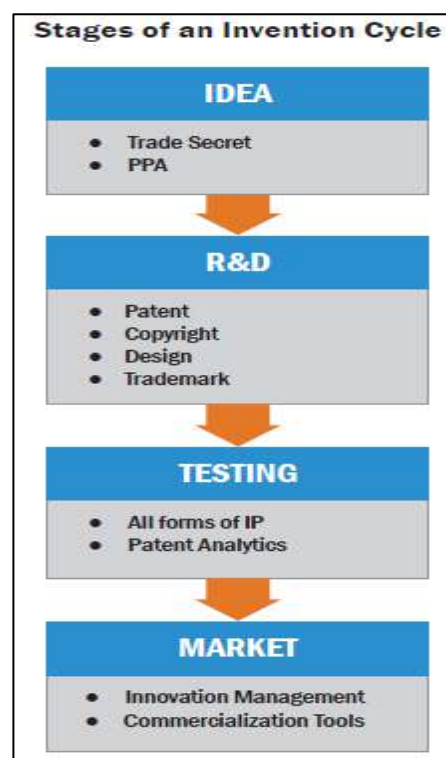
At this stage in order to safeguard an idea, the company or individual(s) can either file a Provisional Patent Application or keep it as a trade secret. The company or individual(s) should further conduct Novelty or Prior Art search to be aware of existing technologies related to the idea.

#### B. R&D Stage

This is an important stage in the innovation cycle and requires appropriate IP protection. Apart from maintaining the Trade Secret for certain aspects, all the information and drawings related to a product may be used to file a Non-Provisional Patent Application or Patent Co-operation Treaty (PCT) application. Manuscripts for literary works can be protected by Copyright and distinctive designs can be protected by filing an application for Design Registration. At the same time, a Trademark application can be filed to protect the name of the product or service.

#### C. Testing Stage

This is the last stage before launching of the product and hence it is recommended that most of the IP filings are completed before the end of this stage. This ensures that the product is safeguarded from



potential infringement before it is finally released in the market. Also it is essential to use certain Patent Analytics tools to determine the strength and scope of the product.

#### **D. Commercialization Stage**

Once the product is in the market, constant monitoring of the IP is required. At the same time, it is essential to use Innovation Management strategies and IP commercialization tool for the best results. Once your Intellectual Property is registered, you have the exclusive right to use and exploit your property. If you do not, there is always a chance that somebody might try to take credit for the intellectual work which you have created or can copy your idea without paying any royalty to you.

Registration of Intellectual Property is futile if it is not properly commercialized. The IP commercialization is done mostly by either selling or licensing the IP asset to another entity. Assignment is the permanent transfer of IP ownership from one party to another, where ownership of all rights is acquired by the assignee. It is recommended that you enter into a Non-disclosure agreements or (NDAs) before the Assignment. This will keep the intended assignment a secret and that confidential information shared will not be revealed except for negotiating purposes.

IP due diligence is another important pre-requisite for gathering information on IP assigned. It is a means of analyzing potential risks involved in the transaction. Due diligence audits are performed by multidisciplinary teams of legal, financial, technology and IP experts.

Licensing of an IP asset permits a third party (licensee) to use the rights associated with IP under certain terms and conditions. The person receiving the license is called the licensee and the person granting the license is called the licensor. Licensor retains the ownership of IP. The licensor still maintains ownership of the asset in this case. Another option for a business is to leverage the IPR assets and form a business partnership with another business. The partnership can then exploit the IPR assets by creating a new entity such as a joint venture.

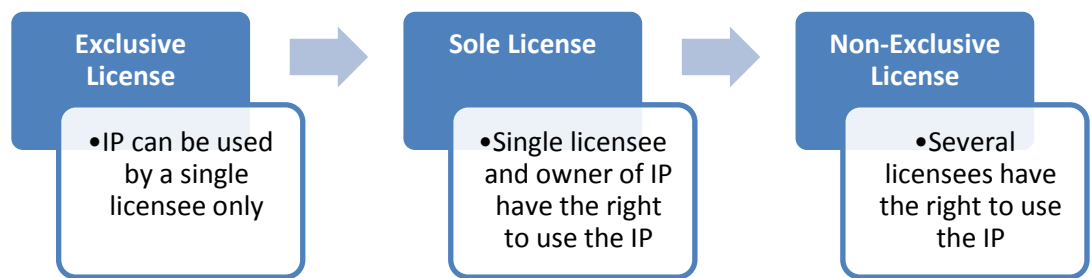
An example of licensing of IPR assets is the license granted by software companies for using their software, which provides the end user with the right to use the software but does not transfer ownership of the software to the user.

#### **6.9.4 Licensing**

By entering into a License Agreement you can permit a third party to use your IP based on mutual conditions. A suitable licensee and a properly drafted license agreement represent a steady inflow of income for the licensor while reducing costs and risks.

Depending upon number of licenses allowed to use the licensed IP, licensing agreements can be categorized into three main types namely

- Exclusive license
- Sole license
- Non-exclusive license.



The biotechnology companies are well-positioned to extract value from their patent portfolios to remove roadblocks on the path to commercialization and success.

For a biotechnology company, the ultimate goal of IP is to protect the investment that goes into developing a commercial product. But as products are often many years away from commercialization, there are several ways IP can be exploited to get financing and complementary technologies needed for short-term survival. There are four key ways that biotech companies can leverage value from an IP portfolio. Although these are the main strategies, they are certainly not the only ones for extracting extra value from patents.

- Out-licensing
- Cross-licensing
- Selling IP or royalties owed on it
- Lending secured by IP.

| Method                             | Advantages                                                  | Disadvantages                                                  |
|------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------|
| Out-licensing                      | Raises capital                                              | Engenders fear of out-licensing too early                      |
|                                    | Is suitable for early-stage technology                      | Cedes some control over reputation and valuation of technology |
|                                    | Narrows company focus                                       |                                                                |
| Cross-licensing                    | Removes blocking patents                                    | Requires giving up exclusive rights                            |
|                                    | Can allow collaboration                                     | Can allow competition                                          |
| Selling IP or royalties owed on it | Raises short-term capital                                   | Requires demonstrable financial return                         |
|                                    | Narrows company focus                                       | Discounts value of IP                                          |
| Lending secured by IP              | Makes use of IP, which may be company's most valuable asset | Interest rates obtained do not generally reflect IP value      |
|                                    | Raises non-dilutive capital                                 | Risks losing IP upon default                                   |

Creative executives, financiers and lawyers may find other ways to obtain short-term value from a company's IP. But a broad and diverse patent portfolio, combined with flexibility and ingenuity, can provide unexpected leverage to remove roadblocks on the path to commercialization and success.

### 6.9.5 Compulsory License

In certain cases, a government permits a third party to produce the patented product/ process without the consent of the patent owner. There are certain conditions laid down in TRIPS Agreement for issuing a compulsory license. For example, usually, the applicant for a compulsory license must try to negotiate a voluntary license with the patent holder. Only when it does not work out, a compulsory license can be granted. Moreover, even after a compulsory license has been granted, the patent owner must be paid adequate remuneration on the basis of the economic value of the authorization.

#### India's 1<sup>st</sup> Compulsory License

In March 2012 India's first compulsory license was granted to Hyderabad-based Natco Pharma to sell a generic version of Nexavar (a kidney/liver cancer drug that goes by the generic name of SorafenibTosylate), but with the condition that a 6% royalty on the net sales (every quarter) will be paid to Bayer, the holder of the Patent. The reasons for granting the compulsory license were:

1. Since Bayer supplied the drug to only 2% of the patient population, the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met.
2. Bayer's pricing of the drug (2.8 lakhs for a months' supply of the drug) was excessive and did not constitute a "reasonably affordable" price.
3. Bayer did not sufficiently "work" the patent in India.

***If my Licensor is granting me license from another country, what are the issues that should be covered in the licensing agreement?***

*To check whether the IP right is covered in the country of your interest, you need to determine whether you are entitled to file a patent or design application in that jurisdiction. In case of a trademark, you would have to make a fresh application and in case of copyright if the country of your interest is a signatory of the Berne Convention, then you are covered. It is also important to make sure that there is no issue or controversy regarding the ownership of the particular IP. This can be determined by checking the present status of ownership of the IP with the respective IP Office.*

### 6.9.6 Protecting your IP in Joint R&D

The most important point to resolve is who will own the IP rights and the rights over improvement of the product/technology. If you have been contracted as a vendor for product or technology development on a market rate basis, then 100% of the ownership of IPR should rest with the company. But in case you have a risk-sharing arrangement, whereby you will be compensated on achieving certain milestones or you have been provided equity instead of cash, then the ownership of the IP should be negotiated with the company to compensate for the risks being taken by you.

There is no fixed formula with regards to IPR ownership but you should put a financial value to the risk in product development and then accordingly seek part ownership of the IPR concerned. But what is of most relevance to you is

the ability to use the product or technology for future use with other clients as well as having access to the rights to improved versions, product or technology concerned.

Alternately, you can choose to negotiate with the company to use the product developed for other clients either at no cost or by paying an agreed-upon royalty, which will provide you with more business opportunities. Ensure a clause is incorporated in the commercial contract with clear details of IPR ownership and rights over future improvement in the product or technology concerned.

In case you have been hired to render services to a large organization where there is no significant generation of IP but the work would involve confidential data and proprietary processes, you would be asked to sign an NDA with the company to protect its own interests. You should always have confidentiality agreements with your own employees and with your contractors to ensure that they do not disclose client confidential information to third parties.

#### **6.9.7 Points to Remember: Entrepreneurs acquiring Technologies**

Entrepreneurs often license or buy technologies or other forms of IP assets from academic or research institutions that have the expertise and resources to undertake basic and applied research. Of late, institutions in India are becoming more entrepreneur-friendly with a business focus. It is important to take care of certain issues, which could crop up in your dealings with institutions, to ensure a successful partnership:

- a. While institutions claim to have developed market-ready products or technologies which have been tested to work at manufacturing level, it is prudent to validate the claims by requesting for a demonstration of the technology and understanding its scope.
- b. Review the patents filed by the Institute with regards to the technology or product you are interested in licensing or buying. Check whether the patents have been granted, pending or abandoned (if the application is not pursued by the applicant then it is abandoned by the patent office). Also the Institute may have filed for patents outside India which needs to be verified.
- c. Cross-check whether the Institute has entered into any agreement with a third party for sale or licensing of the technology and, if so, whether the agreement is exclusive or non-exclusive.
- d. Check if there are any restrictions or preconditions with regards to sale or sublicensing of the technology to someone else since that would restrict your ability to exit the agreement .
- e. Find out who will bear the renewal costs to be incurred for maintenance of patent in case of a granted patent and costs for engaging a professional in case of a pending patent to take it through the grant process.

#### **6.9.8 Innovation Management**

At present, R&D departments are gaining importance because research plays a crucial role as a major contributor to innovation. However, to utilize and encourage innovation, proper management is required. The creation and management of the IP portfolio plays a very important role at this stage. The discipline of effectively managing the different stages in a product cycle is termed as Innovation Management. The purpose is to challenge and facilitate creative potential which would ultimately lead to result orientated, innovative business development. Innovation Management consists of a set of tools that

create a common platform where managers, technical and marketing teams work together to achieve their goals.

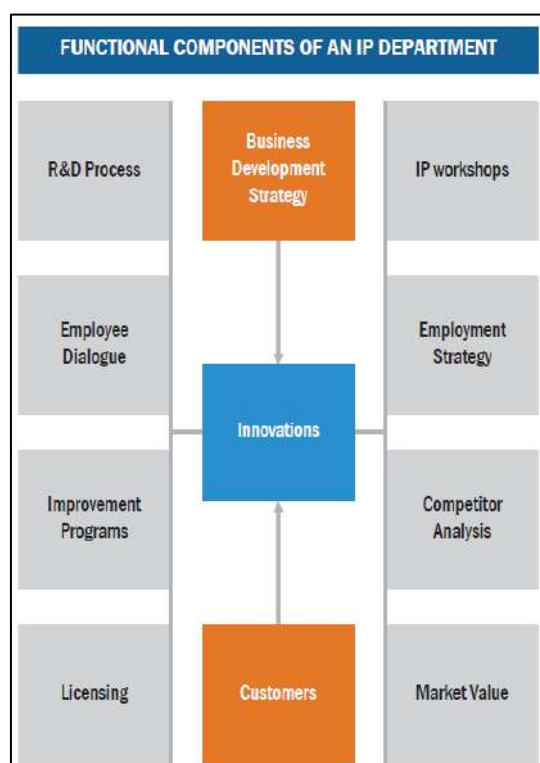
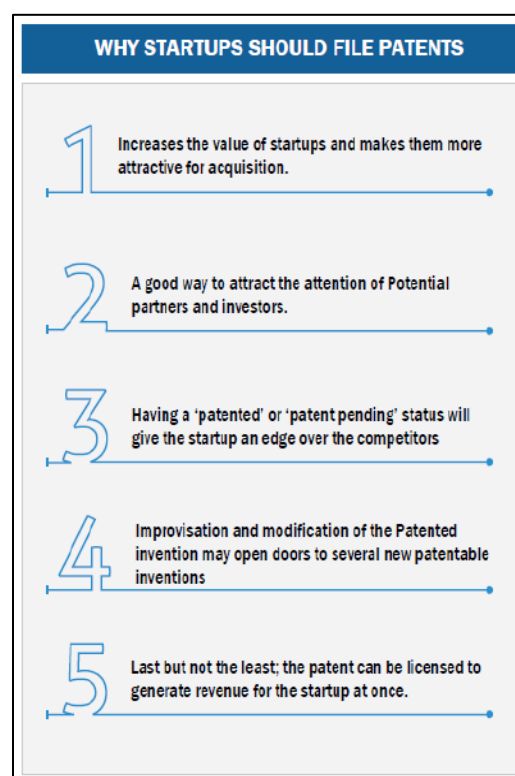
Effective innovation management requires the implementation of a number of processes and the employment of a number of tools. At the outset it is important that the culture of the organization empowers employees and encourages them to submit their ideas. Most importantly, the management should adopt an appropriate innovation strategy to lead the innovation process and to manage an innovation portfolio.

Innovation management helps to realize the potential of your business. The purpose is to be the game changer in the marketplace by measuring the relative impact and importance of your invention. The objectives of innovation management include:

- Creating an innovation strategy suitable for the organization's potential and to enable accomplishment of the vision.
- Building a portfolio of innovation projects for easy management and strategy planning.
- Define a criterion for selecting and prioritizing projects within the portfolio to remove less potential ones.
- Make necessary internal changes and form the right teams.
- Identify potential future partners that can be tapped on requirement, and determine the strategy on how such partnerships are to be formed.
- Promotes and encourages innovation by allowing employees time and incentives.

It is highly recommended to have an in-house IP department to manage and regulate the intellectual assets of a company. The underlying goal of an in-house

intellectual property department is to derive the maximum value from intellectual property assets with reduced cost and improved accuracy.



There is no standard format and plan that applies to all business situations. Each business must consider the nature of its business situations. Each business must consider the nature of its business, the environment of the industry in which it operates, its corporate culture and its business goals, when establishing an IP management program.

### **6.9.9 Developing an IP Portfolio**

The first step is to create an inventory of all the intangible assets your business owns or controls, such as technology, trademarks, domain names, creative works (such as brochures, product catalogue), licenses or rights received for regulatory or government approvals, customer relationships and databases; and determine their criticality and impact on your business. Once you have identified and maintained your IPR and intangible assets, you can decide to prioritize based on their business impact, and on how you can monetize non critical IP assets.

Registering a patent, trade mark or design application is required to safeguard the exclusive rights to an invention or brand. However, this alone is not sufficient to generate significant revenue. With the increase in strength of an IP portfolio, the commercial leverage of the business also develops. In this regard, it is necessary to build and regularly manage an IP portfolio.

#### **Case Studies for Illustrations**

**Case Study 1:** Mr. Amir Khan is a young entrepreneur and graduate in science. He owns and operates a plastic recycling and moulding business. He designed a machine — the Xtrasmooth — that sorts plastics by the quality and thickness of plastic before it is melted and recycled. Mr. Khan's invention will make the plastic-sorting process cheaper and increase the profits for his business. He believes the Xtrasmooth has world-wide market potential and would like to commercialize it. He is seeking advice from his maternal uncle who runs a plastic bottle manufacturing business on how best to protect and commercialize the invention.

#### **Issues to be addressed**

- Trade secrets versus patents
- Non-disclosure or confidentiality agreements
- Impact of disclosure on patent rights
- Requirements for patent protection
- IP strategy and commercialization options

#### **Questions to ponder**

- Under what circumstances is a non-disclosure or confidentiality agreement signed? What are the main elements of such an agreement?
- How should one decide on commercialization options?
- What are the costs and benefits of registering a trade-mark?

**Case Study 2:** Ms. Aparna Sharma has been awarded a prestigious Department of Biotechnology, Govt. of India postdoctoral fellowship to work in a Immunology research lab at the Harvard University. She will be working with a group which is working on developing a new system for creating anticancer (aCC) cells and an a CC cell line that can be coaxed to differentiate into cells that would be useful for the killing malignant cells and treatment of cancer. Although Ms. Aparna is interested in commercializing some of her research, she would like to ensure that doing so would not prevent other researchers from having access to her findings.

#### **Issues to be addressed**

- Ethical issues in patenting and commercialization of cells/artificial cell lines
- Impact of public disclosure
- IP ownership in a university research environment
- Patent application process in foreign jurisdictions.

**Questions to ponder**

- Should Aparna publish or patent the results of her research?
- What is the commercialization process for university research outputs in the life sciences?

Case Study 3: AyurIndiaPharma is a mid size Pharmaceutical company supplying low cost drugs to developing and poor countries. A scientist researcher working in the company appears to have discovered a molecule that seems to have a significant effect in the treatment of hyperglycaemia, a condition in Diabetic Patients. Researcher had further established that the process used for manufacturing the identified compound yields a racemic mixture. Researcher has been able to isolate one particular laevo form of the identified compound which has been found to be highly effective against Hyperglycaemia. Research was done by the in-house IP Cell in different patent databases to verify if any patents have been issued for the chemical compound. The Cell found that in 1993 a patent was issued to another company for the group of compounds that has the same chemical structure, but it had since expired due to non-payment of renewal fees. Further, the patent specification did not talk of any advantage of a particular form of the compound over other compounds. Having little experience in dealing with intellectual property, the researcher wonders if a patent can be filed for her research.

**Issues to be addressed**

- Criteria for patentability
- Value of information found in IP databases
- Defining and protecting a new discovery

**Questions to ponder**

- What rights would a patent give AyurIndiaPharma?
- How does an expired patent affect a new discovery?

Case Study 4: Mr. Lingesh is working in a professor's lab for his summer internship at IIT Delhi. The student's status is unclear as the professor pays a small monthly stipend out of a miscellaneous research grant for the internship. The professor works with the industry- a big soft drink bottling company, in developing novel formulations for Energy Drinks for sportspersons. The student develops and implements an idea for Oxygenated Energy Drink for his project under the guidance of the Professor. The new formulation is tasty, refreshing and provides instant energy. The formulation could be extremely valuable for the company and it wants to file a patent on the formulation.

**Issues to be addressed**

- IP ownership rights for students
- Types of IP protection
- Non-disclosure
- Trade secrets
- Patent registration process.

**Questions to ponder**

- What rights does the student have regarding his idea and implementation?
- What policies are in place to cover this?
- What is your advice to:
  - o Student
  - o Professor
  - o Bottling Company.

## ***FREQUENTLY ASKED QUESTIONS (FAQS)***

### **1. What is a Patent?**

A Patent is a right given to an inventor by Government of a country that allows him/her to prohibit others from practicing the invention by way of from making, using, selling and importing. It does NOT give right to the inventor to commercialize/practice the invention.

### **2. What are the three criteria of patentability?**

The three criteria of patentability are:-

- Novelty
- Inventive Step
- and Industrial Utility

### **3. Is there any Global Patent? Does Indian granted patent gives worldwide protection?**

There is no “Global Patent” or “world patent” or “International Patent”. Patents are territorial rights and can be exerted only within the jurisdiction of a national government which granted the patent.

### **4. What are the components of a complete patent application?**

Field of Invention, Background, Summary, object, Brief Description, Detailed Description, Claims, Abstract and Drawings. Provisional application does not have claims. Claims define the protection on an invention and therefore constitute the legal part of a patent application.

### **5. What is difference between complete and provisional patent application?**

Complete patent application comprises claims whereas provisional patent application may be filed without claims. However, a provisional application has to be followed up with a complete application within 12 months of filing of provisional application. A complete patent application may also be converted to a provisional application by requesting to the Controller. A provisional patent application is never published nor examined; if no complete application is filed in 12 months of filing of provisional application, it is deemed abandoned.

### **6. What is the right time to file a patent application?**

Right time to file a patent application is just after conceiving the idea and after making a working model but before disclosing it to anybody or before publishing it to public. In certain exceptional cases, a prior publication or exhibition of the invention may be exempted.

### **7. When is the complete application published?**

The patent office keeps an invention secret for 18 months and once the period of 18 months from first date of filing of the application is expired, the patent office publishes the application automatically. However, a request for early publication may also be made to the Patent office by paying a prescribed fee following which patent office publishes the application within a month or two.

### **8. When is patent application examined?**

The patent applications are not examined automatically. The applicant/inventor/agent has to file a request for examination along with a prescribed fee. The request has to be made within 48 months of first filing of provisional or complete application.

- 9. What is the time taken for grant of patent and what is term of the patent?**  
Time taken varies from country to country. In India it typically takes 5-6 years for grant of patent whereas in US it takes 3-4 years. The term of patent is 20 years from first date of filing of the first priority application. The rights of the inventor/applicant are accrued only after grant of patent.
- 10. Can a patent application be filed after the invention has been published or exhibited?**  
Generally, a patent application for the invention which has been either published or publicly displayed cannot be filed. However the Patents Act provides a grace period of 12 months for filing of patent application from the date of its publication in a journal or its public display in a exhibition organised by the Government or disclosure before any learned society or published by applicant.
- 11. Is the criteria of novelty with respect to India or world?**  
The criterion of novelty as followed by Indian patent office is that of absolute novelty with no publication/exhibition of the invention anywhere in the world, before the date of application.
- 12. How can an international application be filed by an Indian inventor?**  
Internationally, applications can be filed in various other countries via two routes  
a. Patent Cooperation Treaty (PCT) route  
b. Convention Application.
- 13. What is freedom to operate?**  
An industrial/commercial unit, having a patent or licence to a patent on product/process, is able to make, sell, import, purchase product/process only if it does not infringes on patents held by others in their intended business territory. If a commercial unit is able to prove/analyse that there are no blocking patents, it has freedom to operate.
- 14. Can service names be trademarked?**  
Yes service names can also be protected through trademark.
- 15. Is there any requirement for trademark protection?**  
The trademark or service mark to be protected needs to be distinct. A search can be conducted before hand to ensure the availability of the trade or service mark.
- 16. Can a combination of colours of a capsule be protected as a trademark?**  
Yes a particular colour combination can be protected as a trademark by a pharmaceutical company.
- 17. What is the term of protection of a trademark?**  
The term of protection of an industrial design is 10 years, renewable every 10 years.
- 18. What is the term of protection of an industrial design?**  
The term of protection of an industrial design is 10 years extendable for another 5 years.

## **Experience Sharing: Thinking longevity over valuation**

Dr Nilay Lakhkar (30) returned to India in December 2014 after completing his eight-month post-doctoral stint at Helmholtz Institute of Biomaterials in Germany.

He began traveling across India exploring opportunities where he could put his skills to good use. During one such trip, he met Dr Chandra Sharma in Trivandrum, a foremost researcher in biomaterials and tissue engineering.

"During our discussion, he mentioned the possibility of starting a company focused on technologies that I had worked on in my MSc and PhD research, and pointed me towards Venture Center, Pune, a start-up incubator located at National Chemical Laboratories (NCL)," reveals Dr Nilay Lakhkar, founder & CEO, SynThera Biomedical.

Dr Lakhkar holds a Bachelor's degree in Chemical Engineering from University of Mumbai. He received his Master's and PhD in Biomaterials and Tissue Engineering from the University College London (UCL), UK, in 2008 and 2014 respectively.

### **In the Beginning**

Later, Dr Lakhkar met with the director of Venture Center, Dr Premnath, and was quite impressed with his passion for supporting budding entrepreneurs and the ecosystem he had built on the Venture Center campus.

The duo then began working together, and over the course of the next few months, Dr Lakhkar met various people in his field of expertise, including potential customers, investors and partners in R&D, finance, marketing and distribution, which gave him a good preliminary idea of both the opportunities and the challenges for establishing a well-run medical devices company in India.

"Needless to say, the opportunities far outweighed the challenges, which is how I ended up establishing SynThera in June 2015 at Venture Center Pune," adds Dr Lakhkar recalling his entrepreneurial beginnings.

SynThera Biomedical aims to position itself as India's foremost expert in R&D, manufacture and commercialization of bone augmentation products, specifically, bone graft substitute materials that can be used in a variety of surgical procedures in the dental and orthopedic spaces.

These materials are primarily meant to serve as replacements for bone tissue that may be lost due to injury, disease or congenital deformity.

In the UK, Dr Lakhkar carried out his research at UCL Eastman Dental Institute, one of

world's top centers for dental research, which is part of the UCL Faculty of Medical Sciences, a leading University hub for biomedical research.

Over a combined duration of over 4 years, he won the University Medal for topping his MSc course, and authored and co-authored 15 peer-reviewed publications.

He has presented his research at leading conferences in China, India, the UK and Germany, including the World Biomaterials Congress in 2012.

### **Plan of Action**

After deciding to start his entrepreneurial journey, Dr Lakhkar's first major tasks were to define a product line, and understand how he could structure a business model around the product line.

"This required a lot of brainstorming with relevant experts in R&D, manufacturing, commercialization and finance," he points.

Parallely, he began the process of incorporating SynThera Biomedical, and firming up a share subscription agreement with Venture Center, whereby it would provide cash-and-kind support to the tune of approximately Rs 15 lakh in return for a 5% stake in the company.

"Most importantly, we began to apply for government funding for a proof-of-concept project that would bring our proposed first products to the prototype stage, with the expectation that this would attract further funding from private sources such as angel investors," Dr Lakhkar says.

### **Dragging Formalities**

The company has been funded primarily by his savings and family resources.

It is now applying for a Biotechnology Ignition Grant (BIG) from the Department of Biotechnology worth Rs 50 lakh for a proof-of-concept project concerning one of its proposed products.

"At the same time, we are exploring options to raise funds from private investors," he states.

"Crowdfunding seems quite a good way of getting some initial funding although I'm not sure how successful it would be in our context."

The company's establishment has been reasonably smooth. "Although in line with the present government's thinking on ease of doing business, we would be happier if many of the formalities could be completed more quickly and easily," Dr Lakhkar notes.

### **Emerging and Matured Markets**

The company's products will initially target dental markets, and over the longer term.

It initially plans to commercialize products in India. Its international expansion plans will probably lead first into emerging markets in Asia, Africa and Latin America, after which it would enter mature markets in Europe and the United States.

SynThera's long-term plan is to diversify into the orthopedic market with its products for customers including adult and pediatric orthopedic surgeons and as well as orthopedic cancer specialists.

Its primary customers at present are specialist dentists such as implantologists, oral and maxillofacial surgeons, periodontists, and endodontists.

"We have significant technical know-how in bioactive glasses, a rapidly emerging technology in the bone substitute space, and at the same time, we are committed to exploring other synthetic and natural products, so that one day we can offer a complete set of solutions for surgeries where bone graft materials are required," opines Dr Lakhkar.

As of now, the company needs capital investments mainly for laboratory equipments and facilities to carry out 'Proof of Concept' research for commercial scale manufacturing.

The main equipments required for the task is provided by Venture Center in its on-campus laboratory.

The company's initial focus is on the dental bone graft substitute industry. In India, this sector is set to achieve rapid growth at a reported 38% per year, as an ever increasing middle-class continues to demand dental treatments where these products are used, dental and medical tourism is also a major factor here.

"At the same time, India is very heavily import dependent for these products, with the result that prices are still too high for a large section of India's population to access these products. We see plenty of scope for high-quality, indigenous manufacturers with a heavy R&D focus to really capture the Indian market by combining the two objectives of innovation and affordability, and we feel the timing is just about right to enter the Indian market.

### **Expansion**

Once the company decides on its product line and conducts the required proof of concept studies, its next task will be to proceed with regulatory approvals including clinical trials.

Dr Lakhkar explains, "Simultaneously, the process of carrying out market study, exploring the marketing and distribution channels, upscaling the manufacturing from lab scale-to-commercial scale is under progress."

The start-up is exploring research collaborations with universities and companies both in India and abroad. It is also actively exploring partnerships with companies that operate in the dental and orthopedic sectors, where it can bring its expertise in biomaterials, tissue engineering and regenerative medicine. Dr Lakhkar looks at Infosys founder Mr N R Narayana Murthy as an inspiration.

On a more personal level, he mentions his grandfather, who built a successful textile chemicals business after coming to Mumbai in 1948 from an impoverished village in rural Maharashtra, with next to nothing in his pocket.

He also shares that he would have been a University professor had he not been an entrepreneur today.

### **Start-up Visibility**

He feels that the best way to initially increase start-up visibility is to dive straight into the ecosystem that encompasses the target market and meet as many people as possible who are connected in some way to the products the company wishes to sell.

"This includes introducing the company to as many potential customers, investors, business partners and vendors as possible. We've done many rounds of cold calls and emails so far, and it's an ongoing process, but we have met many very helpful people through this process," Dr Lakhkar remarks.

He also recommends that it's a great idea to start attending business seminars, conferences and other such public forums where entrepreneurs can come face-to-face with many different stakeholders who can provide a wealth of feedback in a short time.

"We have found the feedback received from such market immersion to be invaluable in terms of checking our own initial hypotheses regarding our proposed business model and fine tuning our business plan to the point where we can provide a sustainable offering for both investors and customers. Over the longer term, having a well-developed company website will increase visibility tremendously since most of our customers are not only highly educated but also quite tech-savvy, but initial face-to-face contact with stakeholders is a must," he briefs.

---

## 7. FINANCIAL MANAGEMENT

---

*“Genius is one percent inspiration, ninety nine percent perspiration”  
– Thomas Alva Edison*

### 7.1 Considerations in Managing Capital

The overall objective is to find an "optimal" capital structure - the right mix of capital sources (debt and equity) that minimises the overall cost of capital and maximises values to the shareholders (owners of the business). When we raise capital, we have two choices - issue debt or issue stock. Debt is represented by bonds that are long-term instruments sold to investors. Stock is the ownership interest of the business and depending upon the rules of incorporation, stockholders will have certain rights. Therefore, we start our understanding of capital management by looking at the advantages and disadvantages of the two sources of capital:

Some advantages to using stock are:

- No fixed payments are required to investors; dividends are paid only on earnings.
- No maturity date on the security, the invested capital does not have to be repaid.
- Improves the credit worthiness of the company.

Some disadvantages to using stock are:

- Dilutes the earnings per share to shareholders.
- Issuance costs are higher than debt.
- Issuing more stock can increase the overall cost of capital.
- Dividend payments to shareholders are not tax deductible.

Some advantages to using debt are:

- Interest payments are tax deductible.
- Does not dilute earnings per share or control within the company.
- Cost is fixed; interest and principal do not change.
- Expected returns to investors are usually lower than stock.

Some disadvantages to using debt are:

- Fixed charges must be paid regardless of available earnings or cash flow.
- Adds more risk to the business.
- Has a maturity date and the capital invested must be repaid to investors.

In addition to understanding the pros and cons of financial securities, we also need to recognise that several conditions will impact how we raise capital. These conditions include:

**7.1.1 Economic Conditions:** The demand and supply of capital in the marketplace can impact how capital is raised. For example, expectations of inflation will influence the cost that is paid for capital. Higher rates of inflation erode the values of investments and thus, investors will demand higher rates of return.

**7.1.2 Market Conditions:** The demand for higher rates of return will increase the cost of capital. For example, if we raise capital with a security that is not highly marketable, investors will require higher rates of return for the increased risk.

**7.1.3 Operating Conditions:** The level of fixed costs used to operate the business needs to be considered. For example, higher fixed costs can result in wider variations to operating income from numerous factors - increased competition, slower economic growth, etc. This is referred to as business risk.

**7.1.4 Financial Conditions:** The existing levels of outstanding debt will impact how capital will be raised. Higher levels of debt (including preferred stock) can result in wider variations to earnings due to higher fixed obligations that must be paid (interest to debt holders and fixed dividends to preferred stock holders). This is referred to as financial risk.

Not only do we need to look at various conditions, but also we need to consider how financing will impact capital structure. Capital structure appears on the left side of the Balance Sheet as liabilities and equity; i.e. the long-term sources of funds to finance assets. Assets appear on the right side of the Balance Sheet. Capital structure is the permanent financing of the business through the use debt and stock. The total of all liabilities and equity is referred to as Financial Structure. Therefore, Capital Structure = Financial Structure - Current Liabilities.

Finding the right capital structure encompasses numerous considerations - growth rates in sales, risk attitudes of management, liquidity of assets, control position of the company, etc. Finding the right capital structure also involves finding the right amount of financial leverage. Financial leverage is the financing of assets with fixed obligations - debt and preferred stock. The use of financial leverage increases return on equity up to a certain level of operating income. As you use more financial leverage (debt and preferred stock), higher levels of operating income are needed to cover the additional fixed obligations (interest on debt and fixed dividends on preferred stock).

Generally, the use of financial leverage will improve financial performance whenever returns are higher than the costs of obtaining funds. In a perfect world, management would favour more leverage whenever return on capital exceeds the after tax costs of debt. However, higher returns also result in higher risk to the business (risk return trade-off). Therefore, the use of financial leverage is a balancing act between higher returns for shareholders vs. higher risk to shareholders.

