Mapping Key Areas in Biopharmaceuticals

A Discussion Paper, 2013






Sector Brief

Indian economy has several challenges at its doorstep and one of the silver linings is that India stands at the threshold of Innovation; where Biotechnology remains as a definite solution for a myriad of concerns being faced at national and global level.

The Biotechnology sector is among one of the sectors which have highlighted the profile of the country in the last decade. At the beginning of the decade itself, this industry began to take shape with the sprouting of dozens of start-up innovation companies as well as the diversification of established Pharma players by setting up biotech divisions, to focus on this segment. A lot of significant developments have taken place in the sector since.

Growing at a CAGR of 20 percent, the Indian Biotechnology Industry has evolved rapidly over the last three decades. As per the 11th Annual Indian Biotech Industry survey by *Biospectrum*; the Indian Biotech Industry has grown by 15.1 % in 2012-13, increasing the market's revenues to US$ 3.31 Billion to US$ 3.81 Billion.

With numerous comparative advantages in terms of research and development (R&D) facilities, knowledge, skills, and cost effectiveness, the biotechnology industry in India has immense potential to emerge as a global key player. The next coming years and beyond, India will have to identify the major focus areas in the Biotech sector and come up with a constructive roadmap for the industry, which would move the engines of innovation and generate revenue of US $100 Billion by 2025.

The Indian Biotechnology sector comprises of the following segments:

1. ***BioPharma***
2. ***BioServices***
3. ***BioAgriculture***
4. ***BioIndustrial***
5. ***BioInformatics***

The Indian Biopharmaceutical segment holds the largest market share in the Biotech Industry in India and continues to grab the highest share of the entire Biotechnology sector. This sector invests in innovative product development and clearly a lot of companies see more value in ramping up their service offerings even as they try to master the technological, financial and regulatory challenges, before they are able to offer cutting edge drugs in the market place.

Comprising primarily of Biologics (Biosimilars), Vaccines, Diagnostics, and Stem Cells; the Biopharmaceutical Industry has made great strides in the healthcare related challenges that India presently faces. Over the 5 years the Biopharmaceutical sector has witnessed quite a modest growth in terms of revenue and a few key findings of the sector that will be shaping up the comprehensive establishment of this sector are as follows:

- Growth in India is primarily export-driven: The exports of the Indian biopharmaceuticals have been on a rise since 2010, on the other note domestic sales of Indian biopharmaceutical products have risen only 4-5% per annum in the past two years.
- Industry growth is concentrated in a relatively small number of companies
- Indian Companies manufacture an increasingly wide range of biopharmaceutical products
- Vaccines are the fastest growing sector in the Biopharmaceuticals Industry