Financial leverage can be measured with ratios such as debt to total assets. Financial leverage is also expressed as the Degree of Financial Leverage or DFL. DFL is the percentage change in earnings given a change in operating income (Earnings before Interest & Taxes or EBIT). The higher the DFL, the riskier the business. We can use the following formula to calculate DFL:

$DFL = EBIT / EBIT - I - (P / (1-TR))$  where I is Interest and P is Preferred Dividends and TR is the tax rate.

In addition to financial leverage, there is operating leverage. Operating leverage is the use of fixed costs in production over variable costs. For example, replacing production workers (variable cost) with robots (fixed cost) would be an example of increased operating leverage. As operating leverage increases, more sales are needed to cover the increased fixed costs. Since variable costs have been reduced, profits will increase more given an increase in sales after the breakeven point has been reached. High levels of fixed costs increase business risk. Like financial leverage, we can measure the Degree of Operating Leverage (DOL) as the percentage change in operating income given a change in sales. The following formula can be used to calculate DOL:

$DOL = CM / CM - FC$  where CM is Contribution Margin and FC is Fixed Cost.

Usually firms use one form of leverage over the other to finance investments. For example, manufacturing companies tend to invest heavily in fixed assets and thus operating leverage is used much more than financial leverage. Service type companies have low levels of investment in fixed assets and therefore, financial leverage is widely used to finance the business. Leverage is relative to the type of fixed cost approach that is appropriate for funding the business and leverage by its very definition creates risk. Therefore, the use of leverage will always include a trade-off between risk and return.

## 7.2 **Approaches to Managing Capital**

One way to understand how to manage capital is to look at the various approaches that can be used for finding the right capital structure. As we previously indicated, the right capital structure is that mix of debt and stock that maximises the value of the firm while at the same time maintains a relatively low overall cost of capital. Two very different approaches to capital management are the Net Operating Income Approach and the Net Income Approach.

**7.2.1 Net Operating Income Approach:** This approach to capital management concludes that it does not matter how you mix the capital structure. The value of the business is not determined by how you arrange the left side of the Balance Sheet. Additionally, the overall cost of capital will not change as you change the mix of capital. Therefore, values are determined by the capitalisation of operating income or EBIT (Earnings Before Interest Taxes).

**7.2.2. Net Income Approach:** In contrast to the Net Operating Income Approach, the Net Income Approach concludes that the capital structure of an Organisation has a major influence on the value of the Organisation. Therefore, the use of leverage will change both the cost of capital and the value of the firm. Net Income is capitalised in arriving at the market value of the firm.

Franco Modigliani and Merton Miller have provided some guidance between the Net Operating Income Approach and the Net Income Approach. Modigliani and Miller concluded that capital structure is not a major factor in the determination of values. Values are determined by the investment and operating decisions that generate cash flows. It is cash flows that give rise to values. This approach to valuation has become a mainstay within financial management. But what about capital structures? Mike Jensen, founder of the Journal of Financial Economics, may have resolved the answer to this question. Jensen noted that whenever a company makes a change in its capital structure, it sends a signal to investors. This signalling effect does in fact result in changes to valuations. For example, when the Chairman of the Federal Reserve speaks about interest rates, a signal is sent to the marketplace and valuations quickly change. Therefore, shifts in capital structure do impact the value of a business.

Jensen also noticed that managers have a tendency to guard capital and minimise the distribution of dividends to shareholders. This follows with the so-called "pecking order" of financing whereby managers prefer internal sources of capital to external sources of capital. The specific pecking order is as follows:

- Internal sources of capital - retained earnings / cash
- External sources of capital - debt
- External sources of capital - convertible securities
- External sources of capital - preferred stock
- External sources of capital - common stock

Consequently, capital structures can impact valuations due to the so-called signalling effect. Additionally, the real source of values will reside in cash flows (more specifically free cash flows). Free cash flows are the excess cash that can be withdrawn from a business after paying everything off. And in order to generate free cash flows, management must generate returns in excess of the cost of capital.

## 7.3 **Calculating the Cost of Capital**

In order to evaluate projects of average risk, we must know the overall cost of capital. Cost of Capital is calculated as the weighted average of each component of capital - debt, common stock, preferred stock, and retained earnings. Each component is calculated as follows:

**7.3.1 Cost of Debt (Cd):** Calculate the after tax cost of debt based on the effective interest rate. The following formula is used to calculate the cost of debt:  $Cd = I(1 - TR)$  where I is Interest Rate on Debt and TR is the Tax Rate.

**7.3.2 Cost of Common Stock (Ccs):** Three different methods can be used to calculate the Cost of Common Stock. The three methods are:

- **Dividend Growth** - Dividends paid to common shareholders along with the overall expected growth rate is used to calculate a cost for the common stock. The formula for calculating the cost of common stock is:  $(\text{Dividends in Year 1} / \text{Market Value of Stock}) + \text{Overall Growth Rate}$ .
- **Capital Asset Pricing Model (CAPM)** - The CAPM is the most widely used approach to calculating the cost of common stock. The CAPM uses three components to calculate the cost of common stock - (1) **rf** is the risk free rate earned by investors (such as U.S. Treasury Bonds); (2) **b** is the beta coefficient which expresses the risk of the common stock in relation to the market; and (3) **rm** is the rate earned in the market (such as the Standard & Poor's 500 Composite Index). The CAPM formula is  $Ccs = rf + b (rm - rf)$ .
- **Bond Plus** - A simple approach to calculating the cost of common stock is to add a risk premium to the cost of debt. The formula is  $Ccs = Cd + \text{risk premium}$ . The risk premium is the additional rate that must be paid to common shareholders above what is paid to bond holders.

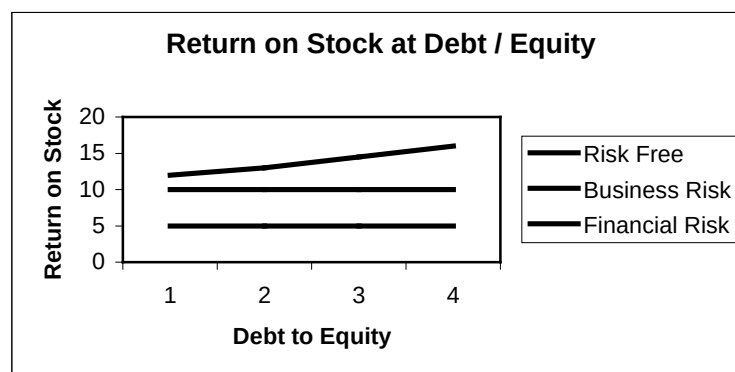
**7.3.3 Cost of Preferred Stock (Cps)** - If your capital structure includes preferred stock, the cost of preferred stock is calculated by the amount of dividends in relation to the market price of the preferred stock. The formula is  $Cps = \text{Dividends} / \text{Market Price of Stock}$ .

**7.3.4 Cost of Retained Earnings** - The cost of retained earnings (internal funds) within a capital structure is similar to the cost of common stock. We can think of the cost of retained earnings in relation to the opportunity cost of how we can use these funds. Generally, the cost of retained earnings is slightly less than the cost of common stock since no issuance costs is incurred.

After we have calculated each component cost of capital, we will calculate a weighted average based on the relative market values of each component. Our overall cost of capital is calculated as a weighted average based on the relative market values of each component of capital. If market values are not available, we may have to use book values. In any event, the weighted average cost of capital is the overall cost of capital that will be used to evaluate capital investments.

## **7.4 *Cost of Equity and Risk***

The Cost of Equity is the rate of return required by those who invest in equity securities.



The expected return can be broken down into two components - Risk Free Rate and Risk Premium. A good benchmark for establishing the Risk Free Rate is the rate paid on 30 day Government Treasury Bonds since the risk of default is virtually non-existent. The Risk Premium can be established by understanding two forms of risk - Business Risk and Financial Risk. In the absence of debt, shareholders are confronted with one form of risk, business risk. Business Risk is the risk of changes to operating income from numerous factors that influence business. When we introduce debt, we have to include financial risk. Financial Risk is the risk of changes to earnings from the use of increased debt. More debt results in higher interest payments, which impacts earnings. Consequently, the Risk Premium consists of Business Risk + Financial Risk. The following graph summarises these relationships:

In the above graph, we have a total risk free rate of 5%. The addition of business risk increases the required rate on stock to 10%. When we introduce debt, this adds financial risk and increases the required return on stock. The final total rate of return on stock with all forms of risk climbs from 12% to 16% over a range of Debt to Equity Ratios. Since the cost of capital represents the rate that must be paid to investors for the use of long-term funds, higher risk to investors will increase the cost of capital.

## 7.5 Working Capital

Working Capital is the money used to make goods and attract sales. The less Working Capital used to attract sales, the higher is likely to be the return on investment. Working Capital management is about the commercial and financial aspects of Inventory, credit, purchasing, marketing, and royalty and investment policy. The higher the profit margin, the lower is likely to be the level of Working Capital tied up in creating and selling goods. The faster that we create and sell the goods the higher is likely to be the return on investment.

The Balance Sheet comprises Long term Assets (real estate, motor vehicles, machinery) and Net Current Assets. The word Working Capital is often used for Net Current Assets. In this chapter we will exclude Cash in Bank from our definition.

Thus the Balance Sheet appears as follows:

|                  | Rs. in '000  |
|------------------|--------------|
| Long Term Assets | 6,000        |
| Working Capital  | 28,000       |
| Cash in Bank     | <u>1,000</u> |
| Total Capital    | 35,000       |

We defined Net Current Assets as Total Current Assets less Total Current Liabilities.

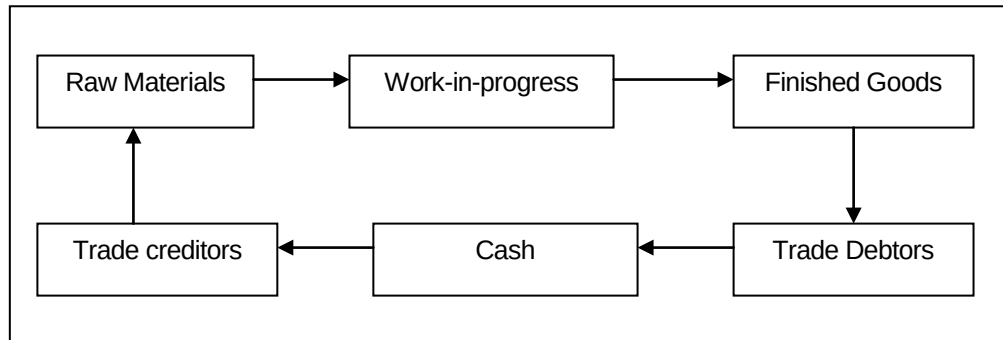
|                      | Rs. In '000    |
|----------------------|----------------|
| Inventory            | 15,000         |
| Receivables          | 17,000         |
| Prepayments          | 6,000          |
| Payables             | (9,000)        |
| Customer Prepayments | <u>(1,000)</u> |
| Working Capital      | 28,000         |

Using this format we can state that any reduction in the Working Capital figure, other than for provisions for write-offs and write-downs, will generate the same amount of cash. Thus if a customer pays Rs. 5 lacs that he owes to the organisation, the Working Capital figure will fall by Rs. 5 lacs, and the cash figure will be increased by the same figure. This revised format is useful when designing spreadsheet financial planning models for business plans or for internal reporting.

### 7.5.1 Working Capital Cycle

The Working Capital cycle or Cash Conversion cycle as it is also called is usually expressed in terms of the number of days. This figure is the average time that it takes to turn investment in goods production into cash and profit.

Working Capital represents the net investment in short-term assets. These assets are continuously flowing into and out of the business and are essential for day to day operations. The various elements of working capital are interrelated and can be seen as part of a short-term cycle. The working capital cycle can be depicted as under:



The working capital cycle is defined as the time period required for the whole operation starting with cash and ending with cash. The total period is broken up into various stages, like raw material waiting period, conversion period, finished stock period, debtors period, and creditors period.

Thus operating/working capital cycle can be described as:

$$\text{Operating Cycle (OC)} = R + W + F + D + C$$

Where

R = raw material and stores waiting period = Average raw material and stores inventory / average raw material and store consumption per day

W = Work-in-progress period = average work-in-progress inventory / Average cost of production per day

F = Finished goods waiting period = Average finished goods inventory / Average cost of goods sold per day

D = Debtors collection period = Average accounts receivable / Average credit sales per day

C = Creditors payment period = Average trade creditors / Average credit purchase per day

The management of working capital is an essential part of the short term planning process. It is necessary for the management to decide how much of each element should be held. Management should be aware of the costs associated with each element of working capital in order to manage them effectively. Management must also be aware that there may be more profitable use of funds for business. The potential benefits must outweigh the likely costs in order to achieve optimum investment.

Working capital needs are likely to change over time as a result of changes in the business environment. This means working capital decisions are rarely one-off decisions. Management must try to identify the changes occurring so as to ensure the level of investment in working capital is appropriate.

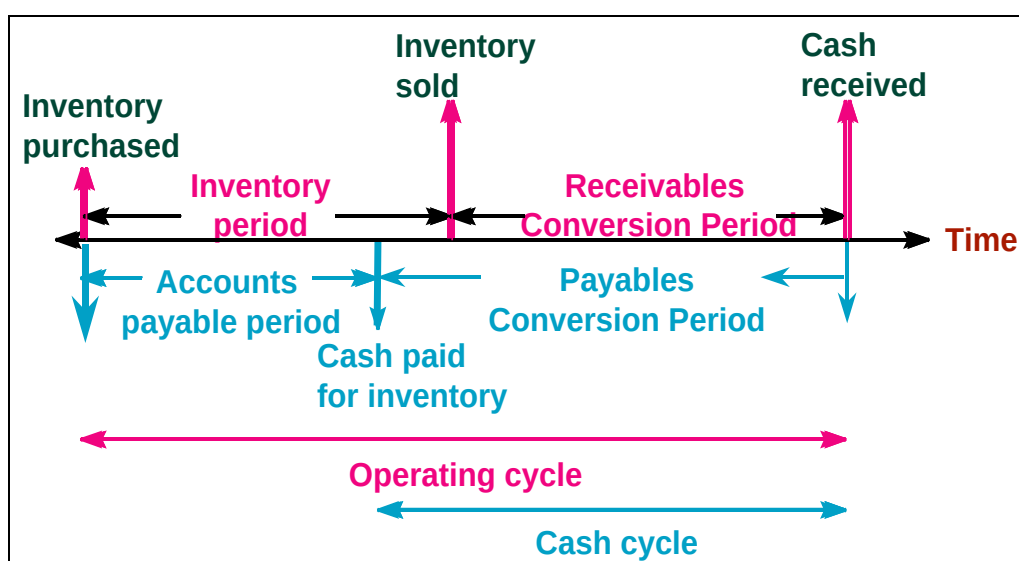
In addition to changes in the external environment, changes arising within the business such as changes in the production method and changes in the level of risk managers are prepared to take can alter the level of investment in working capital.

### 7.5.2 Operating Cycle and Cash Cycle

Investment in working capital is influenced by four key events in production and sales cycle of the organisation:

- Purchase of raw material
- Payment for raw materials
- Sale of finished goods
- Collection of cash for sales.

The diagram given below depicts these events on a cash flow line. The firm begins with the purchase of raw material inventory which are paid after a delay which represents the accounts payable period. The raw material is converted into finished goods and then sold. The time lag between the purchase of the raw material and the sale of the finished goods is the inventory period. Customers pay after some time after the sales are made. The period that elapses between the date of sales and the date of collection of receivables is the accounts receivable period.



The time that elapses between the purchase of the raw materials and the collection of cash for sales is referred to as the operating cycle, whereas the time length between the payment for raw material purchases and collection of cash for sales is referred to as the cash cycle. The operating cycle is the sum of the inventory period and the accounts receivable period whereas the cash cycle is equal to the operating cycle less the accounts payable period.

### 7.5.3 Secret of Working Capital Management

The secret to good working capital management is simple — "use someone else's money every chance you get and don't let anyone else use yours." within reason, of course. To do that, the following strategies might be employed; again within reason. A company wouldn't want to stretch out its payables for so long a period that it's forced out of business.

- Stretch out accounts payable as long as possible. If a bill is due on the 13th, don't pay it on the 10th. If a company has enough clout, they can negotiate longer terms with vendors.
- Turn receivables as quickly as possible. Make it easy for customers to pay. Lockboxes, prepaid envelopes, discounts, etc. may be utilised.
- Turn inventories as quickly as possible. Inventories may be a big investment for a firm and they earn no interest. Just-in-time inventory methods and some other strategies are used to hold down a firm's investment in inventories.

## **7.6 *Blueprint for Good Working Capital Management Policy***

### **General Action**

- Set planning standards for stock days, debtor days and creditor days.
- Having set planning standards (as above) KEEP TO THEM. Impress on staff that these targets are just as important as operating budgets and standard costs.
- Instil an understanding amongst the staff that Working Capital Management produces profits.

### **Action on Stocks**

- Keep stock levels as low as possible, consistent with not running out of stock and not ordering stock in uneconomically small quantities. "Just-in-Time" stock management is fine, as long as it is "Just-in-Time" and never fails to deliver on time.
- Consider keeping stock in suppliers' warehouses, drawing on it as needed and saving warehousing cost.

### **Action on Debtors / Customers**

- Assess ALL significant new customers for their ability to pay. Take references, examine accounts, ask around. Try not to take on new customers who would be poor payers.
- Re-assess ALL significant customers periodically. Stop supplying existing customers who are poor payers - you may lose sales, but you are after QUALITY of business rather than QUANTITY of business. Sometimes poor-paying customers suddenly (and magically !!) find cash to settle invoices if their supplies are being cut off. If customers can't pay / won't pay let your competitors have them - give your competitors a few more problems.
- Consider factoring sales invoices - the extra cost may be worth it in terms of quick payment of sales revenue, less debtor administration and more time to carry out your business (rather than spend time chasing debts).
- Consider offering discounts for prompt settlement of invoices, but only if the discounts are lower than the costs of borrowing the money owed from other sources.

### **Action on Creditors**

- Do NOT pay invoices too early - take advantage of credit offered by suppliers - it's free !!
- Only pay early if the supplier is offering a discount. Even then, consider this to be an investment. Will you get a better return by using working capital to settle the invoice and take the discount than by investing the working capital in some other way ?
- Establish a register of creditors to ensure that creditors are paid on the correct date - not earlier and not later.

## 7.7 Cash Flow Planning

Cash (or money, which means both currency and checks) is the lifeblood of every business. It is the most important asset for the operations of a business. Cash Flow refers to the movement of money in and out of a business during a specific period of time. It is a record of a company's inflows and outflows. Cash inflow is defined as the movement of money into a business and cash outflow is defined as the movement of money out of a business.

Please do not confuse a Cash Flow Projection with a Cash Flow Statement. The Cash Flow Statement shows how cash has flowed in and out of your business. In other words, it describes the cash flow that has occurred in the past. The Cash Flow Projection shows the cash that is anticipated to be generated or expended over a chosen period of time in the future.

One of the objectives of cash flow management is to hold the right amount of cash. If we hold too much cash, we lose the opportunity to earn a return on idle cash. If we hold too little cash, we run the risk of not making timely payments to suppliers, banks, and other parties. We want to have an optimal cash balance that is neither excessive nor deficient. The optimal cash balance is determined by looking at the four reasons for holding cash:

- **Transaction Amounts:** We have to hold enough cash to cover our outstanding payments or transactions. In addition to transaction amounts, we should add any compensating balances required under loan agreements. Therefore, the amount of cash on hand must be transaction amounts + compensating balances.
- **Precautionary Amounts:** We need to maintain cash for unexpected disbursements. This is the precautionary amount of cash.
- **Speculative Amounts:** If we are anticipating making an investment, we will hold a speculative amount to take advantage of opportunities in the marketplace.
- **Financial Amounts:** In order to acquire assets, retire debt, or meet some major event, we will accumulate and hold a financial amount of cash.

## 7.8 Cash Flow Forecasting

One of the best ways to determine the optimal cash balance is to fully understand cash flow patterns. This requires that we plot cash flows and prepare a forecast. A cash flow forecast gives us a detail projection of future cash inflows and outflows. This will help us avoid cash deficiencies as well as excessive cash balances. A cash flow forecast also answers several questions, such as how long can we invest idle cash, when will it be necessary to borrow cash, and when can we purchase new capital assets? A typical cash flow forecast will include: Cash on Hand, Expected Receipts, and Expected Disbursements. Each major receipt and disbursement should be listed as a separate line item. Example below illustrates a basic cash flow forecast.

| Example                                |                 | Investment Receipts:             |               |
|----------------------------------------|-----------------|----------------------------------|---------------|
| Monthly Cash Flow Forecast for January |                 |                                  |               |
|                                        | <u>Rs. Lacs</u> | Investment Income                | - 0 –         |
|                                        |                 | Sale of Marketable Securities    | - 0 –         |
| Beginning Cash on Hand                 | 60              | Sale of Assets                   | - 0 –         |
| <b>Operating Receipts:</b>             |                 | <b>Investment Disbursements:</b> |               |
| Accounts Receivable                    | 1200            | Invest in Marketable Securities  | - 0 –         |
| Other Receipts                         | - 0 –           | Invest in Capital Assets         | - 0 –         |
| <b>Operating Disbursements:</b>        |                 | <b>Financing Receipts:</b>       |               |
| Payroll                                | -850            | Proceeds from Loans              | - 0 –         |
| Taxes                                  | -35             | Proceeds from Asset Borrowings   | - 0 –         |
| Utilities                              | -80             | <b>Financing Disbursements:</b>  |               |
| Insurance                              | -110            | Repay Loans & Debt               | - 0 –         |
| Supplies                               | -60             | Net Change in Cash               | -325          |
| Services                               | -350            | Total Available Cash             | -265          |
| Other                                  | -40             | Minimum Cash Balance             | 40            |
| Net Operating Cash Flow                | -325            | Surplus (Deficit)                | -305          |
|                                        |                 | Activate Line of Credit          | 325           |
|                                        |                 | <b>Ending Cash Balance</b>       | <b>Rs. 60</b> |

The overall objective is to prepare a cash flow forecast that is accurate enough to determine cash sufficiency. As a general rule, it is more difficult to predict cash receipts than cash disbursements. When making estimates about receipts and disbursements, consider using expected values, especially if you are uncertain about final amounts.

## **7.9 Financial Planning and Budgets**

Financial Planning starts at the top of the Organisation with strategic planning. Since strategic decisions have financial implications, you must start your budgeting process within the strategic planning process. Failure to link and connect budgeting with strategic planning can result in budgets that are "dead on arrival."

Strategic planning is a formal process for establishing goals and objectives over the long run. Strategic planning involves developing a mission statement that captures why the Organisation exists and plans for how the Organisation will thrive in the future. Strategic objectives and corresponding goals are developed based on a very thorough assessment of the Organisation and the external environment. Finally, strategic plans are implemented by developing an Operating or Action Plan. Within this Operating Plan, we will include a complete set of financial plans or budgets.

*Financial Plans (Budgets) ⇒ Operating Plan ⇒ Strategic Plan*

### **7.9.1 Sales Forecast**

In order to develop budgets, we will start with a forecast of what drives much of our financial activity; namely sales. Therefore, the first forecast we will prepare is the Sales Forecast. In order to estimate sales, we will look at past sales histories and various factors that influence sales. For example, marketing research may reveal that future sales are expected to stabilise. Maybe we cannot meet growing sales because of limited production capacities or maybe there will be a general economic slow down resulting in falling sales. Therefore, we need to look at several factors in arriving at our sales forecast.

After we have collected and analysed all of the relevant information, we can estimate sales volumes for the planning period. It is very important that we arrive at a good estimate since this estimate will be used for several other estimates in our budgets. The Sales Forecast has to take into account what we expect to sell at what sales price.

### **7.9.2 Detailed Budgets**

We also need to prepare several detail budgets for developing a Budgeted Income Statement. The Production Department will need to budget for materials, labour, and overhead based on what we expect to sell and what we expect in inventory.

Once we have established our level of production we can prepare a Materials Budget. The Materials Budget attempts to forecast the level of purchases required, taking into account materials required for production and inventory levels.

We can summarise materials to be purchased as:

$$\text{Materials Purchased} = \text{Materials Required} + \text{Ending Inventory} - \text{Beginning Inventory}$$

The second component of production is labour. We need to forecast our labour needs based on expected production. The Labour Budget arrives at expected labour cost by applying an expected labour rate to required labour hours.

As production moves up or down, support services and other costs related to production will also change. These overhead costs represent the third major costs of production. Each item that comprises overhead may warrant independent analysis so that we can determine what drives the specific cost. For example, production rental equipment may be driven by production orders while depreciation is driven by levels of capital investment spending.

Once production costs (direct materials, direct labour, and overhead) have been budgeted, we can work these numbers into our beginning inventory levels for Direct Materials, Work In Progress, and Finished Inventory. Beginning inventory levels are actual amounts from the last reporting period. We need to apply our costs based on what we want ending inventory to be. The end-result is a Budget for Cost of Goods Sold, which we will use for our Forecasted Income Statement.

We can now finish our estimate of expenses by looking at all remaining operating expenses. The first major type of operating expense is marketing. Marketing and Sales Manager's will prepare and submit a Marketing Budget to upper level management for approval.

The final area of operating expenses is the administrative costs of running the overall business. These types of expenses will be estimated based on past trends and what we expect to happen in the future. For example, if the company has plans for a new computer system, then we should budget for additional technology related expenses.

### **7.9.3 Budgeted Financial Statements**

Based on the detail budgets we have prepared we can finalise our budgets in the form of a Budgeted Income Statement. A few new line items are added to account for non-operating items, such as income received on investments and financing costs. The Budgeted Income Statement will pull together all revenue and expense estimates from our previously prepared detail budgets.

Now that we have a Budgeted Income Statement, we can prepare a Budgeted Balance Sheet. The Budgeted Balance Sheet will provide us with an estimate of how much external financing is required to support our estimated sales.

The main link between the Income Statement and the Balance Sheet is Retained Earnings. Therefore, preparation of the Budgeted Balance Sheet starts with an estimate of the ending balance for Retained Earnings. In order to estimate ending Retained Earnings, we need to project future dividends based on current dividend policies and what management expects to pay in the next planning period.

Next, we need to account for the acquisition of fixed assets. As a business depletes its asset base, it must re-invest to sustain assets that are the basis for generating revenues. For example, do we need to purchase new machinery or computer equipment? Do we plan to expand our production facilities? Operating personnel and upper-level management will decide on future capital spending. Future capital expenditures are summarised on the Capital Expenditures Budget.

Based on the beginning balance in assets and the budget for capital assets we can estimate an ending asset balance for the Budgeted Balance Sheet.

We will assume that liabilities and interest expense will remain same. However, after we have determined our level of external financing, we will need to revise these amounts. Additionally, we need to analyse trends and ratios in order to ascertain accounts that do not fluctuate with sales. For example, prepaid expense is a current asset that has little to do with sales.

## **Experience Sharing: Battling cholesterol with novel probiotics**

Cholesterol is one of the leading factors behind all the heart diseases across the globe. According to a report by World Health Organizations (WHO), cardiovascular diseases (CVDs) are the number one cause of death globally, and more people die annually from CVDs than from any other cause. Over three quarters of CVD deaths take place in low- and middle-income countries.

In 2012 alone, 17.5 million people died from CVDs representing 31% of all global deaths.

Globally, India seems to be leading in two of the major ailments - diabetes and heart diseases.

Aware of this trend, 25-year-old Mr Hrishikesh Mungi is working hard at his lab at NCL (National Chemical Laboratory), Pune, on solving one of India's major health threats. In 2012, after graduating with an Engineering degree in Biotechnology from KLE Engineering College, Belgaum, Mr Mungi was selected to work on a project on the extraction of bile salts hydrolase enzyme at NCL.

"We soon realized the commercial potential of our research," says Mr Mungi.

His guide, Dr Archana V Pundle, a chief scientist at NCL was the first to point out the research's commercial viability.

Mr Mungi continues, "We then applied for a patent with the help of NCL. We put together a business plan including market survey and future goals for building a commercial enterprise."

The research work was selected by BIRAC (Biotechnology Industry Research Assistance Council) for funding the project further through its BIG (Biotechnology Ignition Grant) scheme. In June 2014, Abhiruchi Probiotics was incorporated by Mr Mungi, with Dr Pundle serving as a scientific advisor and non-executive director of the start-up.

Abhiruchi is a technologically-driven start-up, involved in developing novel probiotic products having health benefits.

Investments worth Rs 50 lakh has been invested in the company so far.

It is currently focusing on developing, manufacturing and commercializing of a cholesterol-lowering probiotic formulation without any side effects on the body.

The company has now acquired provisional patent for lowering cholesterol by the application of probiotics.

"At the moment we are validating the technology, and it'd take another 5 years for

the products to reach the market," adds Mr Mungi, who enjoys playing Cricket.

Mr Mungi's father and grandfather were also entrepreneurs who inspired him to actively pursue entrepreneurship since his early childhood.

He bagged the 'Young Entrepreneur Award' at Eureka 2014, a business model competition conducted by IIT-Bombay.

While developing the technology at NCL, Mr Mungi worked hard for a monthly pay as little as Rs 8000. At times he had to wait patiently for months together to receive his salary.

Talking about the challenges faced, Mr Mungi voices, "Adapting to the mode of operation at the incubator center was challenging initially. Also it was grappling to maintain a balance between research and business documentation processes. Procuring materials and equipments from vendors in terms of quality and price was a huge task."

Abhiruchi now is looking to collaborate with companies, research institutes, academia and the industry to carry out clinical trials on its products. It is also seeking active partnerships to optimize and scale-up its fermentation process, and diversify its R&D.

However, it is not expecting to expand internationally at least for the next 5 years.

He has a couple of recommendations for the Government when it comes to supporting start-ups.

"The Government needs to redesign DSIR

(Department of Scientific and Industrial Research) recognition requirement by DST (Department of Science & Technology), DBT (Department of Biotechnology), and ICMR (Indian Council of Medical Research) while acquiring grants for start-ups, which are available for Government-aided labs. The Government should also support start-ups to acquire equipments and temporary manpower through grants provided by DST, DBT, and ICMR. But again, this facility is available for Government-aided labs," Mr Mungi opines, who looks at Mr Warren Buffet as his entrepreneurial model.

He also firmly believes that for a start-up, validating the idea thoroughly by various means especially with respect to market requirements is crucial.

He signs-off by saying, "We need to drop the idea of being born for something. With hard work and patience, everything can become one's life goal."

---

## 8. FINANCIAL STATEMENTS

---

***“If you work just for money, you’ll never make it. But if you love what you are doing and always put the customer first, success will be yours”  
– Ray Kroc***

Financial statements are prepared to provide a picture of the financial position and the performance of an organisation. These statements are normally prepared on a regular recurring basis. It provides the information to help one to make decisions and judgements. Usually three major financial statements are prepared which are:

- **The Balance Sheet** – giving us the accumulated wealth at the end of a particular period. This wealth may be in the form of different assets e.g. land and buildings, inventory etc. There are some claims against these assets. These are reflected on the balance sheet too.
- **The Profit and Loss Account** – gives us how much profit is generated over a particular period. It takes into account all incomes and expenditures for the particular period.
- **The Cash Flow Statement** – telling us about the cash movements that took place over a particular period. Cash is a vital resource and is necessary for any business to function effectively.

Taken together they provide an overall picture of the financial health of the Company. They are referred to as the final accounts of a business. For external users the statements are backward looking and are based on information concerning past events and transactions. However, the statements can also be prepared using projected figures in order to help assess likely future profits, cash flows, etc.

### 8.1 Statement Showing Financial Position

#### 8.1.1 The Balance Sheet

The purpose of the balance sheet is to set out the financial position of a company at a particular moment in time. The balance sheet is sometimes referred to as a position statement, because it seeks to provide the user with a picture of the financial position. It is a reflection of the wealth of the business and how much wealth is held in which form. To be more specific it can be said that the balance sheet sets out the *assets* of the business on one hand and the *claims* against it on the other.

#### 8.1.2 Assets

Assets are essentially a resource held by the business. Some of the major characteristics of assets are:

- *A probable future benefit exists:* These items have some future monetary value. This value can be through its use in the business or through its hire or through its sale. Even an obsolete piece of equipment that can be sold as scrap is considered as an asset.
- *The business has an exclusive right to control the benefit:* The business has the exclusive right to control the asset. Therefore even if a public road is being used by a tourist agency for its buses it is not regarded as an asset, as these are not owned by or controlled by the business even though all benefits are got from it.

- *The benefit must arise from a past transaction or event:* The transaction or event giving rise to the business's right to the benefit must have already occurred and will not arise at some future date. For e.g. an agreement to purchase a piece of machinery at a future date does not mean it is an asset for the business.
- *The asset must be capable of measurement in monetary terms:* Unless the item can be measured in monetary terms it cannot be regarded as an asset for inclusion in the balance sheet.

The sort of items that normally appear as assets in the balance sheet of a business include freehold premises, land and building, railway sidings, machinery and equipment, furniture and fixtures, vehicles, computers, patents and trademarks, debtors, inventory, investment, cash and bank balances.

### 8.1.3 Claims

A claim is an obligation on the part of the business to provide cash or some other form of benefit to an outside person. A claim would normally arise as a result of an outside party providing fund or any form of assets for the use of the business. Normally claims would be of two types – Capital and Liabilities.

- *Capital:* It is the claim of the owners (shareholders) against the business. The business is viewed as being separate from the owners, Therefore any funds contributed by the owners to help finance the business will be regarded as a claim against the business in the balance sheet.
- *Liabilities:* These are the claims of individuals and organisations against the company which have arisen due to past events and transactions such as supplying goods or lending money to the business.
- Thus when a business required acquiring assets it will have to raise the funds from somewhere. This may be funds from the shareholders or borrowed funds or remain as an outstanding obligation to the supplier, or a combination of these. Thus the total assets will always be equal to the total claims. This is known as the balance sheet equation. When there are manufacturing or trading operations there arises a profit or a loss i.e. there is an increase or a decrease in the owner's stake in the business. Thus the balance sheet equation is extended as under:

**The Balance Sheet Equation: Assets = Capital +(-) Profit (Loss) + Liabilities**

### 8.1.4 Classification of Assets

It is customary to group assets and claims into categories. Assets are normally categorised as either being fixed or current.

*Fixed Assets:* Fixed assets are held with an intention of being used for the production or generation of wealth rather than being held for resale. They are the tools of the business and are held by it on a continuing basis. For e.g. Freehold land, buildings, machinery, railway sidings, furniture, electrical installations, motor vehicles etc.

*Current Assets:* These include cash itself and other assets that are expected to be converted to cash at some near future date. Current assets are held as part of the day-to-day trading activities of the business. Common current assets are inventories, debtors and cash. These are interrelated and circulate within the business. Cash is used to purchase inventories, which is sold on credit and when the trade debtors pay the business again receives the cash.

### **8.1.5 Classification of Claims**

As mentioned above the claims can be classified as capital and liabilities. Liabilities can be further classified as long term liabilities and current liabilities.

*Long term Liabilities:* They represent amounts due to other parties which are not liable for repayment within the next twelve months after the balance sheet date.

*Current Liabilities:* These are the amounts due to the outside parties within twelve months of the balance sheet date.

Unlike assets the purpose for which the liabilities are held is not important, It is only the period for which the liabilities are outstanding that is important.

### **8.1.6 Balance Sheet Formats**

Although there could be a number of ways in which balance sheet information could be presented, in practice there is one basic format. This format has been laid down in the Companies Act, 2013.

### **8.1.7 Interpreting the Balance Sheet**

The Balance Sheet can provide useful insights to the financing and investing activities of the business. The following aspects of the financial position can be examined:

- The liquidity of the business: This is the ability of the business to meet its short-term obligations from its liquid assets.
- The mix of assets held by the business: Businesses with too much of their funds tied up in fixed assets could be vulnerable to financial failures because they are not easy to turn into cash. Thus there has to be a balanced mix of the fixed and the current assets held by the business.
- The financial structure of the business: The relative proportion of the total finance contributions by the owners and outsiders can be calculated to see whether the business is heavily dependent on outside financing. Heavy borrowing would bring in commitments to pay large interest and principal repayment at regular intervals. This would effect the financial position of the business.

## **8.2 Measuring and Reporting Financial Performance**

### **8.2.1 The Profit and Loss Account (Income Statement)**

Businesses exist with the primary aim of generating wealth i.e. profits. The purpose of the profit and loss account is to measure and to report how much profit the business has generated over a specified period.

This requires the measurement of the revenue generated during the particular period on one hand. *Revenue* is the measure of the inflow of assets (cash or amounts owed to the business by debtors) or the reduction in liabilities which arise as a result of operating activity.

On the other hand it is required to calculate the total expenses relating to the particular period. An *expense* represents the outflow of assets (or an increase in liability) which is incurred as a result of generating revenue. Common types of

expenses are the cost of the goods sold, salaries and wages, rent, travelling and conveyance, printing and stationery, postage, telephone and others.

The profit and loss statement thus simply shows the total revenue generated and deducts from this the total expenses incurred for generating this revenue. The difference between them represents the profit (if the revenue exceeds the expenses) or loss (if the expenses exceed the revenue). Thus the equation is:

$$\text{Profit (loss) for the period} = \text{Total revenue less Total Expenses incurred in generating the revenue.}$$

### **8.2.2 Format of the Profit and Loss Account**

The first part of this statement is concerned with calculating the gross profit for the period. The revenue that arises on the sale of the goods is the first item that appears. Deducted from this item are the expenses related directly to the goods sold. These are the cost of acquiring the raw materials, the direct labour expenses and other expenses that are directly related to the production of the goods, in short, the cost of the goods sold. The difference between the revenue from the goods sold and the cost of the goods sold is the *gross profit*.

Having calculated the gross profit any other revenues received by the business are added to this figure. Then other expenses (overheads) that have been incurred for operating the business e.g. administrative expenses, selling and distribution expenses, rates and taxes and others are deducted. The resulting figure is the *net profit* for the period. This is the wealth generated during the period that will be added to the balance sheet.

### **8.2.3 Recognition of Revenue and Expenses**

Revenue is recognised according to the realisation convention. This convention states that the revenue should only be recognised when it has been realised. Normally, realisation is considered to have occurred when:

- The activities necessary to generate the revenue are substantially complete.
- The amount of revenue generated can be objectively determined.
- There is reasonable certainty that the amounts owing from the activities will be received.

Thus the realisation convention means that a sale in credit is usually recognised before the cash is ultimately received. The total sales figure in the profit and loss account would therefore be different from the total cash received from the sale.

While recognising the expenses the matching convention is followed. This convention states that the expenses should be matched with the revenues that they help to generate. Thus for a particular period the amount of expenses may not match the figure of the cash paid. Some of the expenses may remain outstanding but would be considered in the profit and loss account as they are associated with the sales of the particular period.

### **8.2.4 Profit and Loss Account and Balance Sheet- Relationship**

The Profit and loss Statement and the Balance Sheet perform different functions. The Balance sheet is the statement of the financial position and wealth of a business at a single moment in time. The profit and loss statement is concerned with the flow of wealth over a period of time. The two statements are closely related. The Profit and Loss can be viewed as linking the balance sheet at the

beginning of the period with the balance sheet at the end of the period. The amount of the profit or loss is shown separately in the balance sheet as an adjustment to the capital. Thus the profit and loss account gives us the net effect of the operations for the particular period which is reflected as an adjustment with the capital for the balance sheet drawn up on the last moment of the particular period.

### 8.3 Accounting Conventions and Concepts

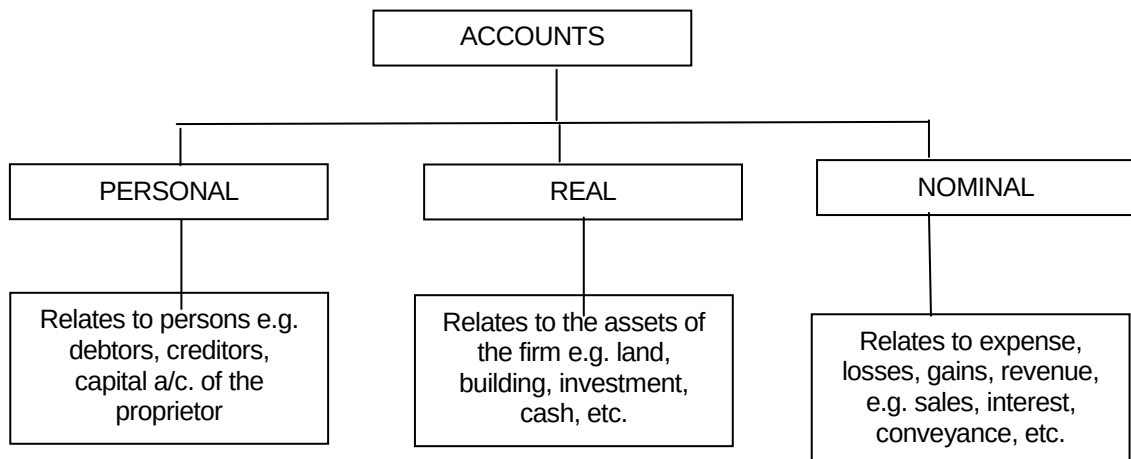
#### 8.3.1 Basic Accounting Concepts

Certain accounting concepts underlie the preparation of the financial statements. These concepts and conventions are followed while preparing the financial statements.

- *Business entity Convention:* The business and the owners or shareholders are treated as separate and distinct entities.
- *Money Measurement Concept:* Only those events should be recorded that can be expressed in monetary terms.
- *Historical Cost Concept:* Assets should be valued by taking into account all the amounts involved to bring it to the present state of capitalization.
- *Going Concern Concept:* This convention holds that the business will continue operations for the foreseeable future and there is no intention or need to liquidate the business.
- *Dual Aspect Convention:* Each transaction has two aspects, both of which will affect the balance sheet. E.g. the purchase of a car would increase an asset i.e. motor car and on the other hand will decrease an asset i.e. cash.
- *Prudence:* This convention holds that the financial statements should err on the side of caution. Operation of this convention results in recording both the actual and the anticipated losses in full whereas the profits are not recognized until they are realised.
- *Revenue Realisation Concept:* This concept does not require to wait for the receipt of cash before recording a transaction because in many cases the receipt of cash occurs much after the delivery of the goods which determines the time of the transaction.
- *Accrual Concept:* Expenditures and Incomes generally accrue over the period and in accumulating effect settled by payments, receipts or otherwise at an agreed point of time. All expenses payable and incomes receivable are to be accounted for ignoring their actual payments and receipts.
- *Consistency:* Accounting policies and procedures should be followed consistently. If the changes are necessary to be made, detailed disclosure of the same along with the monetary effect of such changes in the financial statements should be revealed to all concerned.
- *Accounting Period:* The normal accounting period is one year corresponding to the financial year commencing on the 1<sup>st</sup> April and ending closing on 31<sup>st</sup> March each year.
- *Rules for Debit and Credit:*

| <i>Nature</i> | <i>Increase</i> | <i>Decrease</i> | <i>Normal status of Ledger Balance</i> |
|---------------|-----------------|-----------------|----------------------------------------|
| Assets        | Debit           | Credit          | Debit balance                          |
| Liabilities   | Credit          | Debit           | Credit Balance                         |
| Capital       | Credit          | Debit           | Credit balance                         |
| Expenses      | Debit           | Credit          | Debit balance                          |
| Revenue       | Decrease        | Increase        | Credit balance                         |

- *Types of Accounts:*



- *Double entry Rules for Debit and Credit:*
  - o Debit the Receiver, Credit the Giver- *Personal Account*.
  - o Debit what comes in, Credit what goes out- *Real Account*.
  - o Debit all Expenses and Losses, Credit All Income and Gains- *Nominal Account*.

### 8.3.2 Components of Cost

The different types of costs involved can be grouped under two main heads – direct costs and indirect costs. **Direct costs** are costs that can be identified with specific cost units. That is to say the effect of the cost can be measured in respect of each particular unit of output. The normal examples of these are direct material and direct labour costs. **Indirect Costs** or overheads are all other costs that are those that cannot be directly measured in each particular unit of output.

### 8.3.3 Behaviour of Cost

Costs may be broadly classified as :

- Costs those stay fixed when changes occur in the volume of activity i.e. fixed costs.
- Those which vary with the volume of activity i.e. variable costs.
- Those which are partly variable with the volume of activity i.e. semi-variable costs.

Fixed in this context only means the cost that is not altered with the change of level of activity. However, they may be affected by inflation. Fixed Costs are almost always time based i.e. they vary with the length of time concerned.

The variable cost of materials remains constant per unit of activity irrespective of the level of activity. In some cases the cost may slightly vary due to economies of scale.

In some cases the costs have both the fixed and the variable elements to them. For e.g. there may be a fixed charge as in telephone bills and then a part of the bill which varies with the number of telephone calls made.

### 8.3.4 Flow of Cost

There are two different approaches for determining the cost of the goods sold in a manufacturing concern.

In **Absorption Costing** all costs incurred in the manufacture irrespective of their behaviour with respect to the volume are regarded as product costs and included in the cost of the manufactured product. This method is termed as the absorption costing or full costing. Non-manufacturing costs such as distribution costs, research and development costs, financial costs and administrative cost are regarded as period costs to be expensed in the particular period in which they are incurred or amortised over several accounting periods.

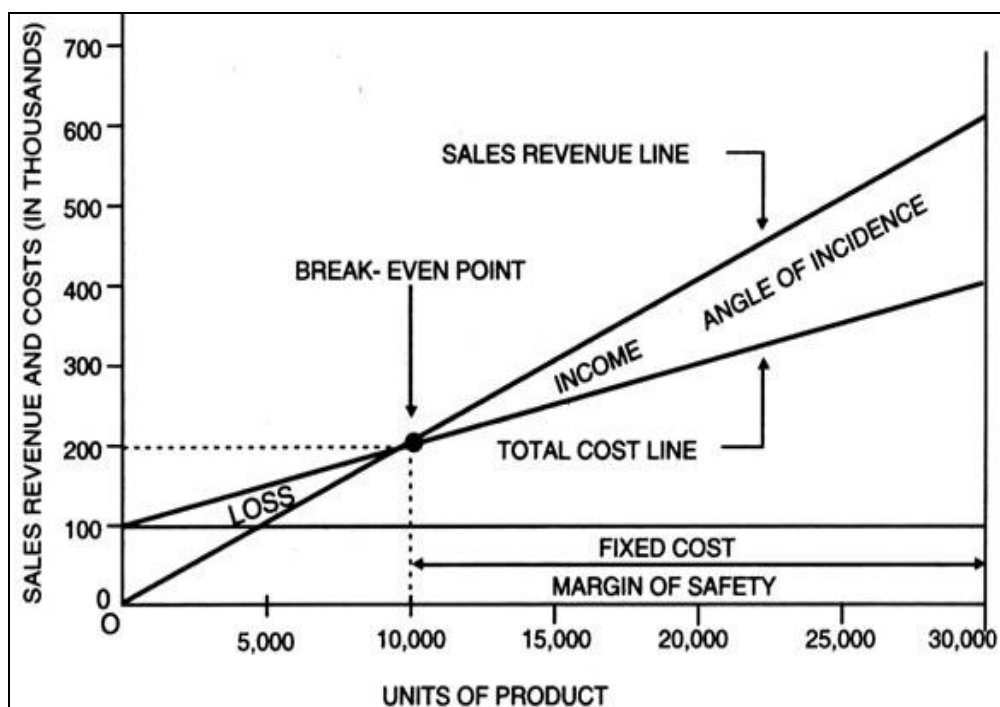
In **Marginal Costing** or variable costing also called direct costing, the manufacturing costs are segregated between fixed and variable. Only the variable costs are considered while valuing inventories and determining the cost of goods sold. The remaining manufacturing expenses are treated as period costs.

### 8.3.5 Break-even Analysis

Break-even analysis also termed as Cost-Volume-Profit Analysis helps answering the following questions:

- At what sales would the company break-even?
- How sensitive is profit to variations in output, selling price, fixed and variable costs?
- How much should a company produce and sell to reach a target profit level?
- Break-even analysis draws from the concept of Variable and Fixed Costs. The analysis is made possible because of behaviour of fixed and variable cost with units of production.

#### The Break -even Chart and breakeven point



The total cost line shows us the combination of the fixed and the variable cost. At zero level activity there is zero sales revenue. The profit (total sales revenue less total cost) at various levels of activity is the vertical distance between the total sales line and the total cost line at a particular level of activity.

At breakeven point where there is no vertical distance between these two lines and thus there is no profit i.e. the activity breaks even. Below the break-even point a loss would be incurred, above breakeven point there will be a profit. At break-even point thus the total revenue is equal to the total cost. A major assumption of the conventional break-even concept is that whatever is produced is sold and there is no carry over stock. Though in real life this is not possible, but the basic model would remain unchanged. The adjustment would come in form a cost of carrying stock that would increase the total cost line. In the basic model, If the number of units to break-even be  $b$ , then  **$(b \times \text{sales revenue per unit}) = \text{Fixed Cost} + (b \times \text{Variable Cost per unit})$**

### 8.3.6 Contribution

The bottom part of the break-even formula, (sales revenue per unit – variable cost per unit) is known as the contribution per unit. It is known as contribution because it contributes to meeting the fixed costs and if there is any excess it contributes to the profit. A negative contribution would mean that the organisation is paying from its own source to make the production and would incur lower loss if the production were stopped.

### 8.3.7 Cost Components

It is necessary to provide a summary statement of the cost components showing how the elements of cost accumulate to give the cost of total product.

|                                 |            |            |            |               |               |
|---------------------------------|------------|------------|------------|---------------|---------------|
| Profit                          |            |            |            |               | Selling Price |
| Selling & Distribution Overhead |            |            |            | Cost of Sales |               |
| Office Overheads                |            |            | Total Cost |               |               |
| Work Overheads                  |            | Works Cost |            |               |               |
| Direct Expenses                 | Prime Cost |            |            |               |               |
| Direct Labour                   |            |            |            |               |               |
| Direct Material                 |            |            |            |               |               |

The terms written vertically represent summation of the cost items written horizontally and encompassed within the height of the vertical terms. Thus Prime Cost is summation of Direct Material, Direct Labour, and Direct Expense. Similarly Works Cost is addition of Prime Cost and Works Overhead.

## Experience Sharing: Allergy Detectives

Erected in 2015, Indoor Biotechnologies India (IBI) was founded by Dr Martin Chapman (62), serving as the president and CEO of this Bangalore-based start-up, along with executive directors Dr James Hindley (32), and Dr Sivasankar Baalasubramanian (Shiv, 43), all of whom are highly-qualified scientists from the academia.

Indoor focuses in manufacturing biologics for allergy and asthma. It manufactures highly purified allergens for allergy research and diagnostics, and is internationally recognized for research on allergen structure, function and immune recognition. It functions with a mission to improve the quality of life of patients with allergies and asthma.

It offers products and services for indoor air quality and environmental sciences, both for research and consumer usage.

The company assesses environmental exposure to allergens at home, workplace, schools and commercial buildings.

The start-up also caters to pharmaceutical and biotechnology companies which are involved in food allergy safety.

Indoor Biotechnologies is organized as 3 affiliated companies - Indoor Biotechnologies USA; Indoor Biotechnologies UK; and Indoor Biotechnologies India, which functions as an independent private start-up. Incubated in Bangalore Bioinnovation Centre (BBC), the start-up is said to be the first occupants at the incubator.

Founder Dr Martin Chapman is a former Professor of Medicine and Microbiology at the University of Virginia (UVA), USA, and a member of the UVA Asthma and Allergic Diseases Center. He is a Fellow of the American Academy of Allergy, Asthma and Immunology, and has served as a consultant to the US National Institutes of Health, the Environmental Protection Agency, academic institutions and Fortune 500 companies.

Both - Dr James and Dr Shiv - have doctoral degrees in Immunology. "Currently the allergy healthcare management in the country is at infancy," opines Dr Shiv. Dr James explains, "India is a country where allergy is not very well understood, and there are not many diagnostics available for allergy sufferers. We as a company see this as an opportunity and want to have a major impact in India, Asia, and globally as well. We want to be the allergy research partner for the world."

The start-up is also in the process of understanding an array of allergens specific to India. "We are planning a survey of Indian allergens under different geographical

conditions. That will give us much information relevant to India, and from that data we will be developing new products," reveals Dr Shiv.

Numerous entrepreneurs feel that while establishing their dream start-ups, they are subjected to too much of paperwork and documentation processes.

"The amount of paperwork one has to go through is enormous. On one side, the Government is talking about FDI. The routes through which the money comes, and the amount of paperwork needed to erect a company is just too much. Its bureaucratic and lacking transparency. It definitely slows things down and sometimes very frustrating. The Government also talks about 'Make in India' and 'Make for India'. But the ground reality is there is no change in the processes which aren't streamlined or happen to be a one-window policy system. There is multiple layers of system. We need one distinct streamlined system that is fool-proof rather than having to encounter multiple documentation, and hundreds of signatures to even start a bank account. Unfortunately, nobody sees the benefit of refining the whole process," explains Dr Shiv.

People in the US and the UK are used to things being more organized. "It seems otherwise in India. It hardly takes a week to start a company in the US or the UK. In India it is very adhoc, random and a very difficult system to understand," says Dr James.

These multiple bureaucratic processes sadly tends to switch off entrepreneurs from starting their companies.

Dr Shiv points, "The Government is promoting FDI, but people are hesitant to come in to the country. Many companies want to enter India, but once they look at the bureaucracy here, they switch off. This is a contrasting or contradictory approach of the Government."

Indoor so far has been self-funded. All the funding came in from Dr Martin and Dr James. They have so far have invested Rs 1.5 crore in Indoor's Indian entity. In the future, the start-up intends to generate money through its services and product sales.

"The money generated," reveals Dr Shiv, "will go into our research and innovation. The Government's grants help us to explore ambitious projects, and the society is going to get benefited in the long run. However, the Government's policies are outdated and needs change."

Since Indoor's 51% stake is owned by foreigners, the start-up will not be eligible to apply for Government grants in the country. In

the UK, young companies get tax relief for R&D. The UK Government has incentivized R&D and offer tax rebates for start-ups.

"In the US, ideas are always appreciated, and it don't matter where the person is from," adds Dr James. The start-up claims of having novel capabilities that doesn't exist in India at the moment.

"It's an opportunity for big companies to try and develop new biologics for allergy management. We cater to the pharma and biotech sectors, and would want to work with major players in this space including Biocon, Dr Reddy's, Torrent, and Sun Pharma among others. We are also targeting MNCs in the food space like Unilever, P&G and ITC. Many corporates are looking to maintain their indoor air quality. That's where we come in the picture of air quality management industry," Dr Shiv emphasizes.

### **Bigger Challenges**

Dr Shiv adds that start-ups nurtured in an accelerator or incubator enjoy certain advantages.

"You have people to share your frustrations with and seek guidance, and see how they get things done. It also enables sharing of ideas. You definitely need people around you to help. You also need some inspiration, and you will find it with other start-up occupants," he mentions.

Taking Indoor's capabilities to the market is going to be a greater challenge, believes Dr Shiv.

"Our next step is going to be a bigger challenge. Today, the biggest, ambitious and high-risk ideas come from start-ups. The Government has to nurture and the industry need to support it. It is okay for start-ups to take the biggest risks and fail. They should be nurtured whether it is in ecommerce, IT or Life Sciences space," opines Dr Shiv.

### **Way Forward**

In the next 2 years, the start-up plans to touch Rs 2 crore in revenues. Indoor's UK and USA entities will oversee their respective regions. The Indian counterpart will act as a hub for whole of South-East Asia. Dr Shiv reveals that the start-up doesn't have any immediate expansion agenda.

"We have a lot of work to do right here in India. But we see ourselves move into broader immunology covering heart diseases, cancer and so on. In the next couple of years, we have to manage well because we cater to a very niche market. However, if we see a good

opportunity, we will definitely expand. We are very opportunistic," he comments.

Dr James shares that the company is looking for strategic partnerships and collaborators with common interests.

"We are looking for collaborators in healthcare and pharma companies. We would be interested in novel technologies or platforms. We offer our expertise in developing products and solutions," Dr James notes, who is a science geek, a passionate golfer and a family's man.

He feels that it is not easy to spread the word in India unlike the West.

"Building relationships takes time here as opposed to the US or Europe. Start-ups are relationship-driven. You can't send an email and expect it to work," he states.

The entrepreneurs observe that Delhi NCR, Chandigarh, and Kerala has good bio innovation centres.

"They could be the potential players in the future for biotech start-ups. Kerala has a good start-up policy, and were the first to come up with it. When you have a policy which is not decided by individuals, decision-making becomes easy. Policies need to be updated as the industry grows and evolves," Dr Shiv stresses.

Dr Shiv loves sports including Cricket and Badminton. Dr Martin is into NIA creative dance and movements.

### **Busting Start-up Myths:**

- Academicians can't be entrepreneurs
- Only businessmen can run businesses

### **Start-up Advice:**

- Check distractions
- Don't be secretive about ideas
- Don't dwell on negatives
- Don't wait till tomorrow. Just do it
- Expect, identify and prepare for risks
- Move on and accept situations/circumstances

### **Entrepreneurship Essentials:**

- Adhering to a plan
- Avoiding excessive detailing and figuring
- Focus
- Following gut instincts (at times)
- Goal-oriented
- Good ideas and passion
- Quality time management
- Willing to take risks and plunge

---

## 9. HUMAN RESOURCE MANAGEMENT

---

***“Great vision without Great People is Irrelevant”  
-Jim Collins***

Human Resource Management ("HRM") is a way of management that links people-related activities to the strategy of a business or organisation. HRM has several goals:

- To meet the needs of the business and management (rather than just serve the interests of employees);
- To link human resource strategies / policies to the business goals and objectives;
- To find ways for human resources to "add value" to a business;
- To help a business gain the commitment of employees to its values, goals and objectives.

### 9.1 ***The link between Human Resources and Business Strategy***

All elements of the business strategy have implications for human resources, as illustrated in the table below. The challenge for management is to identify and respond to these HR challenges:

| <b>Examples of Key Strategy Issues</b>                                              | <b>Possible Human Resource Implications</b>                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What markets should the business compete in?                                        | What expertise is required in these markets? Do existing management and employees have the right experience and skills                                                                                                               |
| Where the business should be located to compete optimally?                          | Where do we need our people? How many do we need?                                                                                                                                                                                    |
| How can we achieve improvements in our unit production costs to remain competitive? | How productive is the workforce currently? How does this compare with competitors? What investment in the workforce (e.g. training, recruitment) and their equipment is required to achieve the desired improvement in productivity? |
| How can the business effect cultural change?                                        | What are the current values of the workforce? How can the prevailing culture be influenced/ changed to help implement a change programme?                                                                                            |
| How can the business respond to rapid technological change in its markets?          | What technological skills does the business currently possess? What additional skills are needed to respond to technological change? Can these skills be acquired through training or do they need to be recruited?                  |

An important part of HRM is the **Human Resources Plan**. The purpose of this plan is to analyse the strategic requirements of the business in terms of manpower - and then to find a way of meeting the required demand for labour.

**Human Resource Planning** involves the forecasting of labor demand and supply for a specified time period based on an organisation's operating objectives and strategy. Its benefits include:

- Prevents understaffing and disruptions to operations.
- Prevents overstaffing and the eventual costs of employee layoffs.
- Provides greater efficiency and effectiveness of other HR functions such as:
  - o **Recruiting** – allows lead-time to implement best recruiting methods.
  - o **Selection** – allows attainment of larger applicant pools and optimal selection ratios.
  - o **Training** – allows training programs to be operated at optimal levels.
  - o **Compensation** – helps prevent wage inflation due to “crisis hiring”.

## **9.2 Workforce Planning**

Workforce planning is one of the most important activities in a business.

It starts with analysis of the strategic position of the business. The results of this analysis then feed into a forecast of the required demand for labour by the business and how this is likely to be supplied. The final stage involves the creation and implementation of a human resources plan which aims to deliver the right number of the right people for the business.

### **9.2.1 How Strategy feeds into the Workforce Plan**

The strategic position and needs of the business have the most important influence on workforce planning; for example:

- **Labour environment:** what is happening to the size of the labour force? What key population and employment trends (e.g. the increasing number of women seeking part-time work; increasing numbers of people working on temporary or short-term contracts) affect the ability of the business to recruit staff? What provision needs to be made for employee pensions (particularly in the light of falling stock market values); what employment legislation
- **Business objectives and scope of activities:** what are the objectives of each business unit? What products are to be sold, in which markets; using what kind of distribution?
- **Business location** - where is the business located? How are the various business units, divisions, functions distributed across the various locations? What specialist skills are essential in each location? What are the workforce implications of decisions on business location?
- **Timetables** - to what extent does the strategic needs of the business require short-term changes in the workforce - or can change be achieved over a longer period. For example, are new retailing or distribution locations to be opened in the next 12 months that require staff?

### **9.2.2 Forecasting Workforce Demand**

Putting a good Human Resources plan together requires a business to make a reasonably accurate forecast of workforce size. Key factors to consider in this forecast are:

- Demand for existing and new products
- Business disposals and product closures
- Introduction of new technology (e.g. new production equipment)
- Cost reduction programmes (most usually involve a reduction in staff numbers somewhere within the business)
- Changes to the business organisational structure
- Business acquisitions, joint ventures, strategic partnerships.

### **9.2.3 Forecasting Workforce Supply**

The starting point for estimating supply is the existing workforce: a business should take account of:

- Scheduled changes to the composition of the existing workforce (e.g. promotions; job rotation)
- Normal loss of workforce, e.g. through retirement, "normal" labour turnover
- Potential exceptional factors, e.g. actions of competitors that create problems of staff retention

By comparing the forecast workforce demand and supply - it is possible to compile a forecast of net workforce size. This then needs to be compared with the strategic requirements for the business. The result is the "workforce gap" (which may be a forecast of too few or too many workers). The role of HRM is to close the gap.

## **9.3 HRM - Policies to Close the Workforce Gap**

The key HRM activities to manage the workforce gap comprise:

- Recruitment plans (how many people, where, what type, how)
- Training plans
- Redundancy plans
- Staff Retention Plans

### **9.3.1 What is Recruitment?**

Recruitment is an important part of a business' human resource planning. In all businesses, people are a vital resource - and they need to be managed as such.

The overall aim of the recruitment and selection process is to obtain the number and quality of employees that are required in order for the business to achieve its objectives.

There are three main stages in recruitment:

- **Identify and define** the requirements. This involves the preparation of job descriptions, job specifications and person specifications
- **Attract potential employees** - there are various methods for doing this - which are described in a separate revision note
- **Select and employ** the appropriate people from the job applicants

It is important to appreciate that recruitment is a continuous process - because of:

- Staff departures (e.g. retirements, sackings, resignations)
- Changes in business requirements (e.g. new products, markets, expanded operations)
- Changes in business location (a relocation often triggers the need for substantial recruitment)
- Promotions

Recruitment is becoming more and more important in business. In particular, this reflects the increasing need for a well-motivated and flexible workforce that requires less management supervision.

## **9.4 Human Resource Management Functions**

Let us now take a brief overview of various Human Resource Management Functions

### **9.4.1 Planning**

- **Strategic Human Resource Management** – The process of developing and implementing HR policies and practices that directly support the major objectives and competitive strategy of the organisation.
- **Job Analysis** – The process of obtaining and documenting information about the major responsibilities, duties, and tasks of each job in an organisation, as well as the major types of knowledge, skills, and abilities required to perform the job.
- **Legal Compliance** – The process of developing human resource policies and practices that meet the requirements of laws.

### **9.4.2 Staffing**

- **HR Forecasting** – The process of estimating (i.e., forecasting) labor demand and supply to meet an organisation's operating needs.
- **Employee Recruitment** – The process of assessing the make-up of the labor market and developing methods for contacting and communicating with job applicants in the market.
- **Employee Selection** – The process of assessing the knowledge, skills, and abilities of job applicants in order to make accurate hiring decisions.

### **9.4.3 Development**

- **Career Counselling and Planning** – The process of obtaining relevant information from employees (such as personality traits, aptitudes, values, and job preferences) in order to assist in the planning of careers within an organisation.

- **Training and Development** – The process of enhancing the knowledge and skills of employees in order to increase job performance and organisational effectiveness.

#### 9.4.4 Rewarding Employees

- **Wage and Salary Development** – The process of developing internally and externally equitable wages and salaries for the jobs within an organisation.
- **Employee Benefits** – The process of developing an effective and competitive benefits package in order to maintain employee morale, reduce employee turnover, and attract job applicants.
- **Pay Incentives** – The process of developing and implementing incentive pay plans, such as merit systems, bonuses, profit sharing, etc., to attract and motivate a high performing workforce.

#### 9.4.5 Maintaining Quality of Work Life and Discipline

- **Managing Employee and Labour Relations** – The process of maintaining awareness of employee attitudes, needs, and grievances, and communicating effectively with employees to maintain positive relations and high morale.
- **Safety and Health** – The process of evaluating and maintaining a safe and healthy work environment for employees.
- **Maintaining Employee Rights and Discipline** – The process of maintaining reasonable and statutory employee rights, such as privacy, speech, and security, and providing consistent and fair disciplinary policies to ensure positive relations with employees.

### 9.5 Compensation

Compensation to the human resources has three major components:

- Wage and salary plans.
- Employee benefits.
- Pay incentive plans.

The compensation may be either those that are directly paid or those which are paid indirectly for e.g.

#### 9.5.1 Direct

- Wages
- Salaries
- Commissions, Bonuses, Gain-sharing, Profit Sharing

#### 9.5.2 Indirect

- Pay for Time Not Worked (vacation, sick leave, holidays, etc.)
- Insurance Coverage (medical, dental, life, etc.)
- Income Security (pensions and disability)
- Services (education assistance, child care, recreation, discounts, etc.)

## **9.6 Environmental and Organisational Challenges for HR Managers**

### **9.6.1 Environmental Challenges**

- Rapid change in technology and market competition.
- Workforce diversity – increased minority make-up of workforce.
- Globalisation – organisations competing and building facilities abroad.
- Rise of internet – increase marketing through internet and information search.
- Legislation – continued local, state, and federal legislation in HR domain.
- Evolving work and family roles – dual career households requiring accommodation.
- Skill shortages – low birth rates leading to shortages of workers.

### **9.6.2 Organisational Challenges**

- Attempts to minimise costs, improve quality, and provide product innovations.
- Decentralisation – distributing responsibility/authority to lower levels in company.
- Downsizing - redefining competitive advantage, eliminating some operations.
- Organisational restructuring – eliminating some operations, combining functions, etc.
- Self-managed teams - used to increase quality and increase employee commitment.
- Small businesses – maintain equitable HR policies to prevent loss of employees.
- Organisational culture – managing culture to support diversity and empowerment.
- Technology – implement new technology to increase production and quality.
- Outsourcing – moving work outside the company to reduce costs and overcome labour shortages.