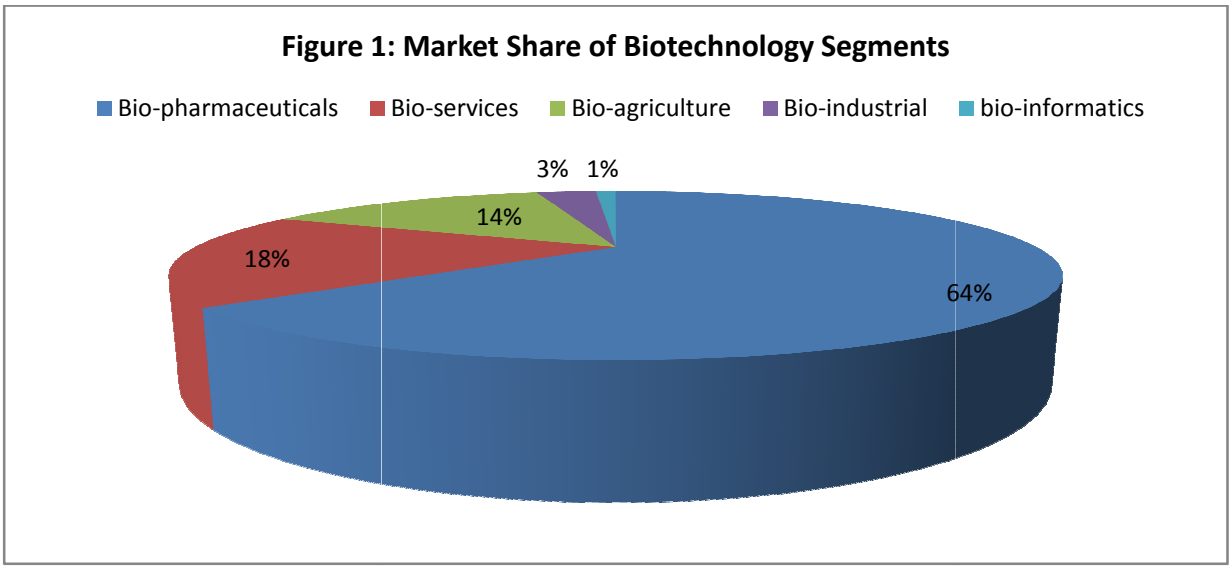


Figure 1: Market Share of Biotechnology Segments

The three major identified areas in the Biotech Sector, which are of importance, are:

- ❖ Biologics: Novel Biologics, Similar Biologics/Biosimilars, Bio Equivalents, Bio Betters
- ❖ Vaccines
- ❖ Cell-based therapies: Stem Cells

Biologics: Biologics is a vast segment that includes novel biological drugs, biosimilars, bio equals, and biobetters. Compared to chemical drugs, there is a continuous increase in biological drugs, which are mostly large molecules and propose specific advantages compared to chemical drugs. There are a number of companies in India involved in novel biologicals development for a variety of disease areas. At the same time, there are many Indian firms involved in development of biosimilars, including bioequals and biobetters, which makes up for a substantial market share in Pharma. It is a known fact that with the upcoming patent cliff in the field of biological drugs, India is globally regarded as having

great potential to become a significant player in the development and commercialization of biosimilars despite facing challenges on the ground. However, it remains to be seen whether India will capitalize on its strengths and emerge as a dominant global manufacturer of biosimilars.

Vaccines: Public health consciousness and economic perspectives have automatically enhanced the importance of vaccines world over. While vaccines have proven the single most cost effective means of controlling the spread of infectious diseases, there is a need for effective, affordable vaccines for a wide variety of potentially preventable infections. This is especially true for diseases such as HIV/AIDS, tuberculosis, malaria, and dengue fever that disproportionately affect the resource poor countries. Existing vaccines that have dramatically reduced the burden of infectious diseases in wealthy countries are often not accessible in the developing world because of the costs associated with manufacturing, delivering and administering these vaccines.

India has made significant strides in vaccines and has been one of the major players in affordable vaccine development and a resource for the global market. However, market study suggests that it hasn't hit its peak still due to some regulatory and supply chain issues, including cold storage. Government support to vaccine firms on these crucial aspects could facilitate their further growth.

With the increase in disposable incomes and the launch of new affordable vaccines by both domestic and international companies, the vaccine market is predicted to grow at a rate of 10-13 percent in the next five years. The Indian Vaccines market in 2012 remained small and under-penetrated with access much lower than in other parts of the world with a value of USD 500 million. *(Source: Transforming India's Vaccine Market, report by OPPI and Mc Kinsey& Company, 2012)*

Cell-based therapies: Cell-based therapeutic research has begun to show significant potential in treatment of variety of diseases including neurodegenerative diseases, cardiac diseases, skin burns, locomotive diseases etc. At the base of this are ***Stem cells***, which have potential to grow into specific cells leading to generation tissues and organ, the phenomenon being championed in laboratories now for therapeutic intervention. This has potential to treat chronic fatigue, stress and anxiety, insomnia, memory problems, Parkinson's disease, rheumatoid arthritis, multiple sclerosis, hepatitis, dermatomyositis, psoriasis, muscular dystrophy and even autism. Stem cells are also used for research and therapy in the areas of liver, pancreas, neurological and cardiological disorders, and ailments related to bones and cartilages.

With so much of potential in the field, India faces a big challenge in terms of clarity for stem cell research, as proper guidelines for stem cell research have not been enforced legally leading to confusion among researchers, common public as well as doctors. This has led to many research companies opting to carry out research and clinical trials in other countries, which is a great loss for India. At the same time, lack of structured regulation and implementation, has allowed malpractices in the field and even at clinic level. This needs to be addressed immediately.