## **9.7 Requirements of a Human Resource Manager**

- **Leadership** – Taking the initiative to find out how line departments could benefit from various HR practices; communicating with line managers to improve HR practices and decisions for their departments.
- **Business Knowledge** – Understanding the mission, goals, and objectives of the company and sub-divisions; understanding the nature of the company's products and services, and operating characteristics. Understanding the organisation's competitive environment and its customers.
- **Strategic Thinking** – Being able to select, design, and integrate HR systems and practices in a manner that supports the organisation's competitive strategy. That is, to customise HR functions such as staffing, training, career development, compensation, and employee relations to “fit” the mission and goals of the company.
- **Process Skills** – Understanding basic management functions such as planning, organising, controlling, and coordinating needed to direct the activities of HR staff and to effectively coordinate with the different line departments within the organisation.

- **HR Expertise (Technologies)** – Understanding the field of human resource management and its primary methods, techniques, and legal requirements in order to design, develop, and implement HR policies and practices that support the organisation's goals and operating characteristics.

## **9.8 Training and Development**

### **9.8.1 Differences between “training” and “development”**

Training – focuses on learning for the current job, the time frame for the training and its use is now (current), the training target is the individual employee, and the goal is to provide current job knowledge and skill.

Development – focuses on broader learning goals for current and future awareness and performance, the target is the work group, department, or whole organisation, the time frame is the long run, and the goal is to prepare employees for future work place demands and changes.

### **9.8.2 Importance of Training in an organisation**

- Technological innovations require changes in job duties, work methods, and skill.
- Changing market conditions requires restructuring of organisations, which change job relationships and responsibilities.
- Workforce diversity is an increasingly important issue for companies.
- There is a continual need for career guidance and development to prevent employee obsolescence.
- Training helps to fulfil employee needs for growth.

### **9.8.3 Purposes of Training**

- **Skills training** – provides knowledge/skills for new employees and helps overcome performance weaknesses for existing employees.
- **Retraining** – maintains employee knowledge/skill as new technology and company strategies shift in response to market competition.
- **Cross-functional training** – instructing workers to perform a wider range of tasks and jobs, which allows (a) more staffing depth, (b) work scheduling flexibility, (c) increased knowledge/skill, (d) greater awareness of operations, (e) career mobility, and (f) job security.
- **Team training** – providing cross-functional training of team members to gain scheduling flexibility and providing managerial training so that teams can be self-managed.
- **Creativity training** – instructing employees how to generate more ideas, to be innovative, and improve problem-solving.
- **Literacy training** – improving job-related reading, arithmetic, and writing skills through both in-house and institutional training programs.
- **Diversity training** – making employees aware of and appreciative of diversity differences, improving communication, and enhancing organisational climate and culture.
- **Customer service training** – attempts to increase awareness of customer needs and provide greater customer satisfaction.

#### **9.8.4 Training Needs Assessment (types of information to be obtained)**

##### **A. Organisational Level**

- Operating plans
- Sales forecasts
- Technology changes
- Productivity analysis
- Organisational strategy changes – such as “restructuring”
- Employee absenteeism, dissatisfaction, and turnover.

##### **B. Job and Task Level**

- Job analysis information
- Task analysis
- List of KSAs
- Technical manuals.

##### **C. Individual Level**

- Test scores from hiring
- Work experiences
- Prior training
- Job performance assessment
- Career interests
- Self-assessment of training program interests.

### **Experience Sharing: Skilling the Next-Gen in Biotech & Pharma space**

*During his final year in college, Mr Mayank Raj Bhardwaj (28), while pursuing his basic technical degree in Biotechnology, saw the dismal condition of his graduated seniors who weren't getting jobs in Biotech*

*Hailing from Uttar Pradesh (UP), he says that all his seniors who graduated in Biotechnology actually didn't have any clear-cut idea about their job profiles or the companies in the sector. Everyone told him: 'Bahar (abroad) bahut scope hai, but kahan pata nahi'.*

*This triggered off something within Mr Bhardwaj. He initially planned to start a career counseling portal specifically for Biotech and Pharma students.*

*But it went on to becoming a start-up offering skill development training programs and providing free career counseling.*

*Two years after graduating, he was armed with a couple of years' experience in a Biotech start-up as a corporate relations manager.*

*It was during his first job at this start-up he was determined to learn all the basic skills needed to build his own start-up in the future.*

*The job offered him extensive learning experience in marketing, operations, financial aspects and overall administration.*

*The young Mr Bhardwaj in 2011 set off on a journey to create his start-up Rapture Biotech, with a vision to offer best-in-class training programs for both academia and corporates in the Biotech and Pharma space. The start-up offers short-term and project training programs for Biotech and Pharma students, while providing skill development trainings for corporate employees.*

*Located in UP, Rapture Biotech's other divisions include Biotechnow and 3S Biosolution. Biotechnow is a centralized platform where any company or institute can offer their training programs. It also publishes its magazine 'Biotechnow' for Biotech career counseling purposes.*

3S Biosolution provides R&D solutions and related services. It supplies, manufactures, and exclusively represents many international brands in India providing bioprocess & R&D solutions, and bioinformatics software for research purposes.

The start-up has tie-ups with 40+ international companies for research products sales in India. Its research team is constantly working on developing cheaper research products.

It also boasts of 100+ tie-ups with major colleges and universities in India.

Similar to other Biotech entrepreneurs, Mr Bhardwaj says that convincing his family about his entrepreneurial decision and arranging for the needed fund to start were two major challenges he faced initially. However, through seed funding and his own personal savings he was able to successfully incorporate his dream start-up.

"The trends are changing nowadays. Venture capitalists (VC) and clients have started accepting and promoting first generation young entrepreneurs. However, VCs fail to understand start-ups' incubation period, and the technical integration of projects," Mr Bhardwaj comments.

The company is expanding its business model through franchise partner program.

It has 2 successful franchises in Agra (UP) and Bhopal (MP). It is also coming up with new franchises in Nepal and Andhra Pradesh (AP). Further, the start-up intends to expand internationally to UAE, Sri Lanka and Bangladesh. It currently has an ambitious target of hitting Rs 10 crore in revenues in the next 2 to 3 years.

To increase its visibility, the start-up has started offering free career counseling programs, workshops in colleges, and an active social media marketing strategy.

From the Government's side, he expects it to enable quick and easy start-up loans, and building Bio-entrepreneurs development centers in the country, and laying emphasis on creating Biotech clusters and Special Economic Zones (SEZs).

"In Western countries, the start-up environment is totally different. They promote entrepreneurship at a very early stage in universities itself," Mr Bhardwaj opines. He says that Personal Genomics, Molecular Diagnostics & Instrumentation are happening areas for start-ups.

Mr Bhardwaj points that Delhi -NCR Region and Pune are the two start-up hubs because of the presence of major Government laboratories and central government offices enabling favorable technical support and acquiring clients.

The entrepreneur highlights patience as the key to be an entrepreneur in the Biotech industry.

"Educational background does play a key role in being a bio-entrepreneur. Candidates from abroad universities or IITs do have advantage, especially when it comes to VC funding part," he states, an admirer of Biocon's CMD Dr Kiran Mazumdar.

Mr Bhardwaj constantly derives motivation by reading success stories of other entrepreneurs. He enjoys playing mobile games as a way to relax and unwind.

"It is better to start now because it is never too early. It is important to self-motivate and believe in oneself. There is no failure in entrepreneurship. It is either a success or a delayed success," Mr Bhardwaj concludes.

#### **Entrepreneurial Mistake to Avoid:**

- Not learning all the sides of a business
- Hiring wrong people
- Having smaller margins

#### **Start-up Myths to Debunk:**

- Entrepreneurs are born, not made
- In Life Sciences, young entrepreneurs can't sustain business for long
- Starting a business is easy

---

## 10. MARKETING STRATEGY

---

***“If you wait until there is another case study in your industry, you will be too late”***  
***-Seth Godin***

The objective of all business enterprises is to satisfy the needs and wants of the society. Marketing is, therefore, a basic function of all business firms. When a salesperson sells washing machines, a doctor treats a patient or a Government asks people to take their children for getting polio drops, each is marketing something to the targets.

Traditionally, small firm owners did not give as much importance to marketing as to other functions such as accountancy, production and selling. Training programmes, enterprise development and the current thrust for competitiveness have now given high priority to promoting marketing awareness among small business owners, and marketing is now assuming its rightful place along with other business functions. Since early 1990s there has been a change in the thinking of businessman from product orientation to consumer orientation.

Modern business concerns lay emphasis on ‘selling satisfaction’ and not merely on selling products. The activities have to be coordinated so as to develop the marketing mix, which provides maximum satisfaction to the customers. That is why marketing research and product planning occupy an important role in marketing. The other important functions of marketing include: buying and assembling, selling, standardisation, packing, storing, transportation, promotion, pricing and risk bearing. Thus, the scope of marketing is very wide and no more restricted to merely selling of products.

### **10.1 What is Marketing?**

Marketing may be narrowly defined as a process by which goods and services are exchanged and the values determined in terms of money prices. That means marketing includes all those activities carried on to transfer the goods from the manufacturers or producers to the consumers.

We shall be learning later in the lesson that marketing is more than a mere physical process of distributing goods and services. It is the process of discovering and translating consumer wants into products and services. It begins with the customer (by finding their needs) and ends with the customer (by satisfying their needs). The scope of marketing can be understood in terms of functions that an entrepreneur has to perform. These include the following:

- **Functions of exchange:** which include buying and assembling and selling?
- **Functions of physical supply:** include transportation, storage and warehousing
- **Functions of facilitation:** Product Planning and Development, Marketing Research, Standardisation, Grading, Packaging, Branding, Sales Promotion, Financing

The components of marketing are:

- **Satisfaction of Customers:** In the modern era, the customer is the focus of the organization. The organization should aim at producing those goods and services, which will lead to satisfaction of customers.

- **Integrated marketing:** The functions of production, finance and marketing should be integrated to satisfy the needs and expectations of customers.
- **Profitable sales volume:** Marketing is successful only when it is capable of maximizing profitable sales and achieves long-run customer satisfaction.

Since marketing is consumer oriented, it has a positive impact on the business firms. It enables the entrepreneurs to improve the quality of their goods and services. Marketing helps in improving the standard of living of the people by offering a wide variety of goods and services with freedom of choice, and by treating the customer as the most important person.

Marketing generates employment both in production and in distribution areas. Since a business firm generates revenue and earns profits by carrying out marketing functions, it will engage in exploiting more and more economic resources of the country to earn more profits.

A large scale business can have its own formal marketing network, media campaigns, and sales force, but a small unit may have to depend totally on personal efforts and resources, making it informal and flexible. Marketing makes or breaks a small enterprise. An enterprise grows, stagnates, or perishes with the success or failure, as the case may be, of marketing. “Nirma” is an appropriate example of the success of small scale enterprise.

## **10.2 Marketing vs. Selling**

The basic difference between marketing and selling lies in the attitude towards business. The selling concept takes an inside-out perspective. It starts with the factory, focuses on the company's existing products, and calls for heavy selling and promoting to produce profitable sales. The marketing concept takes an outside-in perspective. It starts with a well-defined market, focuses on customer needs, coordinates all the activities that will affect customers, and produces profits through creating customer satisfaction.

### **10.2.1 Marketing:** Focuses on Customer's needs.

- Customer enjoys supreme importance.
- Converting customer's needs into product.
- Profits through customer satisfaction.
- Emphasis is given on product planning and development to match products with the market.
- Integrated approach to marketing is practiced.
- The principle of caveat vendor (let the seller beware) is followed.

### **10.2.2 Selling:** Focuses on seller's needs.

- Product enjoys supreme importance.
- Converting product into cash.
- Profits through sales volume.
- Emphasis is placed on sale of products already produced.
- Fragmented approach to selling is practiced.
- The principle of caveat emptor (let the buyer beware) is followed.

### **10.3 Information required for Business and Marketing**

#### **10.3.1 Primary Sources**

- **Customers:** Consumers being the final users of products or services can be an invaluable source of primary data. A representative sample of consumers may be selected and information obtained from them regarding the quality, design, package, price, etc. of the firm's products.
- **Dealers:** The dealers can provide information about the marketing policies of the competitors.
- **Salesman:** Salesmen remain in personal contact with the customers. They can, therefore, supply data to the marketing manager relating to the buying habits and preferences of customers.

#### **10.3.2 Secondary Sources**

- **Press:** Newspapers like the Economic Times and Magazines like Business Today and trade directories regularly publish data about various industries.
- **Government Publications:** Bulletins, periodicals, journals and magazines of different ministries and departments of the Central and State Government.
- **Publications of financial institutions:** Publications of Reserve Bank of India, public financial institutions and commercial banks.
- **Foreign governments and international agencies:** Publications of agencies like the United Nations, the World Bank, the ILO, UNCTAD and the IMF.
- **Publications of trade associations:** Trade associations and Chambers of Commerce collect and publish useful data for the benefit of their members.
- **Private concerns and research institutions:** Business data published by research institutes like National Council of Applied Economic Research, Indian Institute of Foreign Trade, etc.

### **10.4 Recognising Market Segments**

A market consists of large number of individual customers who differ in terms of their needs, preferences and buying capacity. Therefore, it becomes necessary to divide the total market into different segments or homogeneous customer groups. Such division is called market segmentation. They may have uniformity in employment patterns, educational qualifications, economic status, preferences, etc.

Market segmentation enables the entrepreneur to match his marketing efforts to the requirements of the target market. Instead of wasting his efforts in trying to sell to all types of customers, a small scale unit can focus its efforts on the segment most appropriate to its market.

A market can be segmented on the basis of the following variables:

- **Geographic Segmentation:** The characteristics of customers often differ across nations, states, regions cities or neighbourhoods. The entrepreneur can decide to operate in one or a few or all the geographic areas, but pay attention to differences in geographic needs and preferences.
- **Demographic Segmentation:** Variables such as age, sex, family size, income, occupation, education, religion, race and nationality are widely used for market segmentation.

- **Psychological variables:** Personality, life style, social class, etc. can also be used for market segmentation. For example, some products like pens, watches, cosmetics and briefcases are designed differently for common men and status seekers.
- **Behavioural Segmentation:** Buyers are divided into groups on the basis of their knowledge, attitude, use or response to a product.

#### 10.4.1 Marketing Mix

In order to cater to the requirements of identified market segment, an entrepreneur has to develop an appropriate marketing mix. Marketing mix is a systematic and balanced combination of the four inputs which constitute the core of a company's marketing system – the **product**, the **price structure**, the **promotional activities** and the **place** or distribution system". These are popularly known as "Four P's" of marketing. An appropriate combination of these four variables will help to influence demand. The problem facing small firms is that they sometimes do not feel themselves capable of controlling each of the four variables in order to influence the demand.



A brief description of the four elements of marketing mix is as follows:

i) **Product:**

The first element of marketing mix is product. A Product is anything that can be offered to a market for attention, acquisition, use, or consumption that might satisfy a want or need. Products include physical objects, services, events, persons, places, ideas or mixes of these. This element involves decisions concerning product line, quality, design, brand name, label, after sales services, warranties, product range, etc. An appropriate combination of features and benefits by the small firm will provide the product with USP (unique selling proposition). This will enhance the customer loyalty in favour of its products.

Products and services are broadly classified into consumer products and industrial products. Consumer products are bought for final consumption; where as Industrial products are bought by individuals and organisations for further processing or for use in conducting business.

Other ways of classifying products are as follows:

- a. **Convenience products:** These are consumer products that the customer buys very frequently, without much deliberation. They are low priced of low value and are widely available at many outlets. They may be further subdivided as:
  - **Staple Products:** Items like milk, bread, butter etc. which the family consumes regularly. Once in the beginning the decision is programmed and it is usually carried on without change.
  - **Impulse Products:** Purchase of these is unplanned and impulsive. Usually when the consumer is buying other products, he buys these spontaneously for e.g. Magazines, toffees and chocolates. Usually these products are located where they can be easily noticed.
  - **Emergency products:** Purchase of these products is done in an emergency as a result of urgent and compelling needs. Often a consumer pays more for these.

For example while travelling if someone has forgotten his toothbrush or shaving kit; he will buy it at the available price.
- b. **Shopping products:** These are less frequently purchased and the customer carefully checks suitability, quality, price and style. He spends much more time and effort in gathering information and making comparisons. E.g. furniture, clothing and used cars.
- c. **Specialty products:** These are consumer goods with unique characteristics / brand identification for which a significant group of buyers is willing to make a special purchase effort. Eg. Mitsubishi Lancer, Ray ban glasses.
- d. **Unsought products:** These are products that potential buyers do not know exist or do not yet want .For example Life Insurance, a Lawyer's services in contesting a Will.

The above product decisions are very important to ensure the sale of products. A product has both tangible and intangible components. While buying a product, the customer does not merely look for the physical product, but a bundle of satisfaction. Thus the impact that any product has upon a buyer goes well beyond its obvious characteristics. There is a psychological dimension to all customer purchases; what a customer thinks about a product is influenced by far more than the product itself. For example, the buyer of an air conditioner is not purchasing cooling machine only. He looks for attractive colour and design, durability, low noise, quick cooling, etc. These influencing factors must be considered by the small firms to meet the requirements of different kinds of customers.

ii) **Price:**

The second element is the price, which affects the volume of sales. It is one of the most difficult tasks of the marketing manager to fix the right price. The variables that significantly influence the price of a product are: demand of the product, cost, competition and government

regulation. The product mix includes: determination of unit price of the product, pricing policies and strategies, discounts and level of margins, credit policy, terms of delivery, payment, etc. Pricing decisions have direct influence on the sales volume and profits of the firm. Price, therefore, is an important element of the marketing mix. Right price can be determined through pricing research and by adopting test-marketing techniques.

Small firms should think of pricing as a method whereby prices are set with regard to costs, profit targets, competition and the perceived value of products. Because of their simplicity, cost-plus-pricing are attractive to small businesses, though this is not the only mode of pricing utilized by small firms. For example, the profit margin in the cost-plus approach may well be fixed after examining both the nature of the market and the competitor activity within it. It is a mistake for small firms to rely wholly on cost-plus, but very often small firms do that to the detriment of profits and market share.

**Different pricing strategies that are commonly used include:**

- **Market penetration** – charging lower prices for new products to help them enter the market and gain market share quickly.
- **Competitive pricing** – pricing at a slightly lower prices than competitors.
- **Strategic pricing** – emphasising the quality or brand positioning of a product to allow a higher price to be charged.

The pricing policies mainly followed by the small firms are:

- **Competitive pricing:** This method is used when the market is highly competitive and the product is not differentiated significantly from the competitor's products.
- **Skimming-the-cream pricing:** Under this pricing policy, higher prices are charged during the initial stages of the introduction of a new product. The aim is to recover the initial investment quickly. This policy is quite effective when the demand for a product is likely to be more inelastic with respect to price in its early stages; to segment the market into segments that differ in price elasticity of demand and to restrict the demand to a level, which a firm can easily meet.
- **Penetration pricing:** Under this policy, prices are fixed below the competitive level to obtain a larger share of the market. Penetration pricing is likely to be more successful when the product has a highly elastic demand; the production is carried out on a large scale to achieve low cost of production per unit; and there is strong competition in the market.

iii) **Promotion:**

Promotion refers to the various activities undertaken by the enterprise to communicate and promote its products to the target market. The different methods of promoting a product are through advertisement, personal selling, sales promotion and publicity.

iv) **Place or Physical Distribution:**

This is another key marketing mix tool, which stands for the various activities the company undertakes to make the product available to target customers. Place mix or delivery mix is the physical distribution of

products at the right time and at the right place. It refers to finding out the best means of selling, sources of selling (wholesaler, retailers, and agents), inventory control, storage facility, location, warehousing, transportation, etc. This includes decisions about the channels of distribution, which make the product available to target customers at the right time, at the right place and at the right price. By selecting wrong distribution channels or by using the ones it has traditionally used, a small firm could be depriving it of new market opportunities. In a situation where a small firm has only one primary product, the general rise and fall of sales will lead to a rise and fall of the firm, unless the firm learns to consistently adjust its marketing mix to match consumer demand.

A marketing mix must be consistent for any product. Pricing, for example, must be consistent with packaging and perceived product quality. If one of these is not in line with others, then sales might suffer as a consequence. A manager selecting a marketing mix is like a cook or chef preparing meal. Each knows through experience that there is no 'one best way' to mix the ingredients. Different combinations may be used depending upon one's needs and objectives. In the marketing as in cooking, there is no standard formula for a successful combination of ingredients. Marketing mixes vary from company to company and from situation to situation. The right marketing mix is important for any product to have a long life cycle.

### **10.5 Understanding the Product Life Cycle**

Every product passes through four stages in its life namely, introduction, growth, maturity and decline. The concept of Product Life Cycle (PLC) highlights that sooner or later all products die and that if an entrepreneur wishes to sustain its revenues, he must replace the declining products with the new ones. With the product passing through different stages the small scale entrepreneur faces varying challenges, opportunities and problems. Smaller businesses have a good reputation for innovation. Their greatest advantage is the speed at which they can respond to the demands of the market, but only if they understand the market.

Every firm makes sales forecasts during introduction, growth, and maturity stages of the PLC. To achieve the sales target, it formulates promotional, pricing and distribution policies. Thus the concept of PLC facilitates integrated marketing policies relating to product, price, promotion and distribution.

The advantages of forecasting the life cycle of a product to a firm are as follows:

- When the PLC is predictable, the entrepreneur must be cautious in taking advance steps before the decline stage, by adopting product modification, pricing strategies, distinctive style, quality change, etc.
- The firm can prepare an effective product plan by knowing the PLC of a product.
- The entrepreneur can find new uses of the product for the expansion of market during growth stage and for extending the maturity stage.
- The entrepreneur can adopt latest technological changes to improve the product quality, features and design.

### **10.6 Stages in Product Life Cycle**

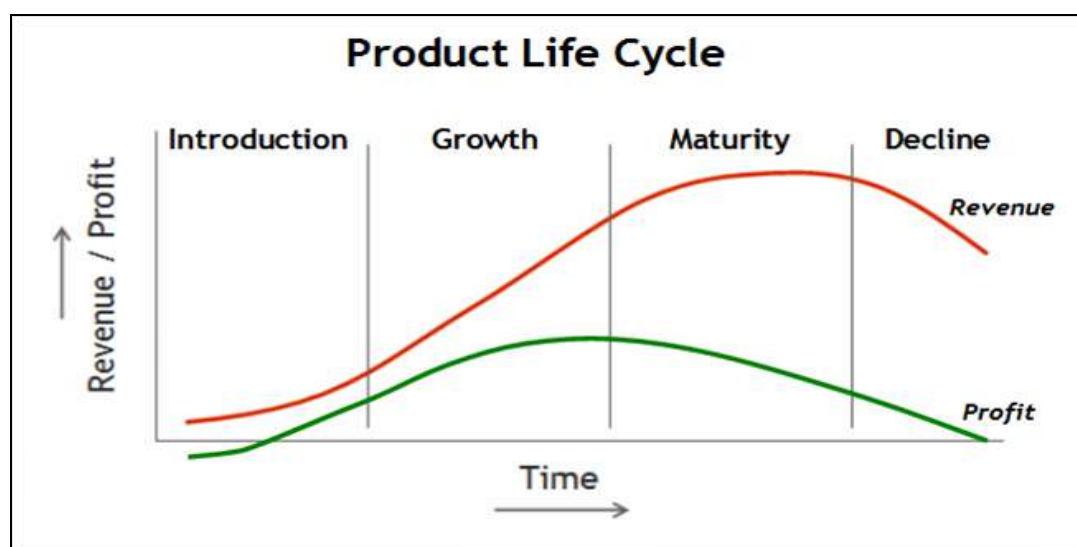
The product moves through the four stages namely, introduction, growth, maturity and decline. As the product moves through different stages of its life cycle, sales volume and profitability change from stage to stage as shown in the figure below.

The entrepreneur's emphasis on the marketing mix elements also undergoes substantial changes from stage to stage. A brief discussion of the marketing strategies in different stages of the PLC is given below.

### 10.6.1 Introduction:

The first stage of a product life cycle is the introduction or pioneering stage. Under this state the fixed costs of marketing and production will be high, competition is almost non-existent, markets are limited and the product is not known much. Prices are relatively high because of small scale of production, technological problems and heavy promotional expenditure. Profits are usually non-existent as heavy expenses are incurred for introducing the product in the market. To introduce the product successfully, the following strategies may be adopted:

- Advertisement and publicity of the product. 'Money back' guarantee may be given to stimulate the people try the product.
- Attractive gift to customers as an 'introductory offer'.
- Attractive discount to dealers.
- Higher price of product to earn more profit during the initial stages.



Stages in Product Life Cycle

### 10.6.2 Growth:

The sales as well as the profits increase rapidly as the product is accepted in the market. The promotional expenses remain high although they tend to fall as a ratio to sales volume. Quite often, smaller firms move into the market during the growth phase.

With their flexibility they can move very quickly and capture a valuable part of the market without the huge investment risks of the development phase. In this stage, the competition increases and distribution is greatly widened. The marketing management focuses its attention on improving the market share by deeper penetration into the existing markets and entry into new markets. Sometimes major improvements also take place in the product during this stage.

The following strategies are followed during the growth stage:

- The product is advertised heavily to stimulate sale.
- New versions of the product are introduced to cater to the requirements of different types of customers.

- The channels of distribution are strengthened so that the product is easily available wherever required.
- Brand image of the product is created through promotional activities.
- Price of the product is competitive.
- There is greater emphasis on customer service.

#### **10.6.3 Maturity:**

The product enters into maturity stage as competition intensifies further and market gets stabilized. There is saturation in the market as there is no possibility of sales growth. The product has been accepted by most of the potential buyers. Profits come down because of stiff competition and marketing expenditures rise. The prices are decreased because of competition and innovations in technology. This stage may last for a longer period as in the case of many products with long-run demand characteristics.

But sooner or later, demand of the product starts declining as new products are introduced in the market. Product differentiation, identification of new segments and product improvement are emphasized during this stage. In order to lengthen the period of maturity stage, the following strategies may be adopted:

- Product may be differentiated from the competitive products and brand image may be emphasized more.
- The warranty period may be extended.
- Reusable packaging may be introduced.
- New markets may be developed.
- New uses of the product may be developed.

#### **10.6.4 Decline:**

This stage is characterized by either the product's gradual displacement by some new products or change in consumer buying behaviour. The sales fall down sharply and the expenditure on promotion has to be cut down drastically. The decline may be rapid with the product soon passing out of market or slow if new uses of the product are found. Profits are much smaller and companies need to assess their investment policies, looking towards investing in newer and more profitable product lines.

As far as possible, attempts should be made to avoid the decline stage. But if it has started, the following strategies may be useful:

- The promotion of the product should be selective. Wasteful advertising should be avoided.
- The product model may be abandoned and all the good features may be retained in the new model of the product.
- Economical packaging should be introduced to revive the product.
- The manufacturer may seek merger with a strong firm.

### **10.7 Branding as a Concept**

A brand is "a name, term, sign, symbol, or design or a combination of them which is intended to identify the goods or services of one seller or group of sellers and to differentiate them from those of the competitors." A brand has three components –

- **Brand name**

A brand name is "that part of a brand which can be vocalized i.e. can be spoken. It is like naming a newborn child. Mercedes, Woodland, Asian Paints, Pepsi, Maggie, Uncle Chips etc. are few examples of the brand names.

- **Brand mark**  
A brand mark is that part of a brand which can be recognized but cannot be vocalized i.e. is non-utterable. It appears in the form of a symbol, design or distinct colour scheme. For example: 'Girl' of Amul, 'Maharaja' of Air India, 'Ronald' of McDonald etc.
- **Trade mark**  
A brand or part of a brand that is given legal protection against its use by other firms is called a trade mark. Thus, a trade mark is essentially a legal term, protecting the seller's exclusive right to use the brand name/mark.

### **10.8 Marketing Limitations for Startups**

All types of business enterprises face marketing problems, but these problems are more severe in case of small scale units because of lack of knowledge, adequate funds and lack of experience. Some of the marketing problems commonly faced by the small scale entrepreneurs in India are:

- **Competition from large scale sector:** Because of scarcity of resources, small entrepreneurs usually use inferior technology. As a result their products are not standardized. The obsolete technology used by them gets translated into inferior quality of products.
- **Lack of marketing knowledge:** Most of the small scale entrepreneurs are not highly educated or professionally qualified to have knowledge of marketing concept and strategy. Their lack of expertise further inhibits their understanding of the prevailing trends in the market.
- **Lack of sales promotion:** Small units lack the resources and knowledge for effective sales promotion. Large scale units mostly have well-known branded names. They also have huge amount of resources to spend on advertisement and other sales promotion tools. Small scale units, on the other hand, have to pay a heavy commission to dealers for their selling efforts, which reduce profits margins.
- **Weak bargaining power:** At the time of purchase of inputs, large scale entrepreneurs manage to get huge discounts and credit. Such facilities are not available to small units.
- **Product quality:** It is costly and difficult for a small unit to have quality testing and evaluating equipment.
- **Credit sales:** The small scale enterprise is invariably called upon to sell on credit. However, when it comes to purchasing inputs, they are denied liberal credit facilities. As a result, they have to borrow excessive working capital than actually needed. This increases the general cost of production and prices, making it non-competitive.

## **Experience Sharing: Forging ahead with perseverance**

Hailing from a Marwari family, Mr Pawan Samdani was always around business-driven people, and was immersed right into the business culture starting from his early childhood. While in school, he always dreamt of being an entrepreneur someday. During his first year in college, he sensed that internet-based businesses would be the future. He started learning web development and created websites. In the third-year of his college, he started developing SaaS products as 'Cloud' seemed to be the buzz at that time.

But it was an internship at the world's largest vaccine maker, Serum Institute, where it dawned on him that his enterprise would be biotechnology-oriented as he was greatly motivated by Serum's work.

"I decided not to sit for placements and started my company right away," recalls Mr Pawan, the 25-year-old founder of Eumentis Informatics, a biotech analytics and consulting start-up incorporated in 2014. Eumentis is a data analytics start-up providing analytics service and develop data-driven products in the field of Biotechnology, Life Sciences and Agriculture. Mr Pawan is from IIT-Delhi, holding both his Bachelor's and Master's degree in Biochemical Engineering and Biotechnology. So far he has self-funded the company with an investment of Rs 3 lakh, and has received support from Venture Center, Pune. After his degree, he was carrying out his research work at IIT-Delhi, and at International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi. Both he and his batch-mate, Mr Krishna Choudhary, discussed about starting their own data analytics company. Simultaneously, the duo was also applying for their respective PhD programs.

Mr Pawan targeted Swiss Federal Institute of Technology (Eidgenössische Technische Hochschule Zürich, ETHZ), European Molecular Biology Laboratory (EMBL), and Sanger Institute, but was rejected in all the three places. However, Mr Krishna was offered a place for his PhD at the University of California Davis, USA. He went to pursue the program. Mr Pawan decided to stick to his decision in starting a bioinformatics company. Before establishing Eumentis, Mr Pawan spent a lot of time gathering information about the need for bioinformatics in Indian research, and then planned the services accordingly. He also wasted no time in looking out for clients right away, alongside acquiring data analytics skills. Currently, the company provides all types of bioinformatics services in genomics, proteomics, transcriptomics and systems biology. It also specializes in Next-Generation Sequencing (NGS) and its analytics, and consult researchers and companies on utilizing NGS in their research.

Eumentis is developing a diagnostic test for Tuberculosis (TB) which can determine drug resistance to most of the antibiotics using NGS. Later on, it intends to develop tools surrounding clinical applications of NGS. It is looking out for partnerships with biomedical device manufacturing companies to develop the device for its TB diagnostic tool.

The company is also working on big data technologies like Apache Spark to carry out large-scale and real-time analytics in healthcare (healthcare IoT data, EMR data, and hospital data).

"People generally use very well-defined and straightforward bioinformatics pipelines for all types of analysis. This is not a good practice. We create very specialized pipeline for each project that we get," points Mr Pawan. According to him, the major challenge was to explore the bioinformatics outsourcing scene in India.

"I found that," he explains, "very few people accepted the fact that they do not have necessary bioinformatics facility or skills to carry out modern day research.

Also researchers are skeptical in outsourcing their bioinformatics work, and are hesitant to even talk about it. Thus, convincing people the need for bioinformatics outsourcing has been a major challenge." At the moment, the company provides bioinformatics services to research institutes. It also intends to continue and expand its clientele, and also cater to biotech companies that need bioinformatics work. "In the future we would like to work with all the big healthcare companies and develop big data analytics tools for them," Mr Pawan adds.

Funding for tool development wasn't a cakewalk for Eumentis. "Twice we applied for BIG grant, and once for the GC-TBC grant for our TB diagnostics using NGS. We got rejected all the three times. We are planning to develop the tool on our own by bootstrapping," he reveals.

As it forges ahead, Eumentis will strategize on concentrating more on developing big data analytics products for the healthcare and medical industry, and use the machine-learning algorithms to build tools to provide intelligent insights; and also develop NGS-based novel diagnostic and prognostic tests. In a year or two, the company plans to reach revenues to fund the development of its analytics products. "We would definitely expand our work to the US first, and then enter the European markets," highlights Mr Pawan. According to him, the best way to begin a start-up is to develop a kick-ass product which will automatically draw mass attention.

"For our service-based business, our main source is word-of-mouth publicity. We also use LinkedIn and other social media to promote our business. Getting published in the print media is also good for start-up visibility," he expresses.

He feels that the Government should start more enterprises like the Biotechnology Industry Research Assistance Council (BIRAC) that help start-ups with funding, and also open incubators for Life Science start-ups at nominal charges.

"I suppose getting funds for a company in the West is relatively easier and quicker than in India. They have a very old start-up culture because of the Silicon Valley revolution," says Mr Pawan, for whom Steve Jobs has been the biggest role model and influencer. The Tatas, Elon Musk and Rahul Yadav also occupy a certain influential position in his life.

Mr Pawan optimistically says that Next-Generation Sequencing is the future.

"It is highly booming, and soon it will be used for all kinds of clinical applications. In the future, genome sequencing will become a norm, and the insights obtained from it would be extensively used in preventive healthcare. It is a great tool for R&D. Its adaptation into mainstream research in life sciences would be extremely beneficial for our country," he predicts.

He also adds that Life Science data management and analytics, IoT for healthcare monitoring, gene editing, Electronic Health Records (EHR), lab-on-a-chip diagnostics, as some of the areas where new start-ups can venture into. Immediate returns is almost impossible in Life Sciences, he tells, when asked about how he explains to investors who anticipate immediate returns.

"I would probably give the examples of all the big biotech companies in India and around the world, and the time it took for them to become successful. As it deals with lives, the product should undergo extensive testing, and the R&D is very complicated and takes a lot of time," he stresses.

Mr Pawan also remarks that Pune is an emerging start-up hub in India.

"The work being done by Venture Center in Pune is really helping start-ups. They provide a very nurturing environment and provide excellent guidance to start-ups. They have also created a list of biotech startups in Pune, and constantly conduct important workshops and seminars for entrepreneurs. A new biotech park was recently opened in Hinjewadi in Pune which is great place for biotech start-ups," he appreciates.

He thinks that the most important qualities in being an entrepreneur in the Life Sciences industry are excellent technical knowledge and perseverance.

"The life cycle of life sciences companies is much longer and it is currently difficult in India to

get the funding easily when compared to e-commerce start-ups. A lot of time goes into research, which is a vital part for any life sciences company. Having a degree from a good college or university is always beneficial to begin start-ups. Also one can find very good co-founders in those places. Having a good degree and team helps a long way in securing funding," he notes.

He reveals that the top ways to raise start-up cash are through angel funding, grants from government or foundations like Bill and Melinda Gates Foundation, B-Plan competitions, incubators or accelerators and bank loans.

Speaking about unusual ways of funding start-ups, he comments, "Bootstrapping, crowdsourcing or crowdfunding, and money from friends and family are other ways. We at Eumentis are currently pursuing bootstrapping to run the company. I believe that in the long run, it is the best way to build a long-lasting brand," Mr Pawan opines.

Should a start-up join an incubator or accelerator, or just simply begin on its own?

"For me it is to grow on its own," he says.

"Accelerators are kind of a shortcut that people take to earn money quickly and this makes it impossible to run a sustainable business. When you grow your business, your process foundation built from years of trial and error, becomes rock solid. For me, business is not about earning loads of money. It is about creating value and an entity that is sustainable." Mr Pawan, an entrepreneur, enjoys traveling, hiking, and trekking. He is also an avid nature lover who loves to cook and has varied interests including spirituality, philosophy, psychology, and hardware, and believes in constantly learning something new. To his credit, so far, he has learnt 10 different programming languages.

He says he would have gotten a PhD and carried out research all his life had he not been an entrepreneur.

As an important piece of advice to budding entrepreneurs, he mentions, "The most important lesson is to never look at peers who earn a lot more money. This depresses and forces one to take unnecessary steps just to earn money in short-term and makes lose focus in the longer run. Secondly, save as much money as possible and avoid spending too much money on hiring or getting unnecessary services. Never start a company with the aim of making tons of money, and never compromise on customer service or quality."

---

## 11. STRATEGIES FOR PARTNERING & COLLABORATION

---

### 11.1 *Strategic Issues Facing Biotech Start-ups*

The type of technology a company has influences the choice of business model, since the technology bears on the need for specialised assets, such as manufacturing and distribution that may or may not be readily available, and on the ease of transferring knowledge about the technology to collaborators, licensees or acquirers. Some technologies are readily written down in standard operating procedures or lab reports, whilst others may be more art than science and their implementation may require extensive personal expertise. However, technology type is not the only factor driving a firm's choices.

The hard reality is that drug development is an expensive process and access to capital is a massive constraint. The high costs are largely driven by the high quality standards inherent in clinical trials and manufacturing in order to pass stringent regulatory hurdles that stand between our innovations and commercialising a product. And for the most part, we need access to assets that are outside of our companies – such as clinical and regulatory capabilities, manufacturing, sales and marketing infrastructure and the like. Financial constraint often impairs our ability to build these assets internally, some of which may be needed to deal with regulatory burden.

The environment is tough. How do biotechs choose the best strategy? Which business models work best? There are no easy answers or good data to help make these decisions. The knowledge and data are simply not available because the biotechnology sector is too early in its life cycle to provide stable patterns of performance. Even the early successful biotechs have significant differences in strategies – Amgen commercialised a few blockbuster drugs, Genentech focused on smaller markets (e.g. specific cancer therapeutics) and Genzyme focused on very rare diseases.

Firstly, companies often endeavour to progress as far along the value chain as possible – capital and capabilities permitting. Certainly this is the trend that has emerged in the wake of the platform company era. There is a strong tendency for start-ups to plug in to the value chain at the point where they either run out of capital or they require complementary assets (such as sales and distribution) that they cannot easily access.

That is to say, biotech start-ups often enter into a partnering transaction when they can no longer raise enough capital to continue along the value chain independently or when they reach some kind of obstacle that they do not have the skills or resources internally to overcome.

Secondly, it is not uncommon for companies to pursue therapeutic indications where there are lower regulatory barriers, such as orphan diseases or acute uses for a drug rather than chronic, thus lowering cost and risk. Many companies focus on reformulations of existing drugs to minimise cost and risk.

Thirdly, in the absence of sufficient capital to bring their innovations to market, biotech companies pursue a number of supporting strategies:

- Leveraging strategies
- Survival strategies
- Alliances
- Strategies for building credibility.

#### **11.1.1 Leveraging Strategies**

Most add value to, or to de-risk, more than one asset, and also to use assets in more than one way to avoid cash constraints. For example, preclinical and phase 1 safety data may be applicable to more than one product based on a single molecule or technology. Similarly, proof-of-concept in a first indication may strongly suggest that proof of concept will be likely in other indications. Companies typically have a pipeline of projects that they intend to develop, and leveraging strategies are used to ensure that money spent enhances the value of several projects.

#### **11.1.2 Survival strategies**

Survival strategies are often tangential. Examples include the provision of contract research or contract manufacturing services to third parties in order to generate surplus cash flow. Survival strategies are aimed at ensuring that the company lives until it earns a return on its core business. Sacrificing the first-born project through an early stage deal provides cash flow that will improve the firm's chances of survival. Sometimes survival strategies are incorporated up-front as part of a business plan, whilst other times they are developed in response to financial pressure.

#### **11.1.3 Alliances**

Alliances are key for pursuing development and commercialisation in the face of capital constraint. Alliances can provide cash-strapped start-ups with access to complementary assets that they cannot afford to develop in house. Furthermore, alliances often provide the third-party validation and credibility, which may support further raising of capital.

#### **11.1.4 Strategies for building credibility**

Credibility for biotech start-ups may come from several sources – the reputation of the team, the science, or key investors and alliance partners. Biotechs can pursue credibility by ensuring that their scientists participate in conferences and by publishing in peer reviewed journals. Firms can also win credibility through cornerstone investors such as large pharmaceutical or biotech companies and respected venture capital firms.

The key strategic issues (capital constraint, regulatory burden and the need for complementary assets and credibility) faced by biotech firms are inter-related. Combine those with project-specific factors, such as market opportunity and competition, and the decisions about 'what', 'when', and 'how' to plug into the biotech and pharmaceutical value chain are shaped.

## **11.2 Points to consider before Partnering & Collaboration**

- **Engage in Business Development from day 1**

Yes, that's Business Development with a capital B and a capital D because it's that important! Their first task would be to get a clear understanding of what big pharma and big specialty pharma companies want ... on the premise that if we build what they want, they'll buy it. It's also important to understand what potential partners would like to see in terms of data before they would commit to a deal. This is essential before designing costly clinical trials.

The BD team should be staying close to the field – including competitors and target partners – building relationships that will help the company remain fully informed while validating product concepts that will smooth the partnering process further down the track.

- **Focus on Commercial Proof of Concept instead of science**

It's important to understand physician and patient needs, the competitive landscape, reimbursement, manufacturability of the product, patent risk etc. Will the product be commercially viable? I've actually seen a company in-license a product that cannot be manufactured at a price below what it would be reimbursed for. It's not uncommon for biotech start-ups to value their development stage assets by discounting cash flows from future revenue streams and then deducting the development costs.

However, if they don't apply standard industry risk factors for the stage of development of the asset then they are going to greatly overestimate the return that they are expecting to get from licensing or selling the asset. For sure, big pharma will not be so generous in their evaluations!

- **Establish Credibility with potential partners early**

How? By publishing science in reputable journals – but of course only after the patents are locked down; by ensuring that we communicate our mission widely to all stakeholders; and by building an experienced medical team and engaging with key opinion leaders. If we inspire the best in the field, there's a high chance that they will be the same that potential partners turn to get opinions on our technology. And most importantly by delivering on our promises - doing what we say we are going to do, and on time.

---

## 12. NEGOTIATION SKILLS

---

***“Negotiation is not a policy. It's a technique. It's something you use when it's to your advantage, and something that you don't use when it's not to your advantage”***  
***–John Bolton***

### 12.1 Do you have what it takes to be a Successful Negotiator?

During negotiations the negotiator will be looking for certain return, exit strategies and other conditions based on how he or she values the potential of your opportunity. At the same time, you'll be looking for certain terms and conditions that you need to maintain control of your business.

Because you and the opposer will have different points of view, skirmishes are likely to occur during negotiations. But if you deal effectively with these differences you can influence the results of the negotiation to get what you want and reach an agreement that's mutually beneficial to you and the opposer. There are a number of outcomes that could occur as a result of negotiations. Depending on how you address the negotiations, you will reach one of the following outcomes.

- **Win-Win:** Both parties achieve their goals and are satisfied with the outcome. For example, both you and the opposer are happy with the terms of the negotiation contract.
- **Win-Lose:** One party achieves the goal at the expense of the other party. For example, the opposer is happy with the terms of the contract, but you believe the opposer will have too much control of your business.
- **Lose-Lose:** Both parties are dissatisfied with the terms of the negotiated contract. For example, you feel that the opposer is demanding too high a return, and the opposer feels that your valuation of your goodwill is exaggerated. The two of you cannot agree on these points, but they are the only items that are preventing you from signing the deal, so you leave them in and close the deal.

As you want to build a long, prosperous relationship with the opposer, you should aim for a win-win agreement so that both parties feel that their needs have been met.

### 12.2 Become a Better Negotiator

The essence of negotiation is dealing with differences between two or more parties. The final result of any negotiation must be an agreement. This can be a mutually beneficial solution, an agreement to disagree or something in between. Both parties must deal with the differences at hand; these differences must be communicated with understanding of the other's points of view and with a logical, open-minded approach to conflict resolution.

Typically a successful negotiator is a strong communicator. It's someone who's willing to do whatever it takes to build a positive business relationship. It's someone who's prepared to make compromises to achieve a larger, more creative and mutually agreeable goal. To be a good negotiator:

### **12.2.1 Focus on Building a Healthy Business Relationship**

Focusing on a positive healthy business relationship helps you work toward a win-win agreement. By knowing that you're in it for the long haul, you may want to be more flexible, open and understanding. You should listen more effectively, seek to understand the opposer's viewpoints and adopt approaches that are conducive to a win-win agreement.

Consider adopting some of the following approaches:

- Use positive negotiation tactics.
- Clarify expectations.
- Separate people from the issues.
- Be Flexible and Creative
- Focus on interests.
- Create solutions that are beneficial to both.

### **12.2.2 Communicate Effectively**

Communication is probably one of the most important elements of the negotiation process. It helps you build trust, ease tension and understand the opposer.

Here are some useful tips that will help you communicate better.

- Encourage dialogue.
- Use your voice effectively.
- Deal with non-verbals.
- Listen effectively.
- Get your point across in writing.

Sometimes you need to put yourself in the other person's shoes. By trying to see things from the other's perspective, you'll gain an awareness of what issues are important to the other person and why.

### **12.2.3 Handle Conflict Effectively**

Conflict will inevitably be part of the negotiation process as you and the opposer have different points of view, goals and interests. To reach a win-win agreement, you need to address conflict in a constructive way.

Being patient, handling stress and controlling your emotions are essential to successful negotiations. You should have a high tolerance for frustration and take whatever time is necessary to reach an agreement. Long negotiations, tedious processes, conflict and unexpected events will increase your stress level. Keep your emotions under control. It's healthy to express how you feel, but don't let your emotions cloud your judgment or negatively affect your business relationship with the opposer.

### **12.2.4 Be Flexible and Creative**

You should seek creative alternatives that benefit both the opposer and you. If you reach a roadblock, think "what else?" and you may be able to unleash previously unexplored possibilities. Be flexible; don't reject the opposer's alternatives too quickly. Avoid the desire to get everything and never give in. Admit that you don't know something or that you were wrong.

More specifically, the opposer's response to your investment proposal and your response to the term sheet are the first negotiation step. Use the term sheet as a guide, not a step-by-step list over which to haggle.

### **12.2.5 Understand Power and Use It Effectively**

Even though you might perceive opposer's as powerful because they control the financing, you also have power. Power can come from a variety of sources, such as:

- having a second-best option if you can't reach a deal with the opposer;
- seeking to establish a two-way communication;
- respecting the opposer;
- probing for the reasons behind the opposer's position;
- looking for alternatives that benefit you both; and
- using an agreed upon method for assessing the value of the investment proposal's elements.

Don't place too much emphasis on only one or two of those sources of power. You should strive to have a good balance of each.

### **12.2.6 Disclose Information Effectively**

When and how information is disclosed can make a difference in the results of a negotiation. Essentially there are two main approaches to disclosing information.

- ***Blurting It All out Reduces Your Credibility***  
The first approach consists of telling everything without any interaction or pauses. The fact that you're providing so much information when the opposer spent little effort asking for it might seem suspicious and reduce the credibility of your information.
- ***Disclosing Bit by Bit Increases Your Credibility***  
The second approach involves more interaction with the opposer. In fact, you disclose information a few bits at a time. Because opposer's sense that they control the flow of the information, they may be more confident about the reliability of the information. Disclosure should be a two-way, not a one-way, process. Be open to pauses in the conversation or silences.

### **12.2.7 Approach Negotiations Logically**

Every issue needs to be discussed. There are two basic approaches you may choose to take.

The first approach consists of addressing the easy points first to build momentum. It's usually easier to start the negotiations by reaching an agreement on minor issues.

The second approach consists of going over issues that are more important to both parties and then using minor issues to sweeten the deal. If you decide to use this approach, be aware of the way you present the issues on which you strongly disagree. In this case it may be appropriate to start by going over past meetings, conversations, resolutions and submitted documents. This would serve to bring the proceedings up to the present. It would also enable you and the opposer to explain the situation with your respective perspectives and express how you feel about them.

### **12.2.8 Use Conflict to Your Advantage**

Conflict that isn't handled effectively is one of the biggest deal breakers within the investment process. During negotiations, parties have different facts (e.g. one party is holding back information from the other), different goals (e.g. both parties seek competing outcomes for exit strategies) or even different values (the oppose wants more control of the business than the entrepreneur is willing to give up). This combination often results in conflict.

Conflict is an essential, healthy part of the investment process. You can prepare for it and use it to your advantage to prove your ability as a competent businessperson and to ensure that the opposer is someone you want as a partner.

- ***Resolving Conflict Can Make You Look Good***

Some conflict will be dealt with quickly and easily. By solving problems during negotiations, you'll have proved your creativity and communication skills, as well as your ability to develop mutually agreeable business relationships. The opposer should be impressed with the application of your management capabilities.

- ***Inability to Resolve Conflict Can Be a Valuable Lesson***

Some conflict will result in irreconcilable differences between you and the opposer. It may not be obvious, but this scenario is critical to your getting the best deal possible. Let's say you hit a brick wall with your opposer during negotiations. You both strongly disagree with each other and, based on what you've just experienced with this particular opposer, you decide that you can never form a positive working relationship. In this case, the presence of conflict has highlighted your mutual incompatibility before you are business partners. It might be time to walk away from the table. It's better to find out these facts before you both sign a legally binding agreement.

- ***Other Positive Outcomes***

The word conflict stirs up images of people embroiled in an argument with tensions running high. Conflict makes us uncomfortable, and often we shy away from a conflict to avoid exposure to certain negative behaviours like anger and stress. By dealing effectively with conflict, some positive results can occur.

- o Different points of view are expressed, increasing the likelihood of reaching a high-quality decision. This is important because weaker alternatives will be discussed and rejected for valid reasons.
- o Problem-solving skills can be enhanced. The participants are encouraged to explore various alternatives.
- o Critical issues are discussed that might not have been. If everyone agrees all the time, then group members start to believe that they can't fail. They don't take the time to evaluate strategies and may make unnecessarily risky decisions.

- ***Understand Conflict Resolution Styles***

Understanding how people deal with conflict may help you see it coming and handle it more effectively. There are several typical styles, but most people rely on one particular style out of habit. Often, too, we may unconsciously react very negatively to another style just because it isn't our own preferred approach.

Be careful about trying to pigeonhole the other person into one style during a negotiation. The way an individual addresses conflict may change based on the situation at hand. And your reactions and behaviour may also influence the other person to adopt a different style.

- ***Examine Your Style and Reactions***

Look over the following styles of handling conflict. Can you identify your own preferred approach? Of the approaches you don't usually take, which ones make you uncomfortable? If an opposer adopts one of those styles, how will you handle your negative reactions? What will you do to exert a positive influence on the situation?

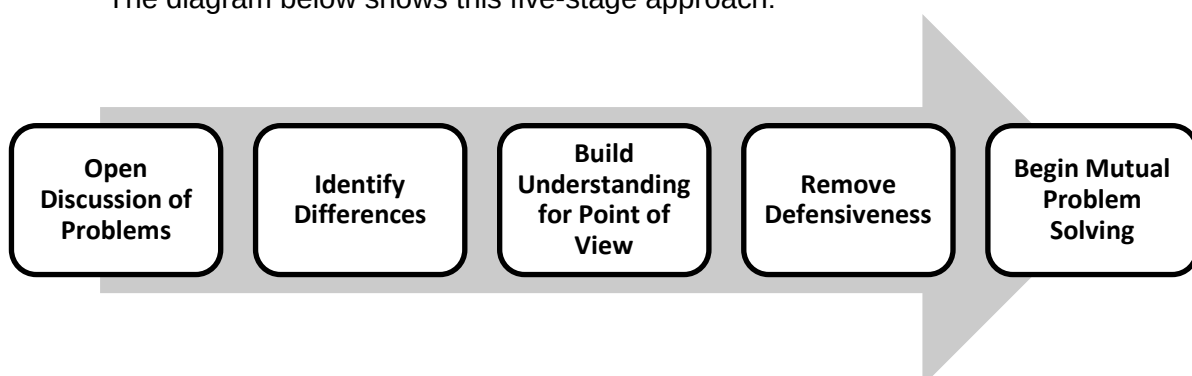
- i) **Avoid** (Run away.) You completely withdraw from the conflict, as if it doesn't exist.
- ii) **Accommodate** (I give up, let's do it your way.) You put aside your goals and basically give in, although inside you are frustrated and angry.
- iii) **Force** (My way or the highway.) You force your point until the other party eventually gives up.
- iv) **Compromise** (Meet you in the middle.) You give up something and so does the opposer, but neither of you is totally satisfied.
- v) **Collaborate** (Let's do it together.) You and the opposer work together to find a solution that satisfies both of you.

- ***Use a Structured Approach***

A structured approach to conflict resolution can help you reach a win-win agreement in your negotiations. The following approach is simple, easy to follow and logical. You should apply it during negotiations when the situation arises. It will instill confidence in the opposer that you are a businessperson committed to building collaborative solutions.

Like any approach, the following one is designed to be a guideline. Adapt it as you see fit. Apply it not only during negotiations but also in your daily operations.

The diagram below shows this five-stage approach:



**The Five-Stage Approach**

**A) Open Discussion of Problems**

During this stage, both parties should feel free to express any concerns that they have, without fear of being ridiculed or judged. You can't expect to deal with your concerns if you don't discuss them, regardless of relative importance. Communicate fully. This approach can be a long process.

Remember that you're setting the tone for any future meetings or transactions, so you want to establish an environment of openness and honesty. This will also facilitate trust building with the opposer.

### **B) Identify Differences**

Imagine if a deal fell through because you and the opposer thought you had incompatible goals but, in reality, you didn't. That's why it's so important to separate real from perceived differences in opinion. Be prepared to explain the rationale behind your demands so that you and the opposer can determine if you have different interests (a true conflict) or just different ways of getting to the same result (perceived conflict).

Conflict arises from a difference in opinion or values. The cornerstone of dealing with conflict is understanding the gaps between your desires and those of the opposer. You need to do this before you can bridge these gaps.

### **C) Build Understanding for Point of View**

You need to gain an understanding of the opposer's needs and ensure the opposer understands your point of view. Conflict resolution techniques that focus on positive outcomes of conflict may help you approach the issue from a more workable angle. Here are some intervention techniques that you can use.

- **Use open body language.** (Maintain eye contact, nod in agreement.) Physically show your willingness to be reasonable and open to discussion. Whether you're listening or speaking, you're still communicating silently with the opposer through your body language. Your audience responds more to what your body is *doing* than to what you are *saying* so try to synchronise your actions with your words. Together they can transmit your message much more clearly than each one can individually.
- **Try to understand the other person's point of view.** Listen to the opposer without trying to think of what you'll say next. Focus on the opposer, giving your full attention.
- **Acknowledge that the opposer has a point of view.** Do this even if you disagree with it.
- **Initially focus on points where you and the opposer agree.** That way you won't waste time discussing those points. Tell the opposer which points you agree with and why. Ask the opposer to repeat the process for you.

### **D) Reduce Defensiveness**

When someone triggers one of our emotional "hot buttons", our instinctive response is to defend ourselves by counterattacking. When we're defensive, it's difficult to see the situation objectively - our logic is clouded by our emotions. This can create a vicious cycle of increasingly hostile exchanges with one party trying to outdo the other.

Defensiveness can be detrimental to the relationship because the focus switches from common goals to individual interests. There are several ways you can break the cycle of defensiveness.

*Disengage* - Back off for a bit.

*Empathize* - Express an understanding for the other side's view.

*Inquire*- Ask questions focusing on the situation, not on the people involved.

*Disclose* - Use "I" statements to tell the other party how you interpret things.

*Depersonalize* - Separate your identity from your tasks/work.

When challenged during negotiations, you'll probably feel personally attacked. Many of the issues causing a difference of opinion were based on your earlier business decisions; the same ones that you thought were brilliant at the time. Don't take things personally. Minimise your defensiveness. Ensure that you don't lose your cool, and keep focused on your goal: successfully negotiating an investment deal.

### **E) Begin Mutual Problem Solving**

The binding thread for all the conflict management techniques is trust. If you have a good relationship with the opposer, both of you will want to work toward a mutually beneficial agreement. You'll likely feel more comfortable using some of the strategies mentioned in this Step, like effective listening and open body language, in order to achieve total understanding. Most of this adaptation will be done subconsciously as your relationship with the opposer improves and your communication and business development skills are enhanced.

#### **12.2.9 Capabilities Check**

The negotiation stage is key to the future well-being of your business and to your ongoing relationship with the opposer. Make sure your skills are top-notch in this area, and if you feel uncertain about some of your capabilities, consider retaining an expert to guide and support you during the give and take of negotiations.

#### **Negotiating Capabilities Check**

| <b>Can You...</b>                                                            | <b>Rate Yourself</b> |
|------------------------------------------------------------------------------|----------------------|
| Remain flexible and creative in pressure situations?                         |                      |
| Recognise where your power lies and use it effectively?                      |                      |
| Disclose information selectively to make the most of it?                     |                      |
| Remain logical even though emotions may be running high?                     |                      |
| Handle conflict effectively?                                                 |                      |
| Use a structured approach to prepare for and manage the negotiation process? |                      |
| Use your understanding of conflict styles positively?                        |                      |
| Communicate effectively?                                                     |                      |

A = Highly Capable B = Need Some Assistance C = Need Expert Help

---

## **13. MANAGING REGULATORY REQUIREMENTS**

---

Biotechnology means collection of technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use such as genetic engineering, cell and tissue culture technologies. There are many applications of biotechnology such as developing various drugs, vaccines and diagnostics, increasing productivity of agriculture, improving energy production and conservation.

Blood biotechnology products and vaccines are the two largest groups of biological manufactured by biotech companies and make up for a large part of biotech pharmaceutical industry. Other products of the kind made by biotechnology companies include hormones, antibody products, larger peptides and a range of group of tissue derived products. At the same time assay systems are generously used by the biotech pharmaceutical industry to develop quality biotech products.

Modern Biotechnology (recombinant DNA technology) is recognized as having great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and healthcare. Biosafety refers to the need to protect the environment including human and animal health from the possible adverse effects of the Genetically Modified Organisms (GMOs) and products thereof derived from the use of modern biotechnology. Biosafety also refers to promoting safe laboratory practices, procedures, proper use of containment equipment and facilities, risk assessment and risk management, evaluation of GMOs etc. Biosafety regulations are to facilitate and regulate use of modern biotechnology work at different stages to achieve the objectives of biosafety.

India's biotechnology regulatory system has experienced a number of changes since the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (Rules, 1989) were first notified under the Environment (Protection) Act, 1986, including the elaboration of a series of guidance documents published by the Department of Biotechnology (DBT) in 1990, 1998 and 1999.

Several countries have also formulated biosafety regulations and guidelines on modern biotechnology for research, production processes, large-scale use of GMOs & products thereof and their release into the environment.

These rules are implemented by Ministry of Environment and Forests (MoEF), Government of India, Department of Biotechnology (DBT), Ministry of Science and Technology and the State Governments through the six competent authorities notified under the Rules which are as follows:

- i. Recombinant DNA Advisory Committee (RDAC)
- ii. Institutional Biosafety Committee (IBSC)
- iii. Review Committee on Genetic Manipulation (RCGM)
- iv. Genetic Engineering Appraisal Committee (GEAC)
- v. State Biotechnology Coordination Committee (SBCC)
- vi. District Level Committee (DLC).

While the RDAC has advisory in function, IBSC, RCGM, and GEAC are involved in regulatory functions. SBCC and DLC are responsible for monitoring the activities related to GMOs in state/district level. RDAC, RCGM and GEAC are constituted at the central level by DBT and MoEF. IBSCs are constituted at all organisations working in the area of GMOs, SBCC in all states and DLCs in districts, wherever necessary. Out of the above, the IBSC is the nodal point for interaction within an organisation for implementation of the biosafety regulatory framework. An IBSC is to be constituted by every organisation engaged in

research, handling and production activities related to GMOs and each IBSC has a nominee appointed by DBT. The role of IBSCs is extremely important as it is a Statutory Committee that operates from premises of respective organisation.

### **13.1 Drugs such as Blood and Blood products, I.V. Fluids, Vaccine and Sera.**

The Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI) is the apex regulatory body under Ministry of Health & Family Welfare (MoHFW), Government of India, which is responsible for the approval of clinical trials as well as new drugs.

Under the Drug and Cosmetics Act 1940, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. The CDSCO is responsible for approval of licenses of specified categories of Drugs such as Blood and Blood products, I.V. Fluids, Vaccine and Sera. Further information is available at –

<http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf>.

### **13.2 Similar Biologics**

The “Guidelines on Similar Biologics” prepared by Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT) lay down the regulatory pathway for a Similar Biologic claiming to be Similar to an already authorized Reference Biologic.

A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability. These guidelines address the regulatory pathway regarding manufacturing process and safety, efficacy and quality aspects for Similar Biologics.

These guidelines also address the pre-market regulatory requirements including comparability exercise for quality, preclinical and clinical studies and post market regulatory requirements for Similar Biologics. These guidelines are for the guidance of all stakeholders and are not meant to substitute or rephrase the Rules made under Drugs and Cosmetics Act, 1940 or any other relevant Acts and are subject to being in conformity with the Drugs and Cosmetics Act and Rules. The Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization In India are available at - <http://dbtbiosafety.nic.in/DBT2016-17/CDSCO-DBT2016.pdf>.

### **13.3 Biopesticides**

Biopesticides are considered to be the best alternative to synthetic pesticides that are highly effective, target specific and reduce environmental risks. These factors led to its application in pest management program instead of chemical pesticides throughout the world. Biopesticides are derived from animals, plants and other natural materials such as fungi, bacteria, algae, viruses, nematodes and protozoa.

In this case the current status of different categories of biopesticides such as microbial pesticides based on microorganisms, botanical pesticides derived from plants, semiochemicals. Biopesticides are governed by the Insecticides Act 1968 and Rules 1971 under the Indian Central Insecticides Board and Registration Committee (CIBRC). The guidelines can be accessed at CIRB website available at <http://www.cibrc.nic.in/guidelines.htm>.

### **13.4 Biofertilizers**

Biofertilizers are best defined as biologically active products or microbial inoculants viz., formulations containing one or more beneficial bacteria or fungal strains in easy to use and economical carrier materials which add, conserve and mobilize crop

nutrients in the soil. In other words, biofertilizer is a substance which contains living microorganisms which when applied to seed, plant surfaces, or soil colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the availability of primary nutrients to the host plant. Biofertilizers are regulated under the Biofertilizers and Organic Fertilizers Covered in Fertilizer (Control) Order, 1985 (Amendment, March 2006 and further amendment November 2009). Further information is available at National Centre of Organic Farming website -

[http://ncof.dacnet.nic.in/Training\\_manuals/Training\\_manuals\\_in\\_English/BF\\_and\\_OF\\_in\\_FCO.pdf](http://ncof.dacnet.nic.in/Training_manuals/Training_manuals_in_English/BF_and_OF_in_FCO.pdf).

### **13.5 Medical Devices**

Medical devices are intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals. The import, manufacture, sale and distribution of medical devices are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945. Further information is available at CDSCO website- [http://www.cdscsco.nic.in/writereaddata/FAQ-IMPORT-&-REGISTRATION-02022013\\_DONEE.pdf](http://www.cdscsco.nic.in/writereaddata/FAQ-IMPORT-&-REGISTRATION-02022013_DONEE.pdf).

### **13.6 In-vitro Diagnostics**

In-Vitro Diagnostic Products are those substances that are intended to be used for or in the use in diagnosis of disease or disorders in human being or animals. IVDs are considered as "Drugs" as defined under sub-clause (i) of clause (b) of Section 3 of Drugs and Cosmetic Act 1940. In-Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945. Further information is available at CDSCO website - <http://cdscsco.nic.in/writereaddata/Final%20FAQS-IVD.pdf>.

### **13.7 Transgenic Plants**

In India, now agricultural scientists are taking keen interest in the transgenic technology for increasing the crop production by incorporating genes responsible for value addition in the end product. Therefore, it becomes a vital component to regulate the flow of the transgenic material in the germplasm exchange process. In this direction, concern is being expressed for biosafety and safe movement of the genetically modified plants. The National Bureau of Plant Genetic Resources (NBPGR) acts as a nodal agency under the Indian Council of Agricultural Research (ICAR), for the purpose of import as well as quarantine processing of transgenic planting material. Accordingly, Department of Biotechnology (DBT) in collaboration with National Bureau of Plant Genetic Resources (NBPGR), has already set some procedures to regulate the import of seeds of transgenic lines from various countries meant for research purpose. Any transgenic material to be imported requires a permission which could be issued by the government after screening by the Review Committee on Genetic Manipulation (RCGM), RCGM examines the desirability of import of transgenic line, from the biosafety point of view under the Environment (Protection) Act, 1986. In accordance with this Act, all transgenic plants are regulated items. Under the PFS order (1989) which governs quarantine regulations, and Plant Quarantine (Regulation of Import into India) Order 2003, which came into force from 2004, NBPGR has been designated as the competent authority to issue import permits for import of seeds by public and private sector agencies for research purpose. The provisions of Plant Quarantine (Regulation of Import into India) Order 2003 are applicable to import of transgenic seeds as well. An importer who wishes to import transgenics after getting permission from RCGM would apply for the issuance of Import Permit to Director, NBPGR, New Delhi. The issuance of import permit of transgenic material is extremely important from the point of view of their potential impact on environment and on agriculture in the country. The guidelines are available at <http://www.moef.nic.in/divisions/csurv/biosafety/Gef2/T5/20%20Dr.%20R%20V%20Singh%20Introduction%20of%20transgenic%20plant%20procedures.pdf>.

---

## 14. FUNDING OPPORTUNITIES AND INCENTIVES

---

***"Investing should be more like watching paint dry or watching grass grow. If you want excitement, take \$800 and go to Las Vegas"***

***- Paul Samuelson***

Business is full of surprises. As an entrepreneur one may face situations that can catch them off guard. Any situation has the potential to become, either a 'disaster' or an 'opportunity'. Whether running a home-based business or a mid-sized venture, the first thing required is money. One cannot imagine a world without money – every day's life and every activity of human being is dependent upon money.

Even, in a bid to minimize losses, it is essential to prepare for the "unexpected" by arranging and protecting the resources. Thus, 'Finance' refers to funds or monetary resources needed by individuals, business houses and the government. The significance of finance in enterprise is elucidated like a lubricant to the process of production. It's one of the most important prerequisite to start an enterprise. Finance is the elixir that assists in the formation of new businesses, and allows businesses to take advantage of opportunities to grow and expand. Right from the very beginning i.e. conceiving an idea; finance is required to:

- Promote or establish the business
- Acquire fixed assets
- Make market investigations
- Develop product
- Keep men and machines at work
- Encourage management to make progress and create value.
- Expand, diversify, improve and grow.
- Be enough to meet unexpected/unplanned business expenses.

'Production', 'Marketing', and 'Financing', deemed as the most important factors for any business survival, rates "Financing" as the first; because nothing can be done without money. Thus, the most critical element for success in business is 'Finance'. Before doing anything, an entrepreneur should clearly answer the following three questions:

- How much money is required?
- Where will money come from?
- When does the money need to be available?