Therefore, it is a must that to have a proper regulatory system in place which would prove to be a major milestone in the history of the stem cell industry in India and also towards minimizing potential side effects or harm to patients.

Focus Areas Identified by FICCI for Leveraging Opportunities in Biopharmaceuticals

➢ Regulations

A strong science-based sector needs to have a **streamlined, transparent and flexible-yet professional regulatory and monitoring system** to be a guiding force for growth. The Indian Biopharmaceutical regulatory system has seen a lot of changes and structure over the last 10 years, but there seems to be room to shape it further to take on challenges and face tough competition to achieve global recognition. A clear regulatory framework would also be able to address the Invention and Discoveries in the area of Biotechnology in a more inclusive manner.

The Government of India can ensure that the format, content and interpretation of all such regulations is common throughout the country and introduce a single window system for securing all clearances and approvals from the various central and state agencies.

1. **Regulatory Framework:** India is emerging as one of the global destinations for Biopharmaceuticals, especially the **Biosimilars** and **Cell-based Therapeutics**, including stem-cell research and regenerative medicine. While these are two distinctly important segments of Biopharmaceutical segment, the inadequacy of structured regulatory guidelines lead to not only additional efforts of Indian companies in these domains to obtain regulatory clearances but apprehension of international firms to collaborate with Indian firms.

   The Biosimilar regulations are going through major changes with both industry and companies attempting to interpret the inadequately defined regulatory guidelines. There are differences in the interpretation and these can best be addressed if Review Committee on Genetic Manipulation (RCGM) and DCG(I) could both have

"SCIENTIFIC CONSULTATION" on the lines of FDA and EMA (European Medicines Agency) manned by personnel familiar with the technologies and a mission to "guide" the industry.

2. **Infrastructure and Compliance:** In order to meet the global standards Indian Industry by and large has to adopt principles of Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) to become global players. A well-defined manufacturing process with its associated process controls, assures that an acceptable product is produced on a consistent basis in accordance with Good Manufacturing Practice (GMP).

   To enter global markets, more thrust has to be given to achieve global accreditation, which will eventually bring the Indian companies more and more into global business platform. The industry platforms for biotech companies in close coordination with the Government of India can help the industry in better consultation regarding regulations and also help create a better infrastructure for drug discovery.

3. **Quality and Safety:** One of the major challenges that the Indian Biopharmaceutical industry faces, is the ongoing questions surrounding product quality and safety. Owing to affordability and easy accessibility, biosimilars have established a good reputation among healthcare professionals. Though biosimilars are gaining popularity in national and international markets, it is important to remember that the biosimilars are not biological generics. In India, these are supported by only limited clinical data at the time of approval. Therefore, there are concerns regarding their efficacy, long-term safety and immunogenicity.

   It is imperative for the Industry to ensure quality and safety in its product since a biosimilar or a Biologic consists of Biological matter. Thus, rigorous evaluations at every stage of processing and checks have to be incorporated.Unlike chemical generics; the biosimilars require more stringent criteria for the evaluation of quality, safety and efficacy.

   Very soon the Biotechnological medicines shall become an important part of future healthcare landscape. With patent expiration of innovator products, the biosimilars will increasingly become available. Awareness of the deviations between biosimilars and innovator products in terms of efficacy, safety and immunogenicity is essential for proper prescription and safety of the patients.

4. **Supply Chain Issues:** Indian biologics manufacturers still depend on global suppliers for input materials such as fermentation vats and other necessary technologies. Therefore the cost of goods on material inputs remains the same globally though the

cost of labour is lower in India. The supplier base in India remains negligible. *(Source: ABLE Report on Indian Biotechnology, the Roadmap to the Next Decade and Beyond, 2012).* Furthermore, creating and strengthening a local supplier base is very essential to bring down the cost of the input material. The medium term goal should be to incentivize local suppliers of equipment that are needed to set up manufacturing of biologics or biosimilars.