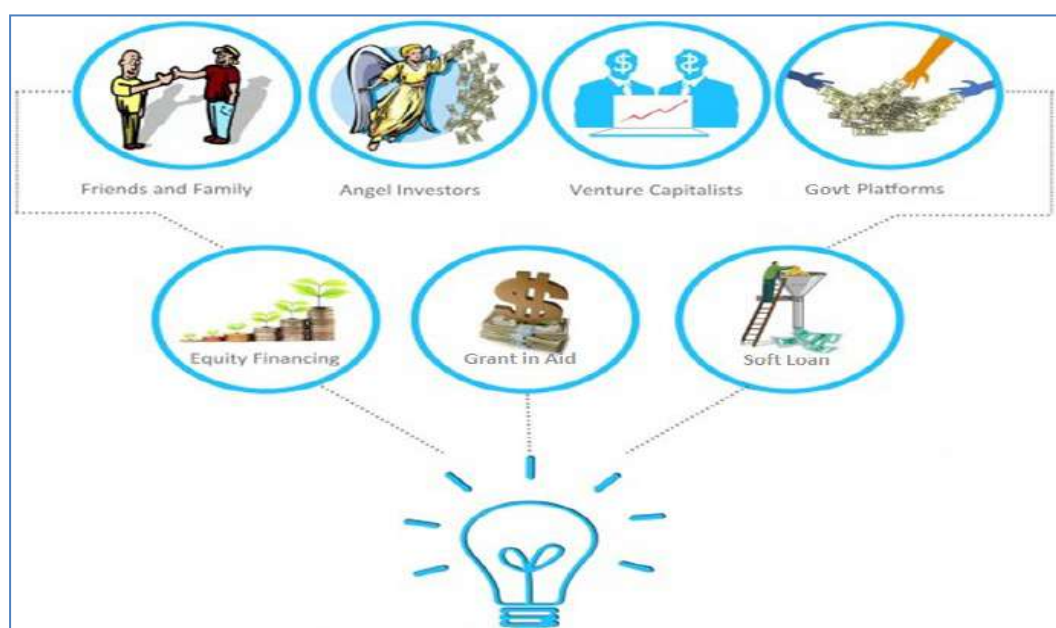
As regards the money needed, it can be estimated by developing a statement of various assets required by the enterprise. Integral to total amount needed is to decide about its arrangement or sources.

### **14.1 Funding Opportunities for Startups**

Biotechnology is a high-growth and high-risk industry. In India, a biotechnology entrepreneur in India is faced with several opportunities and challenges while he sets out to create, develop and commercialize technologies. Apart from identifying the right idea, right markets and being able to recruit the right human resource, the most crucial challenge a bio-entrepreneur faces is raising funds for the new venture. The upfront investment on R&D and clinical trials can be enormous even before initiation of human efficacy trials for regulatory approval. Potential blockbuster market returns are possible, but they usually come with a high front-end investment and a proportionate high risk of R&D.

There are widely known sources of funding such as venture capitalists, angels, banks, and friends and family. The Government, through an array of programs and initiatives, offers funding for technology development, from early-stage development to full-scale commercialization, which the bio-entrepreneurs could take advantage of.

In order to prioritize innovative R&D and promote indigenous technologies through accelerated commercialization, there are government funding sources that have been set-up to specifically support and fund innovative technologies right from idea validation stage to the full-scale commercialization stage. A number of national agencies i.e. Department of Biotechnology (DBT), Department of Science and Technology (DST), Department of Scientific & Industrial Research (DSIR), Council of Scientific & Industrial Research (CSIR), Ministry of Micro Small Medium Enterprises (MSME), National Research Development Corporation (NRDC), Defence Research & Development Organization (DRDO), Technology Information, Forecasting and Assessment Council (TIFAC), etc. have been supporting biotech companies as well as academia in various areas of biotechnology with a view to strengthen innovative R&D and technology development. Several international India-specific Grand Challenges i.e. Wellcome Trust, Bill & Melinda Gates Foundation, Lockheed Martin Corporation, Grand Challenges Canada and bilateral/multi-lateral programmes with other countries also support innovative technology development in India.



With so many funding options out there, raising funds can be a confusing, and somewhat overwhelming, exercise. Further complicating the issue, the type of funding you pursue will depend on the particular needs of your company, your company stage, and the specific milestones you hope to achieve.

That said, knowing the most common funding options gives you the foundation you need to develop your customized fundraising strategy. So here is an overview of the funding options for early-stage startups:

- **Bootstrap**

Okay, this isn't actually "fundraising," but sometimes the best funding option is not to seek funding at all, but rather to cut corners wherever you can and work on building your company from your personal savings. Besides saving you

money, bootstrapping also helps you to focus on execution and build traction without outside interference. It's also a means for avoiding dilution and yielding larger profit margins.

- **Crowdfunding**

Crowdfunding is one of the newer ways of funding a startup that has been gaining lot of popularity lately. It's like taking a loan, pre-order, contribution or investments from more than one person at the same time. The best thing about crowd funding is that it can also generate interest and hence helps in marketing the product alongside financing. It is also a boon if you are not sure if there will be any demand for the product you are working on. This process can cut out professional investors and brokers by putting funding in the hands of common people. It also might attract venture-capital investment down the line if a company has a particularly successful campaign.

This is how crowdfunding works – An entrepreneur will put up a detailed description of his business on a crowdfunding platform. He will mention the goals of his business, plans for making a profit, how much funding he needs and for what reasons, etc. and then consumers can read about the business and give money if they like the idea. Those giving money will make online pledges with the promise of pre-buying the product or giving a donation. Anyone can contribute money toward helping a business that they really believe in.

Also keep in mind that crowdfunding is a competitive place to earn funding, so unless your business is absolutely rock solid and can gain the attention of the average consumers through just a description and some images online, you may not find crowdfunding to work for you in the end.

- **Angel Investment**

Angel investors are individuals with surplus cash and a keen interest to invest in upcoming startups. They also work in groups or networks to collectively screen the proposals before investing. They can also offer mentoring or advice alongside capital. Angel investors have helped to start up many prominent companies, including Google, Yahoo and Alibaba. This alternative form of investing generally occurs in a company's early stages of growth, with investors expecting upto 30% equity. They prefer to take more risks in investment for higher returns.

Angel Investment as a funding option has its shortcomings too. Angel investors invest lesser amounts than venture capitalists

- **Venture Capital**

This is where you make the big bets. Venture capitals are professionally managed funds who invest in companies that have huge potential. They usually invest in a business against equity and exit when there is an IPO or an acquisition. VCs provide expertise, mentorship and acts as a litmus test of where the organisation is going, evaluating the business from the sustainability and scalability point of view.

A venture capital investment may be appropriate for small businesses that are beyond the startup phase and already generating revenues. Fast-growth companies like Flipkart, Uber, etc with an exit strategy already in place can gain up to tens of millions of dollars that can be used to invest, network and grow their company quickly.

However, there are a few downsides to Venture Capitalists as a funding option. VCs have a short leash when it comes to company loyalty and often look to recover their investment within a three- to five-year time window. If you have a product that is taking longer than that to get to market, then venture-capital investors may not be very interested in you. They typically look for larger opportunities that are a little bit more stable, companies having a strong team of people and a good traction. You also have to be flexible with your business and sometimes give up a little bit more control, so if you're not interested in too much mentorship or compromise, this might not be your best option.

- **Bank Loans**

Normally, banks are the first place that entrepreneurs go when thinking about funding.

The bank provides two kinds of financing for businesses. One is working capital loan, and other is funding. Working Capital loan is the loan required to run one complete cycle of revenue generating operations, and the limit is usually decided by hypothecating stocks and debtors. Funding from bank would involve the usual process of sharing the business plan and the valuation details, along with the project report, based on which the loan is sanctioned. Almost every bank in India offers small medium enterprise (SME) finance through various programs.

- **Business Loans from Microfinance Providers**

What do you do when you can't qualify for a bank loan? There is still an option. Microfinance is basically access of financial services to those who would not have access to conventional banking services. It is increasingly becoming popular for those whose requirements are limited and credit ratings not favoured by bank.

- **Friends and Family**

While borrowing from family and friends can be appealing since it's less formal than borrowing from a professional investor, it also holds personal as well as professional risks. If you are going to go this route, make sure you formalize the process and are as transparent as possible about the risks of investment.

- **Government Grants**

The Government of India through its scientific and industrial agencies offers an array of policies, initiatives and incentives for technology development, from early-stage development to full-scale commercialization, for the benefit of the biotechnology entrepreneurs. The Government grants are mostly in the form of grant-in-aid or soft loans.

Some of the key funding schemes of the Government of India beneficial for entrepreneurs are given below –

## **14.2 Schemes of the Department of Biotechnology**

### **14.2.1 Biotechnology Industry Partnership Programme (BIPP)**

The present scheme on Biotechnology Industry Partnership Programme (BIPP) of the Biotechnology Industry Research Assistance Council (BIRAC) is a government partnership with Industries for public support on a cost sharing basis for:

- i. Path-breaking research in frontier futuristic technology areas having major economic potential and making Indian industry globally competitive and focused on IP creation with ownerships by Indian industry and where relevant, collaborating scientists.
- ii. The development of appropriate technologies in the context of recognized national priorities in the area of agriculture, health, bioenergy, green manufacturing, when the scale of the problem has serious consequences for social and economic development.

This is an Advanced Technology Scheme only for high risk, transformational technology/process development. No incremental development will be supported under BIPP.

**BIPP covers four broad categories (I, II, III & IV) as described below:**

**Category I:** Areas with major social relevance but uncertain market driven demand

**Category II:** High risk, discovery innovation research with relevance for making India globally competitive

**Category III A:** Evaluation & validation of already existing products of high national importance promoting local innovation (Clinical Trials)

**Category III B:** Evaluation & validation of already existing products of high national importance promoting local innovation (Agriculture Field Trials)

**Category IV:** Shared cost major facilities, critical for enabling innovation.

#### **Eligibility**

A single or consortia of Indian Company (ies) - Small, Medium or Large having DSIR recognized in-house R&D unit(s). An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and Minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport (Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders) The proposals can be submitted:

- Solely by an Indian Company; or
- Jointly by an Indian Company and National R&D Organizations and Institutions; or
- By a group of Indian Companies along with National Research Organizations etc.

#### **Funding, Cost Sharing & IP Management**

This scheme provides for a BIPP contribution of upto 50% of project cost as Grant- In- Aid and remaining cost is to be met through the company's contribution.

The fund disbursement is milestone based and is released in 5 installments:

- 1st Installment on signing of Contract - 30%
- 2nd Installment on completion of 1st Milestone - 20%

- 3rd Installment on completion of 2nd Milestone - 20%
- 4th Installment on completion of 3rd Milestone - 20%
- 5th Installment on Submission of Report - 10%

#### **14.2.2 Small Business Innovation Research Initiative (SBIRI)**

The scheme implemented by BIRAC is to boost public-private-partnership effort in the country. The distinctive feature of SBIRI is that it supports the high-risk pre-proof-of-concept research and late stage development in small and medium companies lead by innovators with science backgrounds which is unique in nature to support private industries and to get them involved in development of such products and processes which have high societal relevance. It has a direct focus on producing products and has a sense of urgency for producing defined results that only private sector engagement can produce. National consultations will be held after every three to six months to generate ideas in different sectors of biotechnology namely medical, agriculture, food, industry and environment.

##### **Funding Structure**

The SBIRI scheme will operate in two phases viz. for establishment of pre-proof of concepts of innovations and for product and process development. In both the phases, projects will be implemented at the industry site.

##### **SBIRI Phase – I:**

1. If actual project cost is upto Rs. 25 lakhs, 80% of the project cost will be available
2. If actual project cost is between Rs. 25 lakhs and Rs. 100 lakhs, 50% of the project cost will be available
3. If cost is beyond Rs. 100 lakhs, in addition to the Govt. grant of Rs. 50 lakhs, the unit will be eligible for interest free loan upto 50% of the amount (subject to a limit of Rs. 50 lakhs as loan) by which the total project cost exceeds Rs. 100 lakhs.

##### **SBIRI Phase – II:**

1. Soft loan upto Rs. 10 crores for a project as per its requirement.
2. Soft loan upto Rs. 100 lakhs will carry a simple interest of 1% while the interest rate will be 2% (simple interest) on the amount of loan beyond Rs. 100 lakhs.

##### **Eligibility**

1. Solely by an industry; or
2. Jointly by Industry and National R&D Organizations and Institutions: or
3. Collaborative projects of common interest to the concerned sector/area proposed by a group of industries/users, national research organizations etc.

#### **14.2.3 Biotechnology Ignition Grant (BIG)**

The BIG scheme of the BIRAC, Government of India enables technology innovators and entrepreneurs to pursue a promising technology idea, and establish and validate proof of concept (POC) for the idea. By funding establishment and validation of POC, BIRAC wishes to help innovators and entrepreneurs advance an idea closer to eventual commercialization/implementation in the form of technology licenses or creation of start-up companies or raising investments for the company. The scheme aims to support high-risk technology ideas with considerable potential for impact.

**Purpose**

1. To support projects that aim to establish or validate proof of concept for a promising and innovative technology idea.
2. To promote the creation of new start-ups based on innovative technology ideas and/or to support early start-ups to establish and validate their technology ideas up to the POC stage.

**Types of projects supported**

1. Projects that propose a process/ product innovation with significant potential impact or commercial potential
2. BIG funding cannot be used to support PhD student research or any other academic research. BIG grant is not a research fellowship.
3. Technology ideas with no or weak connect with life sciences, biotechnology and bioengineering.

**Financial Support**

1. The funding level is up to Rs 50 lakhs.
2. The fund disbursement is milestone based and is released in 4-5 installments.

**Eligibility**

1. The applicant (individual) has to be physically incubated in an incubator.
2. The Company/LLP must have its own in-house R&D facilities that are functional and adequate to execute the project.
3. Every proposal must clearly identify a Project Leader who will take responsibility for the technical and managerial aspects of the project execution.

**14.2.4 Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH)**

SPARSH is the Social Innovation programme for Products: Affordable & Relevant to Societal Health. The programme is initiated by BIRAC under the aegis of Department of Biotechnology, Government of India.

The programme highlights the need of Innovative solutions to society's most pressing social problems. The scheme is tackling major social issues and offering new ideas for wide-scale change. The scheme aims to invest in ideas and innovations that improve health care of all Indians and provide affordable product development in social sector.

**Category A: Idea to proof of concept**

**Funding Support:** Grant-in-aid assistance up to Rs. 50 lakhs for a period up to 18 months

**Eligibility**

- Biotechnology Indian start-ups
- Limited Liability Partnership
- Indian Academic Scientists, Researchers, PhDs, Medical Degree Holders, Biomedical Engg Graduates

**Category B: Proof of Concept to Validation**

**Funding Support:** Mix of Grant-in-aid (up to 50 Lakhs) & loan assistance not exceeding a total of INR 100 lakhs, over the period up to 24 months.

**Eligibility**

- Companies Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership
- Limited Liability Partnership: The Applicant should own the background Intellectual Property based on which the proposal is made
- Indian institution/ universities/ public research organization who can become co-applicants along with the company/llp as main applicant established in india and having naac/ ugc/ aicte or any equivalent recognition certificate.

**Category C: Access to innovative pilot scale delivery models**

**Funding Support:** Mix of Grant-in-aid (up to 50 Lakhs) & loan assistance, over the Page 9 of 25 period up to of 24 months. The project cost sanctioned for the Company would be matched equally by BIRAC and the Company

Companies: The product should have gained necessary approvals from the concerned regulatory authority (-ies) for pilot studies.

**14.2.5 Industry Innovation Programme on Medical Electronics (IIPME)**

IIPME is launched with an aim to promote and foster cutting edge technologies in the field of Medical Electronics. The project IIPME is a partnership project between the “Department of Electronics and Information Technology”, Ministry of Communications and Information Technology, Government of India and “BIRAC”, a public sector undertaking of Department of Biotechnology, Government of India.

The IIPME is one of its kinds, which directly targets the innovations in the medical electronics start-ups, SMEs and large enterprises and will also help in generating the ideas to keep ready the pipeline of new unmet medical Innovations.

To achieve the desired impact the IIPME funds the innovations in three categories

- Seed Grants (Idea to PoC): This phase is for funding the projects, which are at initial stages of product development cycle. These awards are meant to provide an opportunity to test particularly bold ideas.
- Early Transition: The category is for the projects which have established the Proof of Concept and require incremental prototype innovations and validation; these awards are for projects which are at the early stages of translational research.
- Transition to Scale: The stage is for the projects which have already shown promising data on establishing the Proof of Concept and has generated enough validation data, these awards require demonstration of detailed preliminary data and are meant to provide an opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

**Category A: Idea to proof of concept**

**Funding Support:** Grant-in-aid assistance up to Rs. 50 lakhs for a period up to 18 months

**Eligibility**

- Biotechnology Indian start-ups
- Limited Liability Partnership
- Indian Academic Scientists, Researchers, PhDs, Medical Degree Holders, Biomedical Engg Graduates.

**Category B: Proof of Concept to Validation**

**Funding Support:** Mix of Grant-in-aid (up to 50 Lakhs) & loan assistance not exceeding a total of INR 100 lakhs, over the period up to 24 months.

**Eligibility**

- Companies Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership
- Limited Liability Partnership: The Applicant should own the background Intellectual Property based on which the proposal is made
- Indian institution/ universities/ public research organization who can become co-applicants along with the company/llp as main applicant established in india and having naac/ ugc/ aicte or any equivalent recognition certificate.

**Category C: Access to innovative pilot scale delivery models**

**Funding Support:** A mix of grant & loan for a period of 24 months. The project cost would be matched equally by BIRAC and the industry

- Companies: The product should have gained necessary approvals from the concerned regulatory authority (-ies) for pilot studies.

**14.3 Schemes of the Department of Science and Technology****14.3.1 Promoting innovations in individuals, start-ups and MSMEs (PRISM)**

PRISM aims at to support individual innovators which will enable to achieve the agenda of inclusive development - one of the thrust areas of XIIth five year plan (2012-2017). It would also provide support to institutions or organizations set up as Autonomous Organization under a specific statute or as a society registered under the Societies Registration Act, 1860 or Indian Trusts Act, 1882 leading to development of state-of-art new technology solutions aimed at helping MSME clusters.

**Eligibility**

- Any Indian Citizen having innovative idea or an invention.
- Public funded institutions or organizations viz. Autonomous Organizations or Society registered under the Societies Registration Act, 1860 or Indian Trusts Act, 1882 engaged in promotion of innovation.

**Funding Support**

- Project cost more than Rs. 5.00 lakh and up to Rs. 35.00 lakh.
- Category II is different from Category I in respect of comparatively more rigorous demonstrability of original idea/invention/know-how in the form of working prototype/processes and its testing and trial/patenting/technology transfer etc.
- Proposals to demonstrate novel delivery models to take S&T innovations to effect inclusive growth.

- The proposals shall preferably be in the following focus sectors: Green Technology, Clean Energy, Industrially utilizable smart materials, Waste to wealth, Affordable healthcare, Water & sewage management, any other technology or knowledge intensive area.
- Maximum support under this category is Rs 20.00 lakh or 90% of the approved project cost, whichever is lower.

#### **14.3.2 Department of Scientific and Industrial Research Recognition**

There is an ongoing scheme by the Department of Scientific & Industrial Research (DSIR) under Ministry of Science & Technology. This scheme recognizes R&D departments of manufacturing companies and provides them the status of 'in-house R&D centre', which in turn provides them with indirect and direct tax benefits for their R&D activities. This is to incentivize these companies taking risks by investing in R&D, which can lead to development of indigenous technology and new products benefiting society.

The benefits range from zero customs and excise duty for purchase of R&D capital equipments on receiving R&D recognition certificate to income tax benefit for capital expenses (CAPEX), which includes computers and equipments for prototyping, testing, etc., and operating expenses (OPEX), which includes salaries of technical and scientific staff including their official travel, raw materials consumed, maintenance of equipments, utility bills and other relevant expenses incurred on running the R&D centre under section 35 2(AB) of The Income Tax Act with 200 percent weighted deduction for FY 2016-17, but the same has been decreased to 150 percent from April 1, 2017, as announced in the Union Budget in February 2016.

There is also an interesting benefit. If a product has been patented in two countries, which could be from India, USA, Japan or European Union, and has been launched in India, then it will be eligible from excise duty waiver.

It has also been interestingly seen that companies go for DSIR recognition and approval for strategic reasons beyond financial benefits. In one such case, the Customs Department suggested a Korean pharma company conducting drug discovery in India to avail DSIR recognition so that their consignment does not get delayed in customs. Even a few days delay can be catastrophic for their research projects.

### **14.4 Schemes of the Department of Scientific & Industrial Research (DSIR)**

#### **14.4.1 Patent Acquisition and Collaborative Research and Technology Development (PACE)**

The Department of Scientific & Industrial Research (DSIR) through the PACE scheme facilitates early stage technology/IP acquisition by industries to manufacture "Made in India" products and strengthens the interface between industry, R&D establishments and academic institutions by providing catalytic support for development and demonstration of innovative product and process technologies, traversing the journey from proof of concept or laboratory stage to pilot stage, ready to be launched for commercialization. The scheme assists in development of new technology or the creative/innovative application of the existing technologies to solve problems and to support ingenious and elegant work that matters to the world at large-- not just to peers in a particular field or industry.

### **Funding Support**

- Funding R&D projects of industry alone-Support generally up to 50% of the project cost to industry
- Funding R&D projects of industry in collaboration with R&D organization/ academic institution/ university in India or abroad- Support up to 100% to R&D organizations/ academic institutions/ universities (Public Funded Research Institutions – PFRIs) in India in accordance with GFR/GOI guidelines, but no support to institutions from abroad; and Support to Industry will generally be up to 50% of the project component being undertaken by the industry.

### **Eligibility**

- Technology to be acquired should have a PCT filing or should be patented in any one of USPTO, EPO, Japan, Australia, China, Korea or India
- Technology development and demonstration and technology acquisition under the scheme shall be open for all industries registered in India which are more than three years old and have a healthy financial track record (profit making companies), preferably those having DSIR recognized in-house R&D units.
- The identified R&D organization/ academic institution/ university in India or abroad, for collaboration with the industry should have the requisite expertise and track record in the proposed area of research.

## **14.5 Schemes of the Ministry of Micro, Small and Medium Enterprises**

### **14.5.1 SIDBI Make in India Soft Loan Fund (SMILE)**

The main objective of this scheme is to provide soft loan, in the nature of quasi-equity, and term loan on relatively soft terms to MSMEs to meet the required debt-equity ratio for establishment of an MSME as also for pursuing opportunities for growth for existing MSMEs.

#### **Eligibility**

New enterprises in the manufacturing as well as services sector. Existing enterprises undertaking expansion, modernization, technology upgradation or other projects for growing their business will also be covered. Loans extended under the scheme cannot be used for repayment of earlier loans.

#### **Funding**

##### **Term Loan**

75% for enterprises with total project cost up to 1 crore (for Debt-equity ratio of 3:1) and 2/3rd of the project cost (for Debt-equity ratio of 2:1) for the rest.

##### **Soft Loan**

10% of the project cost subject to a maximum of Rs. 20 lakh.

Up to 15% of the project cost for the enterprises promoted by Scheduled Caste (SC) / Scheduled Tribe (ST) / Persons with Disabilities (PwD) and women, subject to a maximum of Rs. 30 lakh.

Persons belonging to these categories must own controlling stake (i.e. 51% or higher). On expiry of 3 years from the date of first disbursement, the outstanding soft loan together with any dues thereon shall be converted into secured term loan and the entire loan shall carry applicable rate of interest as per internal rating of the borrower.

#### **14.5.2 Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE)**

Availability of bank credit without the hassles of collateral / third party guarantee would be a major source of support to the first generation entrepreneurs to realise their dream of setting up a unit of their own Micro and Small Enterprise (MSE). Keeping this objective in view, Ministry of Micro, Small & Medium Enterprises (MSME), Government of India launched Credit Guarantee Scheme (CGS) so as to strengthen credit delivery system and facilitate flow of credit to the MSE sector. To operationalize the scheme, Government of India and SIDBI set up the Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE) in August 2000 with a committed corpus of 2500 crore to be contributed by Government of India and Small Industries Development Bank of India (SIDBI) in the Contribution ratio of 4:1.

##### **Funding Structure**

- Credit guarantee for MSE loans up to 1 crore, without collateral and third party guarantee.
- Maximum Guarantee Cover of up to 85% of credit facility covered under CGS.
- Guarantee coverage is 50% for credit facility above 50 lakh.

##### **Eligibility**

- All Micro & Small Enterprises as per MSMED Act.

#### **14.6 Schemes of the Technology Development Board**

For the development and application of indigenous technology in a dynamic economic environment, the Government of India enabled the placing of proceeds of the Research and Development Cess on the import of technology into a fund called the Fund for Technology Development and Application. To administer the Fund, the Government constituted a Technology Development Board on 1st September, 1996, under the provisions of the Technology Development Board Act, 1995. This booklet provides guidance to access the Fund.

The Technology Development Board invest in equity capital or gives loans to industrial concerns and other agencies, attempting development and commercial application of indigenous technology, or adapting imported technology to wider domestic applications.

##### **Eligibility**

- Commercial enterprises companies incorporated under companies act, 1956
- If the project is for the commercialization of technology, developed by a domestic R&D institution, the enterprise should apply, along with an agreement signed by the R&D institution willing to transfer the technology.
- Applications from enterprises, with or without any other partners
- Start-up companies and/or technocrat-entrepreneurs, with or without any other partners.

##### **Financial Assistance**

##### **Loan Assistance:**

- TDB provides loan assistance to industrial concerns. The industrial concern may be an on-going one or a new one. The loan carries a simple interest of five percent per annum. TDB does not levy processing, administrative or commitment charges.

- The quantum of loan will be, normally, limited up to 50 per cent of the approved project cost. The duration of the project should not generally exceed three years. The loan is payable in installments that are linked to risk-associated milestones in accordance with the terms and conditions of the loan agreement. The refund of the loan and payment of interest commence one year after the project is completed and the full loan amount is recoverable in five years thereafter. In some cases, TDB may have nominee director(s) on the Board of Directors of the assisted industrial concern.

#### **Equity Subscription:**

- TDB may also subscribe by way of equity capital in an industrial concern, on its commencement, start-up and/or growth stages. The equity subscription is decided by the full Board of TDB. It is up to 25 per cent of the approved project cost provided such investment does not exceed the capital paid-up by the promoters. The pre-subscription conditions include that the promoters should have subscribed and fully paid up their portion of the share capital.
- TDB has a right to have nominee director(s) on the Board of Directors of the company. TDB, in its discretion, may divest its shareholdings in the company after three years of completion of the project or after five years from the date of subscription. The first option to buy back the shares rests with the promoters.
- TDB has recently joined hands with two major private equity investors, i.e. APIDC VCF and UTI to invest in the equity of startups and companies in the growth phase. TDB has contributed Rs. 30 crores to the APIDC VCF (BioTech fund) and Rs. 75 crores to the UTI Ascent India Fund.

## **14.7 Schemes of the National Research Development Corporation**

### **14.7.1 Techno-Commercial Support For Promising Inventions / Innovations**

There are number of value additions required for the laboratory scale technologies to be acceptable by the industry. The objective of this program is to provide essential support to the applicants for overcoming minor issues like testing of the product, authentication of results in field conditions, improvement of prototypes and preparation of comprehensive know-how document. Under this scheme, NRDC provides techno-commercial support to Indian inventors / scientists / technocrats / NRDC Awardees / NRDC Licensees, etc to make the developed technology marketable and acceptable to entrepreneurs and industries.

The techno-commercial support is provided for the following purposes:

- i) Improvements in prototypes to make it commercially acceptable
- ii) Carrying out process trials / field trials / testing / analysis
- iii) Preparation of a pre-feasibility report
- iv) Preparation of video or animation film about working of the invention
- v) Preparation of comprehensive know-how document
- vi) Demonstration of the technology (in deserving cases only)

#### **Eligibility**

- Indian inventors / scientists / technocrats / NRDC Awardees / NRDC Licensees having promising, technically feasible & commercially viable invention/innovation

### **Funding Support**

- Techno-commercial support category-wise can range from Rs. 25,000 to Rs. 2 Lakhs.

## **14.8 Schemes of the Department of Industrial Policy & Promotion**

### **14.8.1 Scheme for Facilitating Startups Intellectual Property Protection (SIPP)**

IPRs are emerging as a strategic business tool for any business organization to enhance industrial competitiveness. Startups, with limited resources and manpower, can sustain in this highly competitive world only through continuous growth and development oriented innovations; for this, it is equally crucial that they protect their IPRs. The scheme for Startups Intellectual Property Protection (SIPP) is envisaged to facilitate protection of Patents, Trademark and Designs of innovative and interested startups.

#### **Objective**

The Scheme of SIPP aims to promote awareness and adoption of Intellectual Property Rights amongst startups. Scheme is inclined to nurture and mentor innovative and emerging technologies among Startups and assist them in protecting and commercialize it by providing them access to high quality IP services and resources.

#### **Eligibility**

- Any startup recognized in terms of explanation 5 of the Notification GSR 180(E) published in the part II, Section 3, Sub Section (i) of the Gazette of India dated 17.2.2016.
- It is further clarified that an entity shall be considered a 'startup' if it meets the terms and conditions laid down in the above mentioned notification.
- The startups covered under this scheme will not require obtaining certificate of an eligible business from the Inter-Ministerial Board of Certification.

### **14.8.2 Technology Acquisition and Development Fund**

TADF is a new scheme to facilitate acquisition of Clean, Green & Energy Efficient Technologies, in form of Technology / Customised Products / Specialised Services / Patents / Industrial Design available in the market available in India or globally, by Micro, Small & Medium Enterprises (MSMEs).

- **Direct Support for Technology Acquisition-** Proposals from Indian industry will be invited for reimbursement of 50% of technology transfer fee or Rs. 20 lakhs, whichever is lower
- **In-direct Support for Technology Acquisition through Patent Pool-** Financial support will be provided in acquiring of technology/Patent from across the Globe based on applications received from MSMEs. Technology/Patent will be licensed to selected companies, with a mutually agreed value and the selected companies will get a subsidy of 50% of the mutually agreed value or Rs. 20 lakhs,
- **Technology / Equipment Manufacturing Subsidies:** The fund will support, via subsidies, manufacturing of equipment / machines / devices for controlling pollution, reducing energy consumption and water conservation. The manufacturing units will be provided with a subsidy of up to 10% of capital expenditure incurred on new plant & machinery subject to a maximum of Rs. 50 lakhs.

- **Green Manufacturing – Incentive Scheme:** The scheme will facilitate resource conservation activities in industries located in NIMZ through the introduction of incentive/subsidy schemes for energy/ environmental/ water audits, construction of green buildings, implementation of waste treatment facilities and implementation of renewable energy projects through financial support under the TADF.

#### **14.9 Technology Information, Forecasting and Assessment Council (TIFAC)**

##### **TIFAC-SIDBI Revolving Fund for Technology Innovation SRIJAN Scheme**

Provide financial assistance to MSMEs towards development, up scaling, demonstration and commercialization of innovative technology based projects.

The assistance is given in the form of early stage “debt” funding on softer terms for development, demonstration and commercialization of new innovations in emerging technological areas, un-proven technologies, new products, process, etc. which have not been successfully commercialized so far.

Maximum assistance is generally not more than Rs.100 lakh per project. Interest rate would be as approved by the Project Approval Committee (PAC) (not be more than 5% p.a.).

All the proposals for assistance under the Scheme shall undergo technical evaluation by TIFAC and financial viability by SIDBI. The assistance is approved by a Project Approval Committee (PAC) consisting of officials of SIDBI and TIFAC.

#### **14.10 Micro Units Development and Refinance Agency Ltd.**

##### **Pradhan Mantri Mudra Yojana – Loan Scheme**

The Government of India has launched 10,000 Crore Startup Fund in Union budget 2014-15 to improve startup ecosystem in India. In order to boost innovative product companies, Government has launched ‘Bank Of Ideas and Innovations’ program.

Government backed ‘PradhanMantri Micro Units Development and Refinance Agency Limited (MUDRA)’ starts with an initial corpus of Rs. 20,000 crore to extend benefits to around 10 lakhs SMEs. You are supposed to submit your business plan and once approved, the loan gets sanctioned. You get a MUDRA Card, which is like a credit card, which you can use to purchase raw materials, other expenses etc. Shishu, Kishor and Tarun are three categories of loans available under the promising scheme.

#### **14.11 Incentives for Startups**

The word R&D is typically confined to large companies with big budgets and a large technical team supporting new product or process development in the organization. This is far from true because a large number of small and medium businesses have been doing R&D by solving customer problems and innovating on their products without realizing the same. Because they may not have a dedicated R&D lab or set up, but it is engrained in the business without giving special emphasis to Research & Development. But there are financial and strategic benefits available for those conducting R&D in India; be it product or technology development across different industry sectors, and the sooner they realize it the better it is for them.