- **Focus on the Venture Funding and the Financial System**

To become a major global player, Indian biotech companies require more venture funding to nurture and catalyze their globally competitive products and services across the globe. There are several entry barriers for many companies in the field of Biopharmaceuticals. First and foremost are the financial resources that are required for the growth of the sector. The Indian industry gives the impression of being **conservative to risk**. This to an extent stems from the reluctance that banks and private investors demonstrate while investing in biotech ventures.

Keeping in mind that several blockbuster biologics are going off-patent in a few years, there have been many start-up and mid-size firms who have put their efforts to enter and be part of the open market. Some of these companies, as of today, are in their first 2-4 years of operations. At the same time, there are also a number of companies who are looking at novel biological products for therapeutic applications. For such early and mid-size companies the funds come from their own resources or sometimes small ignition funds from govt. some venture funding in India and abroad. However, these funds are not sufficient and hence, the funds are serious constraint for the biotech industry. It is known fact that it takes minimum five to six years for a start up engaged in production of similar biologics to move from pilot to lab scale to reach the commercialization stage and without sufficient funds the promotion of the biopharma products through innovation becomes difficult.

Tax incentives are critical for fostering biopharma manufacturing as it needs substantial capital incentives. GOI may provide tax holidays to biologics/biosimilars manufacturing firms. These tax holidays should kick in only when the manufacturing site has been registered and successfully received approval from USFDA/EMEA.

Angel investments for companies that are focussed purely on research with a revenue model to stem out of their product or technology 7-8 years down the line is quite a task to find in India. International competition makes it critical for India to innovate technology rather than catch up on innovative technology, which makes funding at an early stage of the idea critical. Concepts like seed and start-up funding and risks and reward sharing are new in India.

Though the Government will always play a key role through incubation fund and seed capital, there are also a lot of angel investors coming into the biotech space. The govt. policies supporting venture capital funds like tax savings, tax holidays etc. may facilitate a massive entry of the small and medium sized firms, which boast about broad innovation thrust in the Biotech industry.

Stage	Regulations	Venture Funding	R & D and innovation policies	Industry academia linkage	IPR issues	Research and education	Skill building
Research and Development	Ease of access to technology incubators	Mentor innovative and emerging technologies to assist new enterprises in R&D.	Access to resources for Research and innovation	Creation of Policy level framework to forge appropriate linkages with academia and government	Creation for IPR sharing policies	Increased allocation for Govt funding for incubators with research clusters	Priority to industry specific skills
Pre-Clinical development	Less cumbersome and defined Animal and living modified organisms regulations	Dedicated funding by funding agencies for industrially relevant biotechnology projects	Increase in number of animal testing and breeding facilities	Creating platforms for centers of excellence for academia and industry for pre-clinical tests	Strict IPR regime for domestic innovation processes in pre-clinical development	Strengthen the research expertise for creating animal models for various diseases to conduct pre-clinical studies	Priority to industry specific skills Specialized expertise within DCGI to assess quality issues
Clinical development	Robust Clinical Trial policies and access to target population	In India clinical trials can be subsidized by the GoI, especially for procedures like CT scans and MRIs.	Common core lab facilities for testing of samples and high end instruments	Incentivizing interactions among institutions and organizations for stem cells research and trials	Awareness about IPR issues and TRIPS agreement in the domestic market	Establish clear regulatory policies for research and development and cell therapeutics	Training centers for various KOLs
Commercial scale manufacturing	Time bound approvals of the manufactured products. GoI must ensure single window system approval protocol for manufacturing plants.	Tax savings, tax incentives and tax holidays with venture capital through govt lead to entry of SMEs	Collaboration and alliances in Biotech education and R&D	Industry inputs and hands-on training to graduates and post graduates in an industrial R&D set –up	Protection systems for IPR	Increased allocation for Govt funding for basic research and study	Training cells for various process related manufacturing
Globalization	Govt, industry, academia and regulators need to work in synergy for globalization of Indian Biopharma sector	Direct investments from international biotech firms. Also, focus should be on export oriented activity to a global marketing	Upgrading facilities and capabilities to global standards for better routes to innovation	Collaborative projects and purchase of technology between industry and academia	Strengthening confidentiality and IP protection.	Increased collaboration for intensive research and study	Increasing govt. support towards skill building in Life Sciences

Fig 2: Key suggestions and recommendation model for development of the Biopharmaceuticals with respect to every stage

➢ R&D and Innovation Policies

Biopharma segment constitutes two-third of the Indian Biotech sector and has enabled investments in innovative product development. Clearly, a lot of companies see more value in ramping up their service offerings even as they try to master the technological, financial and regulatory challenges, before they are able to offer cutting edge drugs in the market place.

Support mechanisms required for the promotion of the biopharmaceutical industry are very different from the broad innovation thrust required for the pharmaceutical industry.

This is particularly true for countries like India. It is dominated by generic producing export oriented firms and is yet to move up the value chain with respect to innovation and research. There is substantial interest in Indian biotech industry on producing innovative, technology intensive and globally competitive products; however, due to lack of strong peers the industry hasn't taken giant steps.

Therefore, there is a dire need for Government to step in and develop supporting ecosystem for the same, via a) early, mid-size, and large scale funding, b) providing clear regulatory guidelines for novel biologics, c) granting financial rewards for innovation and not just for re-engineering or reproducing new activities in biologics production and d) promoting international ties with industry leaders in other countries.

The government support for the domestic innovation is required in the form of tax incentives, regulations and grants for various initiatives in the sector. Since innovation is always regarded as the entry level barrier with respect to the overall healthcare system, keeping this in view FICCI as a representative of the Industry in the Health Innovation Council by Ministry of Health and Family Welfare can push the Biopharmaceutical sector as one of the focus areas where opportunities in innovation can be mapped out by government and industry.

- **Focus on Industry- Academia linkage**

Translation of research ideas into commercially viable projects has been another area that India is focussed on setting right. Most academic and research institutions are not well equipped to undertake innovative and translational research. India needs support in setting up support, both in terms of scientific expertise pool and also incubation centres with seed funding to help develop ideas to innovation and then to revenue.

While a lot has been talked about Industry-Academia linkages, it cannot be denied that the breakthrough innovations do come from academic inventions, which are further developed

by industry. Therefore, there is a strong requirement to have focused govt. policies (programs) supporting biopharma based academia industry linkage. Upon study, one can find that there are several academic groups involved in exciting biologics or cell-based therapeutics research, which are untapped by or inaccessible by industry due to traditional barriers. Such barriers need to be removed through specific programs and a nation-wide network creation.

Furthermore, one can assess the level of engagement between Academia and Industry in terms of quality and quantity to look for strong industry academia and industry linkages through:

- Collaborative projects between academia and industry
- Projects funded by the industry to academic institutes
- Purchase of technology by industry from academia
- Inputs from academia through membership of bodies such as Institutional Biosafety Committee IBSC, Science Advisory Board, etc
- Review of the industry projects funded by govt. agencies
- Consulting opportunities for academia

- **Public Private Partnership Funding**

Another area of concern for the developing life science industry in India is the **inadequate public-private initiative**. The existing public-funded bodies in India are not too industry friendly. On the other hand the industry in India, while seeking collaborative partners, limit their explorations within Indian public funded bodies and explore opportunities abroad.

A good example of the integration of industry with the Government is, the **Small Business Innovation Research Initiative (SBIRI)** which is a scheme launched by the department of biotechnology to boost public-private-partnership effort in the country. It supports the high-risk pre-proof-of-concept research and late stage development in small and medium companies lead by innovators with science.

There are several different ways to strengthen the academia-industry linkages further through:

Government policies for:

- Scientific and leadership awards Prizes have been used as an inducement scheme by several governments to fast track innovation. This has been true historically as well. One of the ways that GOI can foster entrepreneurship would be to throw 'problem challenges' in biotechnology areas relevant to India
- Establishing public procurement policies for innovative products

- Promote Biotech Entrepreneurship & provide access to risk capital for all stages of Biotechnology Product Development Cycle while focusing on seed and proof of concept funding

In the Biotechnology Industry, the **public private partnerships** have always assisted in technology development; entrepreneurs have been able to work with the public research institutes, standardization and innovation. There are a number of institutes where **P-P-P** can be explored; like the Indian Institute of Science, laboratories of **CSIR, DST and DBT.**

➢ Intellectual Property Rights Issues

Patent has assumed large importance in the recent times since its basic function is to promote innovation, which in turn is an essential component of economic growth and social evolution. Patent is not just an incentive to invest in the innovation process *per se*, but is also necessary for trade and industry worldwide. For developing countries like India, patent is an essential component of the framework to attract foreign investment and faster technology transfer.