#### 14.12 Some of the incentives and support measures presently available for enhancing scientific R&D:

- 100% write-off of revenue expenditure on R&D under section 35(1)(i) of I.T. Act, 1961.
- 100% write-off of capital expenditure on R&D in the year the expenditure is incurred under section 35(1) (iv) of I.T. Act, 1961.
- Weighted Tax deduction @200% on expenditure incurred in approved in-house R&D facility, to companies engaged in business of biotechnology or in any business of manufacture or production of any article or thing (*not being an article or thing specified in the list of the eleventh schedule*) under section 35(2AB) of I.T. Act, 1961. Provision is valid till 31-03-2017.
- Weighted tax deductions@200% for sponsored research programmes in approved National laboratories, Universities and IITs (Section 35(2AA) of I.T. Act).
- Income tax rebate @175% on donations for scientific research made to non-commercial research organization approved and notified under section 35(1) (ii) and 35(1) (iii) of I.T. Act, 1961.
- Tax Holiday for ten consecutive assessment years to commercial R&D companies under section 80-IB(8A) of I.T. Act, 1961 approved before 31-03-2007.
- Accelerated depreciation allowance upto 40% on investment on new plants and machinery based on indigenous technology as per rule 5(2) of I.T. Rules.
- Customs duty exemption on goods imported for R&D and central excise duty waiver on purchases of indigenous goods for R&D to public funded and privately funded institutions registered with DSIR. (Notification No.51/96-customs dated 23 July 1996 and No. 24/2007-customs dated 1 March 2007; Notification No. 10/97-central excise dated 1 March 1997 and No. 16/2007-central excise dated 1 March 2007).
- Customs duty exemption on imports made for use in R&D projects funded by Govt. in industries (Notification No. 50/96-customs dated 23 July 1996).
- DSIR recognized in-house R&D units engaged in R&D in biotechnology and pharmaceuticals sectors can import specified equipment duty free (List 28). In respect of R&D units with manufacturing facilities, the benefits of full customs duty exemption for specified equipment is also available for manufacturing activity to the extent of 25% of the previous year's export turnover.
- Central excise duty waiver for 3 years on specified goods designed and developed by a wholly owned Indian company, National laboratory, Public funded research institutions or Universities and patented in any two countries from amongst India, USA, Japan and in any one country of the European Union. The specified goods are manufactured by a wholly owned Indian Company. This exemption is available based on certification from DSIR (Notification No. 13/99-central excise dated 28th February 1999).
- Various funding schemes under ministries/ department of Govt. of India for Technology development, upgradation and commercialization. (eg. DST, DSIR, DBT, CSIR, ICMR, ICAR, TDB, TIFAC, MNRE, MoEF, MoSteel, MoFPI).

To promote Entrepreneurship in Biotechnology sector, DSIR has announced relaxation in 3 years of existence for granting short term fresh recognition to Biotech start-ups established in Incubator Centre or Technology Parks.

#### The company should submit the following profile:

- a) Name of the Company and Permanent Account Number (PAN No.)
- b) Registration number and date of incorporation under the Companies Act, 1956 as amended in 2013

- c) Complete address of the R&D unit
- d) Brief write up on ongoing research activities and achievements
- e) Details of existing and proposed sources of funding and revenue.

**Eligibility Criteria for Recognition of Biotech Start-ups:**

- a) The applicant should be a Biotech start-up company conducting high end research with a scope for generating IPs and revenues out of it.
- b) The start-up should have qualified R&D manpower and basic minimum R&D infrastructure.
- c) The Company should have focused research objectives based on innovative and recent advanced technologies, a clear business model and sources of funds for sustainability.
- d) The Company should furnish documents / details of collaborations, agreements, MOUs etc. with the Incubator Centre or Technology Parks.
- e) The Company should furnish a list of Biotechnology based projects proposals submitted / approved for Government of India funding.

### **14.13 Special Royalty Tax for Patents**

The Budget 2016-17 has introduced a special 'royalty tax' which lowers the effective rate of tax on income earned from patents. The objective is to encourage indigenous research and development, and to make India an innovation hub. The benefit will be available across knowledge-based sectors of the economy, including pharmaceuticals.

A special patent regime with a 10% rate of tax on income from worldwide commercialization of patents which are developed and registered in India is introduced. Usually, the domestic company which has commercialized the patent would be paying tax from income at the standard rate of 30% after deducting expense. With this proposal, the tax liability on income from commercialization of patents goes down, and thus would be beneficial for knowledge-based firms, experts say, adding that it would reduce the outflow of intellectual property from India.

The aim of the 'concessional taxation regime' extended across sectors, for income derived from patents, is to provide an additional incentive for companies to retain and commercialize existing patents and to develop new innovative patented products. The government hopes it will also encourage domestic companies across sectors, including automotive, electronics and pharmaceuticals, to locate high-value jobs associated with the development, manufacture and exploitation of patents in the country.

#### ***Way Forward***

If you want to grow really fast, you probably need outside sources of capital. If you bootstrap and remain without external funding for too long, you may be unable to take advantage of market opportunities.

While the plethora of lending options may make it easier than ever to get started, responsible business owners should ask themselves how much financial assistance they really need.

### **Funding 101: Equity Funding**

Equity funding is an umbrella term that refers to any means of financing your company in which you receive money in exchange for issuing shares of your stock. There are multiple methods for raising equity capital, but, depending on how you raise this money, you could be giving up anywhere from 1-100% of your business. Equity rounds include:

- **Seed financing**, as the name implies, is the relatively small amount of money a business needs early on to get started. Usually businesses seeking a seed round are still in the concept stage and need just a small capital infusion to cover expenses until they can start earning revenue. Seed money can also be a helpful tool for attracting future money from bigger investors. Because seed capital is smaller and more of a high-risk investment, it generally will come from friends and family or smaller angel investors.
- It can be easier to raise seed rounds from a smaller angel investor, as opposed to going for the brass ring of venture capital investment. With an angel investor, you will usually pay less of a premium in the amount of the stock or percentage of your company you give up because angel investors have other means of making money and may not be looking for as specific a level of return as venture capitalists might be.
- There are downsides to working with angel investors. Often you will need to find multiple investors to give you the kind of capital you need (as opposed to working with just one VC); this can lead to “herding cat syndrome,” wherein you find yourself facing the challenge of managing multiple people and relationships. But, for seed money, your angel investors are still generally going to be a good first bet.
- **Series A.** Series A refers to the first round of stock offered to investors during early-stage rounds. Typical Series A rounds fall in the range of \$2-5M, offer options for 20-40% of the company, and are intended to support a company through the early stages of building a business, from product development to hiring to marketing. Because the Series A round is for more significant cash, investors are usually professional angel investors or boutique VC firms who specialize in this first round of financing.
- **Series B.** Series B refers to second-stage financing. Series B usually happens after the company has already achieved certain business milestones and thus proven its potential viability as a company. This series is also sometimes called a venture round since it is at this point that venture capitalists usually get involved. Venture capitalists don't just offer a greater capital investment for a given round; there's also a greater possibility for going back to this same well for future rounds. Also, experienced VCs can offer the kind of networking opportunities and mentorship that unconnected smaller angel investors may not.
- **Series C.** As companies grow, they might continue to seek additional funds to meet future milestones. Each successive venture round follows alphabetically down the line (e.g. C, D, E...). VCs and private equity investors support these financing rounds as well as future funding rounds that more established companies may have to look forward to such as bridge financing, expansion capital, late-stage capital, and leveraged buyout.

---

## 15. GOVERNMENT INITIATIVES FOR STARTUPS

---

***“Unless incubators can help entrepreneurs cut down on time and make it easier to bring solutions to market, there will be more people doing food delivery apps, not solving food production problems.”***

***Kunal Upadhyay, Chief Executive, CIIE***

The Indian biotechnology industry is one of the fastest growing knowledge based sectors. India currently ranks amongst the top 12 biotechnology destinations in the world, and is a global leader in the production of drugs and vaccines. For an economy like India, biotechnology is a powerful enabling technology that can revolutionize agriculture, healthcare, industrial processing and environmental sustainability. According to a forecast by the Association of Biotechnology Led Enterprises (ABLE), the Indian biotechnology industry sector has the potential to be \$ 100 billion (Rs. 6 lakh crore) industry in the next decade.

The Indian biotechnology industry can be broadly classified into five categories namely biopharmaceuticals, bioagriculture, bioservices, bioindustry and bioinformatics. There are approximately 800 – 850 large, medium, small and startup companies in the biotechnology and allied sectors. Within the different sectors in biotechnology, there are multiple disciplines which are huge specialties on their own.

- Biopharma – Drugs, vaccines, diagnostics
- Bioindustrial – Biofuels, nutraceuticals, enzymes
- Bioagri – Hybrid crops, biopesticides, biofertilizers
- Bioservices – custom synthesis & manufacturing and contract research
- Bioinformatics – data analytics and software and database services.

India is in an advantageous position to harness the potential of biotechnology due to its unique strengths such as availability of rich bio-resources, technical expertise, skilled manpower, progressive government policies and rapidly expanding access to international markets.

Promotion of the Indian biotechnology sector is high on the policy agenda of the Government of India. Biotechnology has been recognized as one of the key priority sectors under the 'Make in India', 'Skill India' and 'Startup India' initiative of the Government of India, being one of the few sectors on strong growth trajectory to drive sustainable economic growth and generate large scale employment opportunities.

The DBT National Biotechnology Development Strategy 2015 – 2020 provides a strategic roadmap for India's emergence as a global biotechnology innovation and manufacturing hub and to contribute towards enterprise creation, innovation and economic growth.

In order to achieve the \$100 billion target of the Indian biotech industry, there is a crucial need to strengthen the existing biotech industries as well as create new biotech industries. Entrepreneurship based on innovation has immense growth potential. Given this context, encouraging and promoting self-employment as a career option for young people will be of highest importance. Most policymakers and academics agree that entrepreneurship is critical to the development and wellbeing of society. Entrepreneurs drive and shape innovation, thereby speeding up structural changes in the economy. Entrepreneurship is thus a catalyst for economic growth and national competitiveness.

There has been an increased activity towards applied research and technology development by both the academia and the industry leading to increase in innovation. There is also an increasing trend to set up start-up companies by technocrats based on technology leads. Moreover a number of first generation entrepreneurs and established companies operating in other areas are showing interest in investment in biotechnologies developed indigenously or sourced from other countries. This has led to increase in corporate research activities. The major constraints faced by such entrepreneurs, which has retarded the pace of investments, include the following:

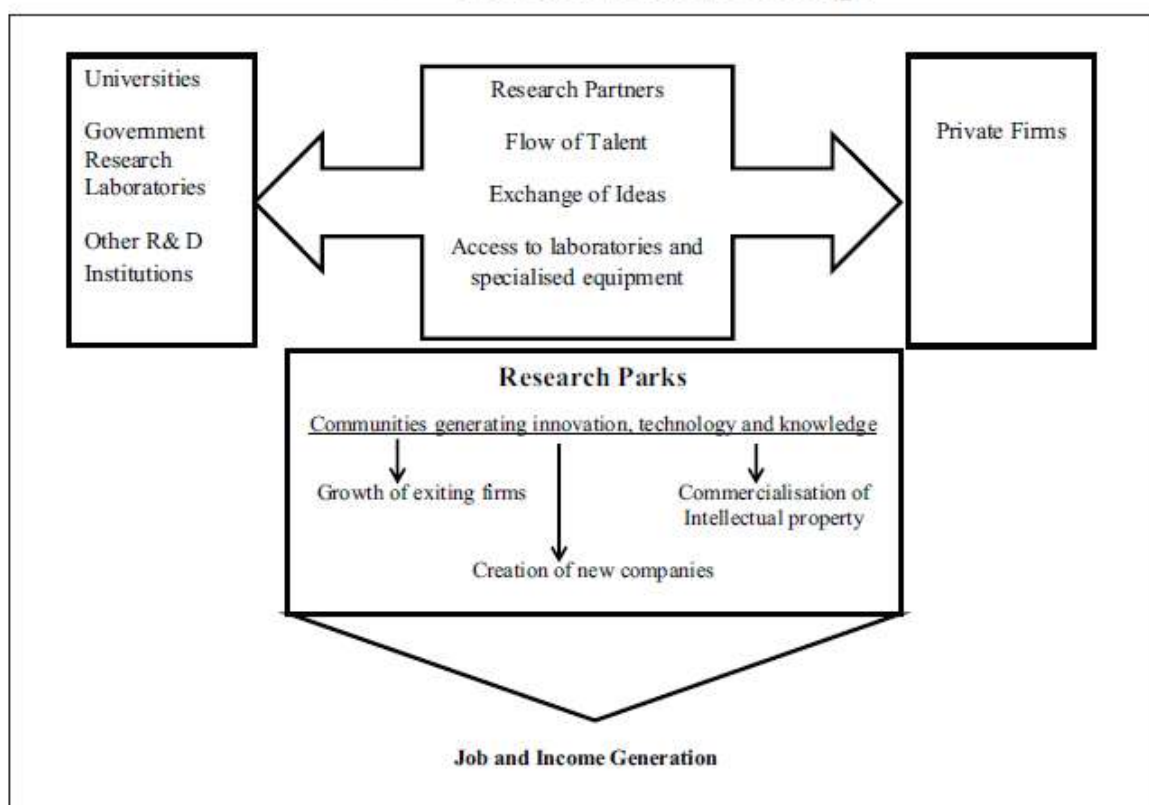
- Large requirement of funds and long gestation period for developing the inventions into commercial projects.
- Difficulty in obtaining financial support for commercialization, particularly venture capital for innovative inventions,
- High-risk perception and lack of adequate incentives necessary to cover such risk and encourage such investment.
- Poor public private interaction and partnership due to lack of information about technologies, technical capabilities, infrastructure availability in institutes and mechanisms and incentives to promote such interactions.
- High rate of technology obsolescence coupled with difficulty in accessing proprietary technologies and intellectual property which are concentrated in the private sector of industrialized nations.
- Cumbersome regulatory protocols in different countries based on diverse biosafety regulations are often difficult and costly to implement.
- Scarcity of appropriately skilled manpower.
- Inadequate information sources resulting in poor regional and inter-regional interactions for technology collaborations and market access.
- Weakness in specialized areas such as IPR and biosafety resulting in delays and inability to gear up to rapid global technological advancements.

To promote innovations and investments in biotechnology, biotech parks, technology incubators and special economic zones have been set up in India to promote technology incubation and scale up as well as manufacturing activities by providing infrastructure support, facilities and incentives so as to minimize the above constraints for technology development, commercialization and large-scale manufacturing.

### **15.1 Biotech Parks**

Biotech parks are promoted in our country to help the entrepreneurs and technopreneurs for starting their own ventures in biotechnology. These are essentially built-up structures where common facilities are available for smooth initiation and conduct of business. It is specially suited for technopreneurs who have a technology with them but have no idea on the commercial viability of that technology. The presence of the core-shared facility would help in reducing capital costs for the clients in the Park as they would be able to use state of the art equipment in the facility without having to invest on their own in various fields. The biotech parks will also have an incubation centre and business facilitation centre to help create economic value.

## Research Park Concept



Source: Driving Regional Innovation and Growth: The 2012 Survey of North American University Research Parks, p. 6.

The broad concept is that of a facility, where the interface of research with commerce and industry is facilitated for better utilization of the technology.

### **15.1.1 Functions of Biotech Park**

Biotechnology parks perform the functions as encouraging and supporting incubation and development of biotech innovations. The facilities in the incubator include physical facilities in the form of office space, dry and wet laboratories, specialized equipment and instrumentation facilities, pilot plant and scale up units and good communication network. In addition, the park provides developed land at cost effective rate for carrying out manufacturing activity.

### **15.1.2 Facilities/Services & Incentives at Biotech Parks**

Biotech parks are equipped with state-of-the-art facilities, along with which it comprise the following:

- Technology incubation center (TIC)
- Specialized facilities
- Common facilities
- Business support facilities (BSF)
- Business enterprise zone (BEZ).

- **Technology Incubation Center**  
TIC would consist of laboratory modules, specialized facilities and a well-equipped instrumentation facility. The laboratory space could be leased out to the tenant for specified periods. TIC would enable the tenants to translate their research ideas into commercialisable technologies as well as upgradation of existing technologies without making huge investments on buildings, equipment etc., initially. This facility would be useful for technically competent small and medium scale enterprises (SME) and entrepreneurial scientist with limited financial resources particularly because of non-availability of financial assistance for R & D projects under conventional funding schemes. This facility could also be used for small scale manufacturing of the biotech products by SMEs.
- **Specialized Facilities**  
These would consist of fully equipped laboratories in the areas of commercial importance and of relevance to the state. The new quality control norms and certification system demands proper testing and validation of bio products (biofertilizers, biopesticides, tissue cultured plants etc) and so the facilities proposed in the park can help the tenants in the initial phase to meet the quality standards. These facilities could be leased out to companies, contract research organizations or contract manufacturing organizations for facilitating cost effective development of technologies/products and manufacturing. In the first phase of the park the following facilities are proposed to be set up. It consists of facilities for Plant Tissue Culture, animal Testing, Medicinal plant extraction facility, biopesticides & biofertilizer production etc.
- **Common Facilities**  
The common facilities in the park are cold storages and warehouses to facilitate small-scale companies to store their finished goods and raw materials. Other facility includes the common effluent treatment plant to ensure elimination of harmful live microorganisms, as bacteria, will be carried out by the units in the parks themselves. Some parks specializing in medical biotechnology will have a common secondary effluent treatment plant that will collect all the bacteria killed in effluent from the primary effluent plants of individual units for further treatment and disposal.
- **Business Support Facilities**  
This facility consists of Administrative office consisting of management, and other linked departments responsible for park's administration. Biotechnology Information Centre (BIC), a bioinformatics facility for accessing all the on line journals and other IT tools a facility, Meeting rooms for making presentations etc., would be equipped with state of the art equipment such as LCD/digital projector, slide projector, overhead projector, public address system etc. Apart from these amenities the park is also equipped with a Consultancy cell to encourage biotech consultants specialized in providing the following services by offering space initially at concessional rates such as.
  - i. Technology transfer assistance.
  - ii. Fund syndication.
  - iii. Project assistance.

- iv. Marketing assistance.
- v. Single window clearance.
- vi. Facilitation of regulatory approvals

Besides these facilities the park also consists of commercial shops, cafeteria, parking space for tenants and PFUs would be dealing in items such as stationery, raw materials, laboratory consumables and lab ware etc. as required by the tenants. These shops could be leased/ purchased by stationery sellers and other service providers including biotech consultants.

- **Business Enterprise Zone**

The Business Enterprise Zone would consist of developed plots, roads, water supply & sewerages, effluent treatment facility, telecom network and power supply. The developed plots would be required by medium and large-scale enterprises. These plots would be leased out to the tenants.

At the central level, the Department of Biotechnology (DBT) is the main agency responsible for developing biotechnology related infrastructure in India. The DBT has extended its support to set up biotechnology parks in different parts of the country. Beside the central government's initiatives, many state governments' have supported several biotech parks in India.

Among biotechnology parks, 'Genome Valley,' is the first and perhaps the most successful biotech cluster of India. Beside this, Andhra Pradesh has about five other successful biotech parks. With all these biotech parks Andhra Pradesh is considered to be the leader of biotech industry. The success of Hyderabad cluster is because of the strategic location of "Genome Valley".

This table provides a comprehensive list of current and proposed parks in several Indian states.

The state wise distribution of parks shows that Andhra Pradesh and Kerala have maximum number of parks (six parks in each state) and 77 of parks in the other states is as follows: Karnataka (5), Tamil Nadu (5), Maharashtra (4), Rajasthan (4), Gujarat (3), Himachal Pradesh (2), West Bengal (2), Assam, Goa, Haryana, Madhya Pradesh, Orissa, Punjab, Uttar Pradesh, and Uttaranchal have one park each which is either proposed or already established.

## **15.2 Technology Business Incubators**

Since their emergence in the 1950s, business incubators have proliferated around the world, often supported by governments as a means of spurring economic development. In India, the Government's Department for Science and Technology (DST) first invested in Science and Technology Entrepreneurs Parks (STEPs) in the 1980s, and then from the early 2000s, in Technology Business Incubators (TBIs). DST has so far funded over 60 TBIs. Most are based within academic institutions, but some are public-private partnerships with other types of 'host' organisations, such as the Indian Angel Network. India also has a growing number of private incubators, set up by entrepreneurs, investor networks and corporations.

### 15.2.1 What does it mean to Incubate a new company or organisation?

Incubators are entities that aim to help new companies start up, survive and grow. They tend to provide at least four of the following five things: office space, business services (e.g. legal/ accountancy), coaching and mentoring, funding, and access to networks. Given business incubators have been around for over 60 years now, it's not surprising that designs and methods have proliferated.

Traditionally, business incubation was real-estate based: shared office space alongside advice and assistance. Now, however, the term is used much more broadly, to cover models ranging from short-term, highly-structured, intensive '*accelerator*' programmes, to longer-term, flexible support, as well as competitions, courses and co-working spaces. Recent approaches emphasise not only helping a firm to 'survive its formative years', but also ensuring it has a 'positive impact on the economy and society'.

### 15.2.2 How many different Models of Incubation are there?

Incubation can be differentiated in a number of ways, for example:

- Business model (e.g. commercial/not-for-profit)
- Host institution (e.g. university/municipal/corporate/investor)
- Target enterprises (e.g. highly selective/open to all/sector specific/pre-company formation)
- Methods used (e.g. shared office space/online platform/structured, time-limited accelerator programme/employed staff or volunteer mentors).

### 15.2.3 What do Incubators aim to achieve?

One of the most useful differentiators is what the incubator is aiming to achieve. Goals can include local economic development and job creation, high growth venture acceleration, entrepreneurial education, commercialisation of science, accessing or nurturing new markets, building investment pipelines, improving the lives of the poor and creating micro-businesses and rural livelihoods.

The impacts of many incubators may go far beyond the target firms, although these impacts are often poorly measured. For example, the focus on measuring the impact on the firm often overlooks the importance of incubators in developing the skills and experience of individual entrepreneurs. Even failed attempts to launch a firm can provide valuable experience for subsequent entrepreneurial activities.

Meanwhile, there has been rapid growth in *seed accelerator programmes*. These are differentiated from traditional incubation models by their support for time-limited cohorts of companies rather than individual firms, among other features. This has led to a lot more research on the ecosystem and network building effects of incubators and accelerators. For example, one study found that accelerators positively affected the availability of seed and early-stage venture capital funding for startups in their areas, not just for incubatees. Another found that 40 per cent of early-stage investors had sourced a deal through introductions made by incubator programmes.

### 15.2.4 Distribution of Incubators across India

There is, considerable diversity in the types of incubators in India - from Government-funded Technology Business Incubators to privately funded social innovation specialists - and in the models they use to support entrepreneurs. However, Indian incubators are clustered around hotspots in higher income states. This figure depicts the Indian government-funded incubation landscape.



### 15.2.5 Typical Infrastructure provided by Incubators

The overall space could range from 5,000 sq.ft. to 25,000 sq.ft. depending on the thrust area of the Incubator, number of ventures to be supported, and the requirements of support facility space. The table below gives an indication of venture and support facility space. These are typical figures and can vary with the type of incubator and location.

| No. | Thrust Area                             | Space per Venture                          | Support Facility                                                                                            |
|-----|-----------------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| 1   | <b>ICT / EMBEDDED SOFTWARE</b>          | 150 - 200 sq.ft.<br>Cabin spaces           | Discussion rooms, conference room, shared computing facility, hi-speed Internet with good security features |
| 2   | <b>MANUFACTURING, ENERGY, CLEANTECH</b> | 500 - 1,000 sq.ft.<br>Sheds/<br>Workspaces | Shared common testing and equipment facility (depends on the domain), discussion rooms, conference room     |

|   |                               |                                                      |                                                                                                 |
|---|-------------------------------|------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| 3 | <b>BIOTECHNOLOGY</b>          | 250 - 1,000 sq.ft<br>Lab + Office area               | Wet labs, testing labs, support equipment areas, clean rooms, discussion rooms, conference room |
| 4 | <b>ELECTRONICS / HARDWARE</b> | 150 - 500 sq.ft.<br>Workstation + Office space       | Shared common equipment and testing facilities, discussion rooms, conference room               |
| 5 | <b>MIXED USE</b>              | - 100 - 250 sq.ft.<br>Typically, mostly cabin spaces | Discussion rooms, conference room.                                                              |

### 15.2.6 Types of Incubation Models

Incubators vary in the way they deliver their services, in their organization structure and in the type of clients they serve. The different types of incubation models to support young entrepreneurs prevalent in India is given below –

| No. | Model                       | Typical Features                                                                                                                                                                                                                                                                                                                   |
|-----|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Support-led incubation      | Rolling application process, or one or more application deadlines each year. Tailored, individual support (sometimes alongside group or peer support) provided by staff or external mentors. Sometimes, but not always, time-limited. Seed funding sometimes provided.                                                             |
| 2   | Impact accelerators         | Seed funding sometimes provided. Open, competitive application process. Upfront investment, usually in exchange for equity. Time limited (e.g. three-six months) with intensive support, including events and mentoring. 'Cohorts' of startups, rather than individual companies. Periodic graduation, with Demo Day/Investor Day. |
| 3   | Classic incubator workspace | Rolling application process. Office or desk space and access to shared facilities like meeting space. Strategic advice, coaching or mentoring. Seed funding or opportunities to apply for investment sometimes provided.                                                                                                           |
| 4   | Co-working spaces           | Flexible desk and meeting space. Opportunities to meet other ventures or entrepreneurs. Programme of events or learning.                                                                                                                                                                                                           |
| 5   | Social venture academies    | Modules or training delivered through classes specifically aimed at social entrepreneurs or ventures (but not part of a wider qualification like a degree).                                                                                                                                                                        |
| 6   | Impact angel networks       | Group of high-net-worth individuals looking to invest, sharing cost and process of search and due diligence. Investment, plus mentoring, support and connections.                                                                                                                                                                  |
| 7   | Prizes and competitions     | Widespread publicity for the prize and its aims. Shortlisting by competition organisers. Pitching or face-to-face 'final'. Follow-up support and publicity for the winners.                                                                                                                                                        |

### 15.3 Special Economic Zones

The Special Economic Zones (SEZs) Act came into force in India on February 10, 2006. Although the Indian government conceptualized SEZs way back in 2000, the absence of a SEZ Act was acting as a deterrent to the flow of private investments into the zones.

The philosophy behind SEZs globally is to attract more capital to enhance economic activity in the location and step up exports. Tax sops offered make it a profitable proposition to invest in such ventures. SEZs defined as "specifically delineated duty-free enclave and shall be deemed to be foreign territory for the purposes of trade

operations and duties and tariffs," act as engines for export led economic growth in India. The benefits offered by the government to the developer and the unit-holders through exemptions from all types of taxes and levies have proved to be most conducive and are the force behind private developers to set up and develop SEZs.

As large biopharma and biotech companies are the primary beneficiaries of the SEZs, this topic has not covered in detail for the participants of the workshop for prospective and startup entrepreneurs.

## **15.4 Policy Initiatives**

The Government of India has introduced several initiatives such as setting up Ministry of Skill Development and Entrepreneurship, NITI Aayog and Atal Innovation Mission and initiatives such as 'Startup India', 'Make in India', 'Skill India', 'Digital India' and 'Ease of Doing Business in India' to foster and nurture entrepreneurship and manufacturing in India.

India's first integrated National Policy for Skill Development and Entrepreneurship was launched in 2015. The Policy acknowledges the need for an effective roadmap for promotion of entrepreneurship as the key to a successful skills strategy.

The Vision of the Policy is *"to create an ecosystem of empowerment by Skilling on a large Scale at Speed with high Standards and to promote a culture of innovation based entrepreneurship which can generate wealth and employment so as to ensure Sustainable livelihoods for all citizens in the country"*.

Amongst these initiatives, 'Startup India' Initiative is quite beneficial for the prospective and startup entrepreneurs – participants of this workshop.

### **15.4.1 Startup India Initiative**

'Startup India' is a flagship initiative of the Government of India, intended to build a strong eco-system for nurturing innovation and Startups in the country that will drive sustainable economic growth and generate large scale employment opportunities. The Government through this initiative aims to empower Startups to grow through innovation and design. In order to meet the objectives of the initiative, Government of India has launched an Action Plan on January 16, 2016 to address all aspects of the Startup ecosystem.

With this Action Plan, the Government hopes to accelerate spreading of the Startup movement:

- From digital/ technology sector to a wide array of sectors including agriculture, manufacturing, social sector, healthcare, education, etc.; and
- From existing tier 1 cities to tier 2 and tier 3 cities including semi-urban and rural areas.

The Action Plan covers the following areas for Startups:

1. Simplification and Handholding
2. Funding Support and Incentives
3. Industry-Academia Partnership and Incubation.

### **Startup India “Startup Definition”**

Any Legal entity will be identified as a startup.

1. Till up to five years from the date of incorporation.
2. If its turnover does not exceed 25 crores in the last five financial years.
3. It is working towards innovation, development, deployment, and commercialization of new products, processes, or services driven by technology or intellectual property.

#### ***Points to be remember:-***

A corporation, entity or a business is termed as a start-up if

- The entity is registered under Companies Act, 2013
- It is registered under section 59 of Partnership Act, 1932, as a partnership firm
- Or registered under Limited Liability Partnership Act, 2002, as a limited liability partnership
- Sole Proprietorship Firms are not under the Startup India Scheme.

The Startup Action Plan can be accessed at [www.startupindia.gov.in](http://www.startupindia.gov.in).

## ***Frequently Asked Questions (FAQs) for Startups***

**1. What qualifies as a “Startup” for the purpose of Government schemes?**

An entity (Private Limited Company or Registered Partnership Firm or Limited Liability Partnership) shall be considered a “Startup” – a) Upto 5 years from the date of its incorporation/ registration, and b) If its turnover for any of the financial years has not exceeded INR 25 crore, and c) It is working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property. The entity should not have been formed by splitting up or reconstruction of a business already in existence. A proprietorship or a public limited company is not eligible as startup. A one person company, being a private limited company is entitled to be recognized as a 'startup'.

**2. How does a Startup obtain benefits under various Government schemes including the ones announced in the Action Plan on January 16, 2016?**

For availing various benefits, an entity would be required to be recognized as a Startup by applying on Startup India Mobile App/ Portal. In order to obtain tax benefits, a Startup shall be required to be certified as an eligible business from the Inter-Ministerial Board of Certification. A Startup incorporated between April 1, 2016 and April 1, 2019 shall be eligible to obtain tax benefits proposed under the Section 80 IAC of Finance Act 2016.

**3. For how long would recognition as a “Startup” be valid?**

An entity would cease to be a 'startup' upon expiry of: a) 5 years from the date of its incorporation/ registration, OR b) If its turnover for any of the financial years has exceeded INR 25 crore; OR Startups would be required to intimate DIPP of any such cases within a period of 21 days.

**4. What is the timeframe for obtaining certificate of recognition as a “Startup” in case an entity already exists?**

The certificate of recognition would be issued within one working day upon successful submission of the application with all the necessary documents.

**5. An entity is yet to be registered/ incorporated. Can I visit the Startup India Portal and Mobile App to register/ incorporate my entity as either a Private Limited Company or Registered Partnership Firm or Limited Liability Partnership?**

There are two options available in such cases.

- a) Option 1: An entity can register itself through MCA or Registrar of Firms using the existing processes and subsequently register itself on the Startup India portal and mobile app as a “Startup” to avail the benefits.
- b) Option 2: An entity can register itself through the Startup India portal and mobile app using a seamless process. This facility would be made available in the second phase of the Startup India portal and mobile app launch.

**6. What documents would qualify as a supporting document to the application to register as a “Startup”?**

One of the following documents is required to be uploaded along with the application for registration as a Startup on Startup India portal and mobile app:

- a) recommendation (with regard to innovative nature of business), in a format specified by Department of Industrial Policy and Promotion, from any Incubator established in a post-graduate college in India; or
- b) letter of support by any Incubator which is funded (in relation to the project) from Government of India or any State Government as part of any specified scheme to promote innovation; or
- c) recommendation (with regard to innovative nature of business), in a format specified by Department of Industrial Policy and Promotion, from any Incubator recognized by Government of India; or
- d) Letter of funding of not less than 20 percent in equity by any Incubation Fund/ Angel Fund/ Private Equity Fund/ Accelerator/ Angel Network duly registered with Securities and Exchange Board of India that endorses innovative nature of the

- business. Department of Industrial Policy and Promotion may include any such fund in a negative list for such reasons as it may deem fit; or
- e) Letter of funding by Government of India or any State Government as part of any specified scheme to promote innovation; or
  - f) Patent filed and published in the Journal by the India Patent Office in areas affiliated with the nature of business being promoted.
- 7. If during the Registration process, an applicant marks the response to “Do you want to avail Tax benefits” as “No”, would I be allowed to change the response to “Yes” later?**
- Yes. In such cases, option to opt for such benefits may be indicated at a later stage as well. Once a user opts for availing the benefits, his/ her application would be evaluated by the Inter-Ministerial Board. Once certified by the Board, the benefits may be availed.
- 8. If an entity does not have a PAN. Would I be allowed to register my entity as a “Startup”?**
- Yes. An entity without a PAN can be registered as a Startup. However, it is advised that a valid PAN of the entity is provided at the time of registration, as each entity is separately taxable person.
- 9. What will be the constitution of the Inter-Ministerial Board?**
- The Inter-Ministerial Board of Certification would consist of: a) Joint Secretary, Department of Industrial Policy and Promotion; b) Representative of Department of Science and Technology; and c) Representative of Department of Bio-technology.
- 10. Would a One Person Company (OPC) be eligible to avail benefits under the Startup India initiative?**
- Yes. One Person Companies are eligible to avail benefits under the Startup India initiative.
- 11. Which incubators are authorized to provide a recommendation/ support/ endorsement letter?**
- As per the notification no. G.S.R 180(E) dated February 17, 2016 of the Government of India, an incubator must fall in one of the following categories to be authorized to provide a recommendation/ support/ endorsement letter to an entity: a) Incubator established in a post-graduate college in India b) Incubator funded by Government of India or any State Government as part of any specified scheme to promote innovation c) Incubator recognized by Government of India With regards to (c), an incubator shall be recognized by DIPP on application.
- 12. Is there any prescribed fee(s) that can be charged from the Startups for providing them with a recommendation/ support/ endorsement letter?**
- Yes. A maximum fee of Rs. 5000 can be charged by the incubators for issuing a letter of recommendation to Startups. In cases where an incubator is required to form a panel of external experts to assess the innovativeness of the product/service/process, a maximum fee of Rs.10,000 can be charged by the incubators.
- 13. Which are the bodies and agencies that fall under the category of “Funding Bodies”?**
- As per the notification no. G.S.R 180(E) dated February 17, 2016 of the Government of India, Alternate Investment Funds, Venture Capital Funds, Angel Fund and Seed Funds registered with SEBI will be eligible for providing recommendation/ support/ endorsement letter to entities in which not less than 20 percent equity is taken up by such funds. A list of SEBI registered VCFs and AIFs has been published on Startup India portal.