Intellectual Property (IP) is central to the biotechnology industry, and brings with it a dimension, facilitating collaborative activity, whether it is drug discovery or clinical or market-related trials. A streamlined and efficient patent protection, in addition to the industry's maturing relationship with capital markets are the hallmarks of a global leadership in biotechnology.

In Intellectual Property Rights, a clear regulatory framework needs to be created in India to address the Inventions in the area of Biotechnology in a more inclusive manner. India needs to implement strong patent legislation, data exclusivity, and improve IPR infrastructure and enforcement in order to achieve its potential as an R&D powerhouse. Indian biopharmaceutical companies and researchers, especially in the biotechnological sector can also benefit from increased diffusion of knowledge and innovation that results from international partnerships and increased integration.

The expiry of patent protection of many biopharmaceuticals has initiated the development of a category of alternative versions of innovator biopharmaceuticals known as biosimilars. Because of the structural and manufacturing complexities, these biological products are considered as similar, but not generic equivalents of innovator biopharmaceuticals. The term **“biosimilar”** is in common use in the European Union, while the term **“follow on biologics”** is more popular in the American context.

Despite the arrival of the New Product Patent Regime, there are many concerns with regard to IPR, such as narrowing the definition of patentability only to **NCE's (New Chemical Entities)** and broadening the scope of Compulsory Licensing to include affordability.

India's First Pharmaceutical Patent Goes to Roche

In March 2006, Roche became the first Indian company to receive a patent under the product patent regime. The product patent has been granted for Pegasys (peginterferon alfa-2a) for the treatment of hepatitis C, under the country's "mailbox" facility for post-1995 inventions. The patent is valid for 20 years from May 15, 1997, during which time no other firm can launch a generic version in India.

The lack of intellectual property awareness and know-how is the major worry and the early implementation of a biopharmaceutical patent regime would strengthen India's R&D sector, attract more foreign investments and provide a basis for Indian firms to begin tackling diseases that have a serious effect on the country.

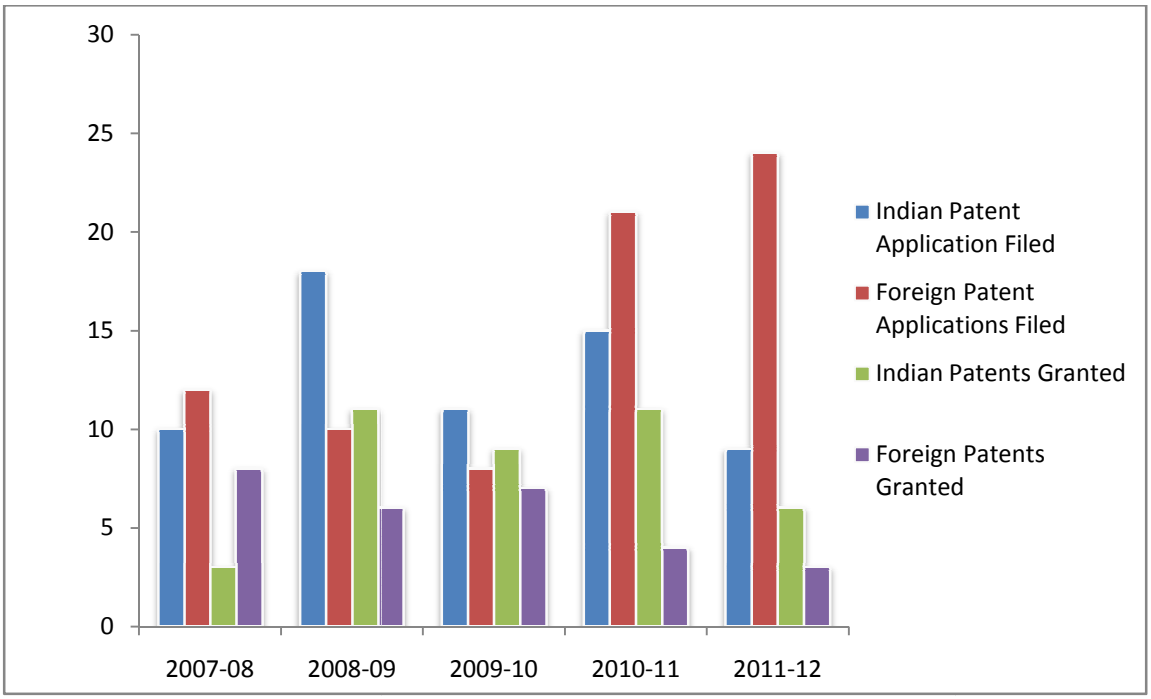


Fig3: Patent Applications Filed/Patents Granted (2007-08 to 2011-12)

Source: Biotechnology Patent Facilitating Cell, Department of Biotechnology, GoI

➢ Skill Building

India faces an urgent need to increase the pool of dedicated experts in the regulatory space who have expertise and experience in handling biologicals and set up systems for training and management of risk.

Research and development in biopharma requires highly specialized skill sets which are not abundant in India. Although there is an increase in well trained returnees, the numbers are not sufficient to fill the skills gap. To become a global destination for biopharmaceutical research, the country needs to focus on building manpower up to global standards, which includes upgradation /skill building of existing manpower in industry and also improving education system in academic institutes. Several skill sets currently appear tough to find in the Indian Biotech sector.

One of the reasons for the deficit in skills is cultural—as yet, the transfer of skills from academia to industry remains inefficient. Many biopharma companies also have a limited pool of experts who can handle both Indian and foreign regulatory systems. One of possible approaches is Karnataka's Biotechnology Finishing Schools, which has helped produce technically skilled manpower in the state for last couple of years.

The Government of India may tie up with leading research centres in the world and send at least 25 researchers every year for short term and long term training at the world renowned training institutes. Moreover, the Government can also collaborate with training centres of the leading biopharmaceutical companies in India for cutting-edge training provision to the manpower.

*In May 2013, the **National Skills Development Council** approved the Life Sciences Sector Skill Council, which will address the skill needs of Biotechnology, Pharma R&D, Clinical Trials and Pharmaceuticals Manufacture sub sectors.*

➢ Research and Education

Biopharmaceutical products require highly specialized and focused manpower. India faces a **challenge in harnessing university talent** to right and relevant use in the industry – whether towards research or towards services. Indian research institutes have traditionally been good at handling serious research products but have limitations in training their students to bridge gaps in the requirements of the industry.

There is still only a limited system for attracting and nurturing postdoctoral students, who comprise a key research workforce in the west. The strength of the west's postdoctoral

system is one of the reasons for India's short coming in this area. Today, most Indian postdoctoral students go abroad and rarely return. In India, the academic research that normally leads to the development of biopharmaceuticals is still largely carried out by young students working towards their PhDs. Therefore, the R&D techniques in India still remain weak by western standards in India.

The research and education system has to be geared up for specific requirements of the sector. The setting up of new institutions like **National Institute of Pharmaceuticals Education and Research (NIPER)** is of the important initiatives by the Government. Though the number of public undertakings operating in the biopharma sector is limited, the public research institutions play a significant role in the growth of private biopharma industry in the country. Furthermore, the industry input for curriculum design is essential and hands-on training for undergraduates and postgraduate students in an industrial R&D set up is important for the sector to flourish.

The Government has addressed the problem of educated but unqualified candidates in its **Draft National Biotech Development Strategy**. This plan included a proposal to create a National Task Force that would work with the biotech industry to revise the curriculum for undergraduate and graduate study in life sciences and biotechnology. The government's strategy also stated intentions to increase the number of PhD Fellowships awarded by the **Department of Biotechnology to 200 per year**. These human resources will be further leveraged with a **"Bio-Edu-Grid"** that will knit together the resources of the academic and scientific industrial communities, much as they are in the US.

Government Initiatives towards the Biotech Sector- Story So Far

The Indian government has been proactive and supportive in driving the growth of the biotechnology sector by offering grants and tax incentives, and implementing investment-friendly regulations.