---

## 16. PREPARING BUSINESS PLAN

---

***“A man who does not plan long ahead will find trouble at his door”  
-Confucius***

The importance of planning should never be overlooked by you. For any business to be successful and profitable, the owners and others involved in the management must have a clear understanding of the firm's customers, strengths and competition. They must also have the foresight to plan for future expansion. Whether it is a new business or an existing business in the process of expanding, money is often an issue. Taking time to create an extensive business plan provides one with the insight into their business.

This chapter will take you through the step-by-step process of developing a business plan. A business plan is very specific to each particular business. However, while each business needs a unique plan, the basic elements are the same in all business plans. To complete an effective business plan you must dedicate time to complete the plan. It requires you to be objective, critical and focused. The finished project is an operating tool to help manage your business and enable you to achieve greater success. The plan also serves as an effective communication tool for financing proposals.

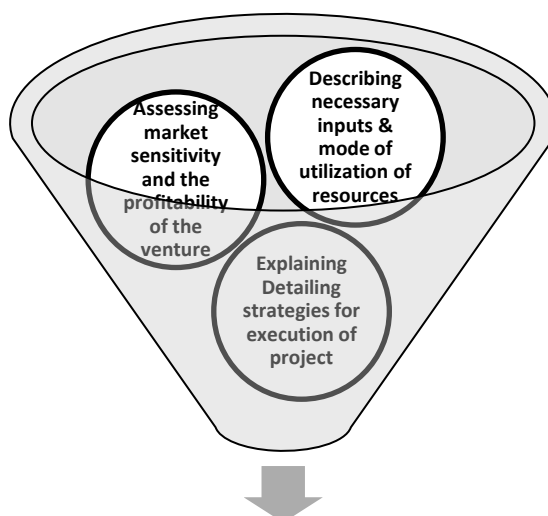
### 16.1 Why Write a Business Plan?

Why should a business go through the trouble of constructing a business plan? There are six major reasons:

- **Promotes Objectivity:** The process of putting a business plan together forces the person preparing the plan to look at the business in an objective and critical manner.
- **Feasibility Study:** It helps to focus ideas and serves as a feasibility study of the business's chances for success and growth.
- **Operational Tool:** The finished report serves as an operational tool to define the company's present status and future possibilities.
- **Better Management:** It can help you manage the business and prepare you for success.
- **Communication:** It is a strong communication tool for the business. It defines various critical factors of the business - purpose, competition, management and personnel. The process of constructing a business plan can be a strong reality check.
- **Financing Proposal:** The finished business plan provides the basis for your financing proposal.

Planning is very important if a business is to survive. By taking an objective look at the business one can identify areas of weakness and strength. One can identify the needs that might have been overlooked, spot problems and resolve them before they escalate, and establish plans to meet the business goals.

## ***Business Plans are Key Decision-making Tools***



The business plan is only useful if it is used. A large percentage of new businesses fail in the first two years. Failure is often attributed to a lack of planning. To enhance chances of success, one must use the plan. A comprehensive, well-constructed business plan can prevent a business from a downward spiral.

Please note that the business plan provides the information needed to communicate with others. This is especially true if financial support is being sought. A thorough business plan will contain the information to serve as a financial proposal and should be accepted by financiers.

The following points should thus be kept in mind while developing a business plan:

- **The target audience:** While working your business plan, keep in mind the intended audience and why you are writing plan. For example, if you are trying to get debt financing, the emphasis should not be on the huge profit potential but on the certainty that the debt can be repaid.
- **Business strategy:** The first part of the business plan should be geared towards helping develop and support solid business strategy. The plan should explain the market, the industry, target customers and competitors. The second half of the business plan should explain how to execute your selected business strategy. Your products, services, marketing and operations should all closely tie in with your strategy.
- **Competition:** As an entrepreneur, you need to identify where you will do things in a manner similar to your competitors and where you will do things differently, what will be your real strengths and real weaknesses. Focus your plan on being different than your competitors'. Think over the points-Can you find a unique strategy? Can you position your products differently? Can you use different sales or marketing vehicles? Your business plan should be able to answer these questions.
- **Be realistic:** So many business plans do not work in the real life as there are always going to be some unseen expenditures, cost overruns, expensive problems and items that you simply overlooked. So forecast realistically and try to have a contingency reserve.
- **Involvement of people for creating the business plan** In seeking funds from banks, venture capitalists or other outside investors, the chances of success

are greater if your management team includes a person whose name carries some weight, to get the plan in synchronized fashion, and to get any disagreements, out in the open. The more input people have in creating the plan, the more responsibility they will feel towards it.

- You should keep your business plan **factual and brief**.

## 16.2 *Formats of Business Plan*

The depth and detail in the business plan depends on the size and scope of the proposed new venture. There is no fixed content for a business plan as it varies according to the entrepreneur's goals and audience (i.e. who are being targeted).

Thus, it is common for especially start-ups to have three or four formats as follows for the same business plan.

- **Elevator pitch:** It is a three minute summary of the business plan's executive summary. This is often used as a teaser to awaken the interest of potential funders, customers, or strategic partners.
- **A pitch deck with oral narrative:** A hopeful, entertaining slide show and oral narrative that is meant to trigger discussion and interest potential investors in reading the written presentation, i.e. the executive summary and a few key graphs showing financial trends and key decision making benchmark.
- **A written presentation for external stakeholders:** A detailed, well written, and pleasingly formatted plan targeted at external stakeholders.
- **An internal operational plan:** A detailed plan describing planning details that are needed by management but may not be of interest to external stakeholders.

## 16.3 *Components of Business Plan*

|   |                       |
|---|-----------------------|
| a | • Executive Summary   |
| b | • Business Venture    |
| c | • Product/Service     |
| d | • Market              |
| e | • Marketing Strategy  |
| f | • Competitor Analysis |
| g | • Marketing Plan      |
| h | • Production Plan     |
| i | • Operational Plan    |
| j | • Manpower Planning   |
| k | • Organizational Plan |
| l | • Financial Plan      |
| m | • Risk Assessment     |

### a) *Executive Summary*

The first page of your business plan should be a persuasive summary that will entice a reader to take the plan seriously and read on. The Executive Summary should follow the cover page, and must not exceed two pages in length.

The summary should include:

- A brief description of the history of the organisation
- The objectives of the organisation
- A brief description of the products or services

- The market the business will compete in
- A persuasive statement as to why and how the business will succeed, discussing the business's competitive advantage
- Projected growth for the company and the market
- A brief description of the key management team
- A description of funding requirements, including a time-line and how the funds will be used.

**b) *Business Venture***

This section of the business plan generally begins with the "mission statement" by the entrepreneur describing the size, scope and nature of the enterprise. What the entrepreneur hopes to accomplish with that business, along with a clear description about the following key elements is covered under project description.

**Site:** Location of enterprise, owned or leasehold land, industrial area, no objection certificate from the Municipal Authorities if required, needs to be determined.

**Physical infrastructure:** Availability of the following items of infrastructure should be mentioned in the business plan.

**Raw material:** Whether indigenous or imported, sources of supply etc.

**Labour:** Type of labour required, provision for their training, number of manpower required etc.

**Utilities:** These include: power, fuel, water, gas, electricity, etc. Business plan needs to clearly state: (a) type of utilities required, (b) load sanctioned (c) sources and quality of water used quantum of coal, coke, oil etc. required and the suppliers of the same.

**Pollution control:** The sewage system, and the sewage treatment plant, water harvesting system, arrangement for dumping and disposing of the other types of waste or emission all need to be discussed in the plan.

**Transport and communication system:** Requirements for transportation and communication facilities, modes and means opted for, bottlenecks etc. are duly covered in by the business plan.

**Machinery and equipments:** A complete list of items of machinery and equipments required indicating their size, capacity, type, cost and sources of their supply should be disclosed.

**Production process:** A mention of the process involved in production, the installed licensed capacity of the plant, the technology to be used, whether available locally or imported, shifts involved, needs to be present in the business plan.

**c) *Product/Service***

It is important to thoroughly understand your product offering or the services you currently provide or plan on providing. It is important to highlight the competitive advantage your product or service has over the competition. Or, if you are entering a new market, you should answer why there is a need for your offering.

If appropriate, discuss any patents, copyrights and trademarks the company currently owns or has recently applied for and discuss any confidential and non-disclosure protection the company has secured.

Discuss any barriers that you face in bringing the product to market, such as government regulations, competing products, high product development costs, the need for manufacturing materials, etc.

Areas that should be covered in this section include:

- Is the product or service already on the market or is it still in the research and development stage?
- If the product is still in the development stage, what is the roll out strategy or timeline to bring the product to market?
- What makes the product or service unique? What competitive advantage does the product or service have over its competition?
- Can the product or service be priced competitively and still maintain a healthy profit margin?

**d) *Market***

Investors look for management teams with a thorough knowledge of their target market. If you are launching a new product, include your marketing research data. If you have existing customers, provide an analysis of who your customers are, their purchasing habits, their buying cycle.

This section of the plan is extremely important, because if there is no need or desire for your product or service there won't be any customers. If a business has no customers, there is no business.

This section of the plan should include:

- A general description of your market
- The niche you plan on capitalizing on and why
- The size of the niche market. Include supporting documentation
- A statement and supporting documentation as to why you believe there is a need for your product or offering by this market
- What percentage of the market do you project you can capture?
- What is the growth potential of the market? Include supporting documentation
- Will your share of the market increase or decrease as the market grows?
- How will you satisfy the growth of the market?
- How will you price your goods or services in the growing competitive market?

**e) *Marketing Strategy***

Once you have identified who your market is, you'll need to explain your strategy for reaching the market and distributing your product or service. Potential investors will look at this section carefully to make sure there is a viable method to reach the target market identified at a price point that makes sense.

Analyse your competitors' marketing strategies to learn how they reach the market. If their strategy is working, consider adopting a similar plan. If there is room for improvement -- work on creating an innovative plan that will position your product or service in the minds of your potential customers. The most effective marketing strategies typically integrate multiple mediums or promotional strategies to reach the market. The following are some promotional options to consider.

- TV
- Radio
- Print
- Web
- Direct mail

- Trade shows
- Public relations
- Promotional materials
- Telephone sales
- One-on-one sales
- Strategic alliances.

If you have current samples of marketing materials or strategies that have proved successful, make sure you include them with your plan.

Developing an innovative marketing plan is critical to your company's success. Investors look favourably upon creative strategies that will put your product or service in front of potential customers. Spend time developing this section.

Once you have identified how you will reach the market, discuss in detail your strategy for distributing the product or service to your customers. Will you mail order, personally deliver; hire sales representatives, contract with distributors or resellers, etc.?

#### **f) *Competitor Analysis***

Understanding your competition's strengths and weaknesses is critical for establishing your product's or service's competitive advantage. If you find a competitor is struggling, you need to know why, so you don't make the same mistake. If your competitors are highly successful, you'll want to identify why. You'll also want to explain why there is room for another player in the market.

Specific areas to address in this section are:

1. Identify your closest competitors. Where are they located? What are their revenues? How long have they been in business?
2. Define their target market.
3. What percentage of the market do they currently have?
4. How do your operations differ from your competition? What do they do well? Where is there room for improvement?
5. In what ways is your business superior to the competition?
6. How is their business doing? Is it growing? Is it scaling back?
7. How are their operations similar to yours and how do they differ?
8. Are there certain areas of the business where the competition surpasses you? If so, what are those areas and how do you plan on compensating?

Analysing your competitors should be an ongoing practice. Knowing your competition will allow you to become more motivated to succeed, efficient and effective in the marketplace.

#### **g) *Marketing Plan***

This section goes beyond the production process by describing the market conditions and strategies related to how:

- a) Products/services will be distributed
- b) Priced
- c) Promoted.

This valuable document is a guideline regarding the marketing objectives, strategies and activities to be followed by the new enterprise. The marketing plan represents a significant element in the business plan for a new venture as it effectively establishes how the entrepreneur will complete and operate in the market place by providing answers to three basic questions:

**1) Where have we been?**

This segment focuses on:

- Some history of the market place,
- Marketing strengths and weaknesses of the new venture,
- Market opportunities and threats.

**2) Where do we want to go?**

- This primarily addresses the marketing objectives and goals of the enterprise in the next 12 months.

**3) How do we get there?**

This question discusses:

- the specific marketing strategy that will be implemented,
- when it will occur,
- who will be responsible for the monitoring of activities.

Normally, each year the entrepreneur should prepare an annual marketing plan so as to gel well with the changing business environment and its forces.

**Steps in preparing the Marketing Plan**

Potential investors regard the marketing plan as critical to the success of the new venture. Thus, the entrepreneur should make every effort to prepare it as comprehensive and detailed. Generally, procedure for preparing the marketing plan involves following steps:

**i) Business situation analysis**

'Where we have been?' – is the question responded to as the first step in designing the marketing plan. Mostly a review of past performance and achievements of the enterprise are stated here in but for a new venture, focus shifts rather towards:

- o Personal profile of the entrepreneur
- o Emphasis on products development
- o What 'need' it satisfies
- o Any other enterprise/experience of the entrepreneur
- o Any marketing segmentation, if planned.

**ii) Identify the target market**

For a new venture, it's very essential to define clearly the specific group of potential customers whose needs the enterprise aims to fulfil. This identification of the "target market" is pretty tedious task as it involves:

- a) Deciding what the general market or industry entrepreneur wishes to pursue is based, on market research or industry analysis done and complied with by competent people or the entrepreneurs.
- b) Divide the market into smaller groups based on:
  - i) Consumer's characteristics viz.
    - o Geographic (State, Country etc.)
    - o Demographic (Sex, age, etc.)
    - o Psychographics (Personality, life style, etc.).
  - ii) Buying situations viz.
    - o Buying conditions (time available etc.)
    - o Usage
    - o Desired benefits (features of product).

- c) Select segment or segments to target.
- d) Develop a marketing plan integrating according to product, price, distribution, promotion.

**iii) Conduct SWOT analysis**

It is important for the entrepreneur to consider in the 'target market' his/her enterprise's:

- Strengths
- Weaknesses
- Opportunities
- Threats

Marketing plan needs to consider the strengths and weaknesses of the new venture to ensure its success.

**iv) Establish goals**

"Where do we want to go?" is answered well by establishing –

- Realistic, attainable and well defined goals and objectives for the enterprises
- Quantifying the goals so that they could be measured for control purposes
- Setting standards to measure those goals which are qualitative in nature
- Limiting the goals to a specific number so that there are no chaos, confusions or overlapping. Otherwise, even controlling and monitoring will be difficult.

**v) Define marketing strategy**

"How do we get there?" demands specific activities to be outlined to meet the enterprise's so established goals and objectives. The marketing strategy and action plan comprise of decisions pertaining to the following 4 P's:

a) Product b) Price c) Promotion d) Place.

**vi) Implementation and monitoring of the plan**

Evolving a marketing plan is not a mere formality. It is meant to be a commitment by the entrepreneur to a specific strategy. It is important for the entrepreneur to be flexible and be prepared to make adjustments if necessary in the plan.

**h) Production Plan**

Production, the most important activity of an enterprise, because it is here that transformation of raw material into finished product takes place with the help of energy, capital, manpower and machinery. Being highly complex and tedious, the manufacturing operation needs to be well planned. No doubt it will be nature of venture which will decide the magnitude of importance and disclosure required under the production plan. Most likely there are three situations before the venture viz.

- No manufacturing involved: If the new venture does not include any manufacturing function, say it's a trading firm or a service provider, then this section will stand eliminated from the plan.
- Partial manufacturing: If some or all the manufacturing process is to be subcontracted or outsourced, then the production plan should describe:
  - i) Name and location of subcontractor(s)
  - ii) Reasons for their selection

- iii) Cost and time involved
- iv) Any contracts that have been completed etc.

In such cases, a clear mention of what entrepreneur intends to do himself and what he plans to get it done from outside is required.

- Complete Manufacturing: If the manufacturing is to be carried out in whole by the entrepreneur, he/she will need to describe:
  - i) Physical plant layout,
  - ii) Machinery and equipment required to perform the manufacturing operations
  - iii) Raw materials and suppliers names, addresses, terms and conditions,
  - iv) Cost of manufacturing
  - v) Any future capital equipment required etc.

"Picturing ahead every step in a long series of separate operations, each step to be taken in the right place of the right degree, and at the right time and each operation to be done at maximum efficiency", quoted Alford and Beathy, is the objective of a production plan.

Hence, a production plan helps to plan the work in such a manner that one can clearly form an idea about:

- a) Production schedule and/or budget
- b) Machinery, equipment requirement
- c) Manufacturing method and process involved
- d) Plant layout
- e) Time, motion and work study
- f) Manpower requirement
- g) Inventory requirement.

#### **i) Operational Plan**

Where the production plan aims at "plan your work", there operations plan ensures "work your plan". It is actually a blue print prepared right in advance of actual operations -

- Ensuing orderly flow of materials in the manufacturing process from the beginning (raw state) to the end (the finished products)
- Facilitating continuous production, lesser work-in-progress and minimization of wastage
- Coordinating the work of engineering, purchasing, production, selling and inventory management
- Describing the flow of goods / services from production point to the consumers
- Introducing a proper system of quality control
- Undertaking the best and most economic production policies and methods.

Thus, the operational plan organizes for the movement of material, performance of machines and operations of labour, however sub-divided, into a defined direction, coordinating for desired manufacturing results in terms of:

- Quantity
- Quality
- Time
- Place and
- Cost.

**Elements of operational plan:**

The operation plan, in a way is planning:

- For production in advance of operations
- Establishing the exact route of each individual item, part of assembly
- Setting starting and finishing dates for each important assignment/work
- Regulating the orderly movement of goods through the entire manufacturing cycle i.e. right from procurement of all materials to the shipping of finished goods.

**j) *Manpower Planning***

Every organisation comes into existence when a number of persons join hands. All these people work to achieve the organizational goals set by the entrepreneur. Human resource is of paramount importance for the success of any organisation.

An organisation's performance and resulting productivity are directly proportional to the quantity and quality of its manpower. Thus, the best assurance that the enterprise will flourish, requires the entrepreneur to properly plan out for a rich and continuous supply of qualified personnel. In order to build up loyal, efficient and dedicated personnel, entrepreneur needs to pay adequate and proper attention to human resource planning.

This planning is a process by which an entrepreneur ensures that he/she has the right number of people, and the right kind of people with appropriate skills, at the right place and the right time to do work for which they are economically most suitable. Manpower planning thus helps to assess:

- **What kind of people are required?**

To carry on its work, each organisation needs personnel with the necessary qualifications, skills, knowledge, experience and aptitude for work.

Thus, as the most basic thing, the entrepreneur must clearly state: (a) what kind/type of person is required to be hired for getting his work done. (b) as each person would have a different positions, duties and responsibilities, it becomes imperative for the entrepreneur to clearly workout a wide range of personnel ranging from managers, supervisors, administrators, engineers, technical, skilled and unskilled class. (c) Nature of business activity helps entrepreneur to a large extent in deciding the type of manpower required.

- **How many people are required?**

This question deals with the quantity of personnel the enterprise needs. The number of people required for various positions throughout the enterprise gets affected by:

- o The total work to be done
- o How much work can an average person do in a specified time period?
- o Level of absenteeism expected.
- o Rate of labour turnover
- o The present number of employees
- o The future plans for expansion and diversification.

- **How to procure personnel?**

As the next step in manpower planning, entrepreneur clearly mentions the strategies, methods, policies, rules and regulations pertaining to personnel:

- o Recruitment
- o Selection
- o Training.

Procurement of "right person, at right job, at right time" is the objective of human resource plan.

### **The Management Team**

For most investors the experience and quality of the management team is the most important aspect they evaluate when investing in a company. Investors must feel confident that the management team knows its market, product and has the ability to implement the plan. In essence, your plan must communicate management's capabilities in obtaining the objectives outlined in the plan. If this area is lacking, your chances for obtaining financing are bleak.

If your team lacks in a critical area, identify how you plan on compensating for the void. Whether it is additional training required or additional management staff needed, show that you know the problem exists, and provide your options for solutions.

When preparing this section of the business plan you should address the following five areas:

1. Personal history of the principals:
  - a. Business background of the principals
  - b. Past experience -- tracking successes, responsibilities and capabilities
  - c. Educational background (formal and informal)
  - d. Personal data: age, current address, past addresses, interests, education, special abilities, reasons for entering into a business
  - e. Personal financial statement with supporting documentation.
2. Work experience:
  - a. Direct operational and managerial experience in this type of business
  - b. Indirect managerial experiences
3. Duties and responsibilities:
  - a. Who will do what and why
  - b. Organisational chart with chain of command and listing of duties
  - c. Who is responsible for the final decisions?
4. Salaries and benefits:
  - a. A simple statement of what management will be paid by position
  - b. Listing of bonuses in realistic terms
  - c. Benefits (medical, life insurance, disability...)
5. Resources available to your business:
  - a. Insurance broker(s)
  - b. Lawyer
  - c. Accountant
  - d. Consulting group(s)
  - e. Small Business Association
  - f. Local business information centres
  - g. Chambers of Commerce
  - h. Local colleges and universities
  - i. Federal, state, and local agencies
  - j. Board of Directors
  - k. World Wide Web (various search engines)
  - l. Banker

## **Personnel**

The success of a business can often be measured by its employees. A large percentage of consumers will go elsewhere if they don't receive prompt and courteous service. You must consider the following questions in completing this section of the business plan:

- What are your current personnel needs (full or part-time)? How many employees do you envision in the near future and then in the next three to five years?
- What skills must your employees have? What will their job descriptions be?
- Are the people you need readily available and how will you attract them?
- Will you be paying salaries or hourly wages?
- Will there be benefits? If so, what will they be and at what cost?
- Will you pay overtime?

### **k) Organizational Plan**

You may start any kind of business, but surprisingly, all of them will fall into one of the four basic categories:

- Manufacturing – a business that makes a tangible product
- Wholesale – a business that buys products in bulk from the manufacturers to be sold in smaller lot to retailers
- Retail – a business that sells directly to the final consumer for final satisfaction
- Service – a business that sells intangible such as time or expertise.

Thus, the organizational plan is that part of the business plan that describes the proposed venture's form of ownership. Each type of business differs significantly in terms of:

- Commencement procedures
- Legal constraints
- Financial requirement
- Accounting methods
- Marketing and promotional strategies
- Risk and liability.

That's why it is important to be able to categorise the business first and then to carefully choose a legal structure for it. As already dealt in detail in the beginning of the chapter, the entrepreneur have access to following forms to choose from to start his/her venture:

- a) Sole proprietorship
- b) Partnership
- c) Joint Hindu family
- d) Cooperative, or
- e) Corporation.

We know, each of these forms has important implications on (i) Taxes (ii) Liability (iii) Continuity (iv) Financing (v) Ownership. You are already familiar with the merits and demerits associated with the different forms of organisation. No form is the best form.

Entrepreneur in light of multiple factors (as already discussed) decides the legal structure, best suited to attain his/her dream. Thus, the organizational plan is that part of the business plan that describes the proposed venture's opted form of ownership adequately mentioning:

- i) Terms and conditions associated with the selected form
- ii) Lines of authority and responsibility of members of the new venture
- iii) Names, designation, addresses and resumes of the members
- iv) Stake of members in the organisation
- v) Roles and responsibilities of each member
- vi) Procedure for solving conflicts/disputes amongst members
- vii) Forms of payment for the members of the organisation
- viii) Voting rights, managerial and controlling rights of the members.

All this information provides the potential investor with a clear understanding of who controls the organisation and how other members will interact in performing their management functions.

As it is important to begin the new venture with a strong management team, committed to the goals of the enterprise, it is the organizational plan that helps the entrepreneur to carefully evaluate and decide that legal structure for his organization that could affect :

- Long-term effectiveness of the enterprise, and
- Profitability.

To conclude, both the entrepreneur and the potential investors stands to gain from the organizational plan as the design of the organization so opted helps even in:

- Specifying the types of skills needed and the roles that must be filled by the members i.e. helps to decide the enterprise's formal organisation, and
- Representing the attitudes, behaviours, dress, communication styles etc., thus chalking out informal organisation or culture.

### **1) *Financial Plan***

Finance is one of the most important pre-requisites to establish an enterprise. Availability of finance facilitates the entrepreneur to bring together men, material, machines and methods to produce goods/services. As timely availability of funds in right volume is key to entrepreneurial success, the entrepreneur should develop a sound financial plan discussing:

- a) Financial requirements
- b) Sources of raising funds
- c) Exact assessment of the revenue, cost, profits, cash flow dynamics, stock of inventory, loans etc.

A Financial plan is a projection of key financial data about:

- The potential investment commitment needed for the new venture, and
- Economic feasibility of the enterprise.

To simplify, the financial plan is so designed that the entrepreneur and the investors could have a clear picture of:

- How much funds are required?
- Where will funds come from?
- How are they disbursed?

- The amount of cash available
- General financial well-being of the new venture i.e. probable revenue forecast for the first year at least.

As the financial plan must explain to any potential investor how the entrepreneur plans to meet all financial obligations and maintain its liquidity in order to either pay off debt or provide good return on investment, several financial projection techniques and tools are made use of by the entrepreneur. In general, the financial plan will need three years of projected financial data to satisfy any outside investors.

### **Components of financial plan**

Major financial items that should be included in the financial plan are:

- Proforma investment decisions
- Proforma financing decisions
- Proforma income statements
- Proforma cash flow
- Proforma balance sheet
- Break-even analysis
- Economic and social variables.

#### **A) Proforma investment decisions:**

This part of financial plan relates to how the enterprise's funds are invested in different assets so that the enterprise is able to earn the highest possible returns on investment. An estimate of various components of capital nature i.e. fixed assets and of working capital should be clearly mentioned in this part of business plan. Carefully, clearly and sequentially the entrepreneur should mention investment required in for:

- Land and building
- Machinery and plant
- Installation cost
- Preliminary expenses
- Margin for working capital
- Expenses on research and development
- Investment in short-term assets viz. raw material, level of cash, etc.

This part helps to understand the total amount of finance required by the entrepreneur. Inadequate funds or excess funds, both have the capacity to severely damage the financial fortune of a business. Therefore, these decisions must be taken with utmost care.

#### **B) Proforma financing decisions**

This section summarizes all the projected sources of funds available to the venture to raise finance from, which you have already studied in previous class. Typically, sources of funds are:

- Owners i.e. Owner's funds
- Outsiders i.e. Borrowed funds

The entrepreneur's job is to ensure the selection of the best overall mix of financing for the enterprise so that:

- The cost of capital and the financial risk stands minimized
- Return on investment and profitability stands maximized.

**C) Proforma income statement**

The proforma income statement is the projected net profit calculated from projected revenue minus projected costs and expenses. Basically, it summarizes all the profit data during the first year of operations of the new enterprises. In preparing the proforma income statement, 'sales by month' must be calculated first, making use of forecasting techniques as the basis. Following are the most commonly adopted techniques for forecasting:

- Marketing research
- Industry sales
- Survey of buyers' intentions
- Expert opinions
- Financial data on similar start-ups
- Some trial experience of self or others.

While calculating the projected sales and expenses, it is not important to be conservative for initial planning purposes. A reasonable profit that is earned with conservative estimates lends credibility to the potential success of the new venture.

**D) Proforma cash flow**

Profit and cash flow are not the same, when from sales we subtract expenses, the result is profit and when from cash receipts we subtract cash payments, the resultant figure is the cash flow. Proforma cash flow reflects the projected cash available with the enterprise as a result of subtracting projected cash disbursements from projected cash accumulations. Cash flows only when actual payments are received or made. Mere sale which might be on credit, will not generate cash. Similarly, all bills are not paid immediately by the enterprises. For simplification and internal monitoring of cash flow purposes, many new entrepreneurs prefer a simple determination of "Cash in LESS cash out", giving them a fast indication of cash position.

The entrepreneurs find it difficult to project cash flows as determining the exact monthly receipts and disbursement is not so easy. Thus, while working out the cash flows, an entrepreneur normally follows a conservative approach, making some necessary assumptions so that enough funds could be maintained to cover the negative cash months.

**E) Proforma balance sheet**

This document helps the enterprise to reflect the position of the business at the end of its first year. A summary of the projected assets, liabilities and net worth of the entrepreneur is depicted through proforma balance sheet.

**F) Break-even point**

Every firm wants to maximise its profits. The Breakeven point is that level of volume of production at which firm neither makes a profit nor a loss. Here, the total revenue is equal to the total cost of a firm, at the given level of capacity.

Thus, calculation of break-even point is quite useful for the entrepreneur as it helps in assessing:

- The minimum level of output to be produced.
- The effect of change in quantity of output upon the profits.

- The selling price of the product.
- The profitable options in line of production.

Thus, the break-even analysis is a useful technique for determining how many units must be sold or how much sales volume must be achieved in order to break-even. It helps to indicate the volume of sales needed to cover total variable and fixed expenses by the new enterprise.

**G) Economic and social variables**

In view of the social responsibility of business, the abatement costs, i.e. the cost of controlling the environmental damage should also be stated in the plan. It's always advisable to mention in the business plan, the socio-economic benefits expected to acquire from the proposed investment like:

- Employment generation
- Import substitution
- Ancillarisation
- Export promotion
- Local resource utilization
- Development of the area

Wherever, it is not possible to quantify the expected benefits, they should be analyzed and their importance emphasized.

**m) Risk Assessment**

There are some hazards, risks, or/and obstacles always present in the competitive environment. In a business plan, entrepreneur should:

- 1) Identify potential hazards
- 2) Develop alternative strategies to either prevent minimize or respond to the risk.

\*\*\*\*\*

---

# REFERENCES

---

1. Innovation and Entrepreneurship in Biotechnology – An International Perspective Concepts, Theories and Cases  
Damian Hine (Senior Lecturer, University of Queensland, Australia) John Kapeleris (Deputy CEO, Australian Institute for Commercialisation, Brisbane, Australia) 2006
2. The Business of Biosciences – What makes a biotech entrepreneur?  
Springer <http://www.springer.com/978-1-4419-0063-0> 2009
3. Building a conducive environment for life science–based entrepreneurship and industry clusters  
Mark J. Ahn and Michael Meeks, Journal of Commercial Biotechnology. Vol 14. No 1. 20–30 January 2008
4. Critical success factors for biotechnology industry in Canada  
Sandra Vanderbyl and Sherry Kobelak, Journal of Commercial Biotechnology. Vol 13. No 2. 68–77 February 2007
5. Report of the Expert Committee on Innovation and Entrepreneurship  
NITI Aayog, New Delhi, August 2015
6. Fuelling Entrepreneurship – The Story Of Technology Business Incubation In India  
National Science and Technology Entrepreneurship Development Board (Nstedb)
7. India is the nesting ground for young entrepreneurs and new start-ups  
Nikita Agarwal International Journal of Applied Research 2015; 1(7): 578-582
8. Creating And Safeguarding A Strong Intellectual Property Portfolio  
SIDBI, 2015
9. Managing Ideas: Commercialization Strategies for Biotechnology  
Joshua S. Gans and Scott Stern – Melbourne Business School, University of Melbourne (Gans), Kellogg School of Management, Brookings (Stern)
10. National Biotechnology Development Strategy – Promoting bioscience research, education and entrepreneurship  
Department of Biotechnology, Ministry of Science & Technology, Government of India, 2015
11. Good Incubation In India – Strategies for supporting social enterprise in challenging contexts  
Madeleine Gabriel, Florence Engasser and Kirsten Bound, January 2016
12. Entrepreneurship  
A study by National Knowledge Commission, 2008
13. Startup India Action Plan  
<https://www.startupindia.gov.in/actionplan.php>

14. Strategic management aspects of Indian pharmaceutical industry  
Ritu Mahajan & Keshav Sharma, Asian Journal of Management Research Volume 2  
Issue 1, 2011
15. The Entrepreneurship Guide to a Biotech Startup  
Peter Kolchinsky, 2001
16. India Brand Equity Foundation  
<https://www.ibef.org/>
17. Ministry of Skill Development And Entrepreneurship  
<http://www.skilldevelopment.gov.in/#>
18. Department of Science and Technology  
<http://www.dst.gov.in/>
19. Department of Biotechnology; Ministry of Science and Technology  
<http://www.dbtindia.nic.in/#>
20. Biotechnology Industry Research Assistance Council  
<http://www.birac.nic.in/>
21. National Institution for Transforming India, Government of India  
<http://niti.gov.in/#>
22. National Science and Technology Entrepreneurship Development  
<http://www.nstedb.com/>
23. Council of Scientific & Industrial Research  
<http://csirhrdg.res.in/>
24. Indian Council of Agricultural Research (Ministry of Agriculture and Farmers Welfare)  
<http://www.icar.org.in/>
25. Indian Council of Medical Research  
<http://www.icmr.nic.in/>
26. Ministry of Micro, Small & Medium Enterprises  
<http://msme.gov.in/>
27. Department of Industrial Policy & Promotion  
<http://dipp.nic.in/#>
28. BioSpectrum Asia Edition  
<https://www.biospectrumasia.com/>
29. BioSpectrum India  
<https://www.biospectrumindia.com/>