The setting up of a separate Department of Biotechnology (DBT), under the Ministry of Science and Technology, the department has promoted and accelerated the pace of development of biotechnology in the country. Department has launched several schemes to promote Innovations in Biotechnology in India like **Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP), Biotechnology Industry Research Assistance Council (BIRAC) Biotechnology Industry Research Assistance Program me (BIRAP)**

1. Specific initiatives in the Biotechnology sector have largely been taken up by the Ministry of Science and Technology's DBT. The department focuses on globalization of R&D, industry-academia partnerships and institutional infrastructure. The

Department of Biotechnology (DBT), Government of India and Biotechnology Industry Research Assistance Council (BIRAC) have identified and supported many innovative nationally relevant ideas / products/ processes for further development and commercialization. This support to industry innovation research through public private partnership has always aimed at developing innovative technologies with respect to affordable product development.

2. BIRAC has a financial assistance scheme called Biotechnology Industry Partnership Programme (BIPP) which is a unique initiative with industry for support on a cost sharing basis for a development of novel and high-risk futuristic technologies in key areas of national importance and public good. The DBT is operating this scheme to promote and nurture innovation in research in biotech enterprises, specially start-ups and SMEs.

3. The Department of Biotechnology has also set up interdisciplinary life science centres in universities nationwide. Three bio clusters, established in Bangalore, Faridabad and Mohali, each have a pipeline of students, strong interdisciplinary research and technology platforms.

4. There are several Indian states including Andhra Pradesh, Karnataka, Maharashtra, Himachal Pradesh, Uttar Pradesh, Kerala and Gujarat who have introduced additional financial and policy initiatives to encourage investment in biotechnology.

5. DBT has also taken efforts in the direction to establish the Drug Regulatory Authority to ensure standards in the Industry, a Biotech Regulatory Authority to streamline and regulate the country's biotechnology sector and a public-funded R&D Bill.

6. The Biotechnology Regulatory Authority of India Bill, 2013 was introduced in the Lok Sabha on April 23, 2013 by the Minister for Science and Technology, Mr. S. Jaipal Reddy. The Bill aims to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures.

7. The guidelines on similar biologics have finally come out from the CDSCO, Ministry of Health and Family Welfare, which will provide some insights to the regulatory regime of the Biosimilars.

8. The Indian government has set up a USD 2.2 billion venture fund for supporting drug discovery and research infrastructure development projects. This is a crucial step as it increases the funding required for innovative work by the Indian biotech sector. Furthermore, the government has brought out a few avenues to encourage

investment in the Indian Biotech Sector and also promote R&D and innovation in the sector.

9. FDI up to 100% is permitted through the automatic route for the manufacture of drugs and biopharmaceuticals. The Department of Biotechnology (DBT) is the nodal agency for the sector's policy promotions regarding R&D, global cooperation and manufacturing activity. Towards this end, DBT set up 35 facilities between 2002 and 2007 to produce and supply biologicals, reagents, culture collections and laboratory animals to scientists, industries and students at nominal costs.

10. In recognition of the need of training and education for generating interdisciplinary human resource relevant to biotechnology, the Government of India and UNESCO, have taken a joint decision to establish the Regional Centre for research, training and education in biotechnology under the auspices of UNESCO. The UNESCO Regional Centre for Biotechnology was established in Faridabad, Haryana by the end of 2010. Further, the Department of Biotechnology (DBT), Government of India, has also decided to set up a unique Health Biotech Science Cluster (HBSC) at Faridabad.

11. **Key Biotech Clusters in India:** Bangalore, in Karnataka is the Biotech capital for India. India houses 380 biotech companies of which a majority of 198 are in Karnataka and 191 in Bangalore alone. The other key clusters include Mumbai and Ahmedabad in the West (Maharashtra and Gujarat respectively), Hyderabad (Andhra Pradesh) in the South and the area in and around New Delhi in the North. The Western belt houses companies that are large pharmaceuticals with a prominent manufacturing and R&D base, who have active interest in pursuing the manufacture of bio-generics. Hyderabad has several vaccine manufacturers and other large biotech companies involved in research. The regions in and around New Delhi house several key research centers and universities that are involved in research.