

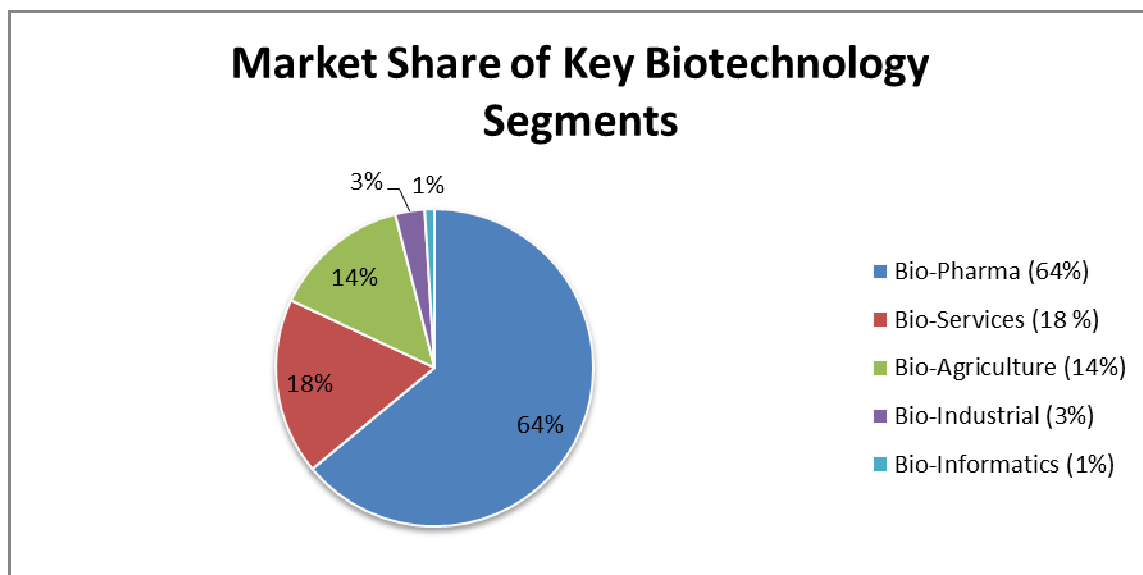
Name of the Report: Biotechnology in India

Year 2014

New Delhi/India

1. Summary of the Sector

Biotechnology is steadily emerging high potential growth sector India and has the potential to take the country into the next big league of internal and international investment. The country has done well in pharmaceutical sector and this has helped evolve the biotech sector over the last decade. According to Investment and Technology Promotion (ITP) report, biotechnology market is estimated to reach USD 11.6 billion by 2017 with an estimated growth rate (CAGR) of 22 percent. The key growth drivers of the US \$ 4.3 billion industry include robust domestic demand, growth in contract services; focus on research and development (R & D) initiatives and strong government support for the sector. The existing biotechnology network in the country comprises nearly three hundred national laboratories and a number of universities. Included amongst top 12 biotech destinations in the world, India has immense potential to emerge as a global key player. Majority of biotech companies operate in the bio-pharma sector which accounts for approximately 64 percent. Bengaluru is the biotech capital of India with 60 percent companies.



Source: www.ibef.org

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2. Government Policy

India aims to spend USD 3.7 billion on biotechnology in its 12th Five Year Plan. Foreign Direct Investment (FDI) is allowed up to 100 percent through the automatic route for manufacturers of drugs and pharmaceuticals in the sector. Biotechnology Regulatory Authority of India (BRAI) Bill has been tabled in the Parliament for introduction. In a move to standardize procedure, the Indian Parliament passed the Clinical Establishment Bill 2010, which would make registration of clinical trials as well as clinical research organizations mandatory in the country.

Center and State Government provide incentives to boost the biotech industry such as:

- a) Customs duty exemption on goods imported in certain cases for R &D
- b) 150% weighted tax deduction on R & D expenditure.
- c) 3 years excise duty waiver on patented products
- d) 100% rebate on own R & D expenditure
- e) 125% rebate if research is contracted in public funded R &D institutions

3. Current Market Size & Trends

The industry continued to deliver positive growth rates for the year 2013 with 15.1 percent CAGR; the total industry size was USD 4.3 billion at the end of the financial year.

According to data released by the Department of Industrial Policy and Promotion (DIPP), the drugs and pharmaceuticals sector has attracted FDI worth US \$ 8.15 billion between April 2000 and June 2013. India has the third largest revenues in Asia after China and South Korea.

Fast-paced growth is likely to continue; the industry is expected to increase in size to USD 11.6 billion by 2017, driven by a range of factors including growing demand, intensive R & D activities and strong government initiatives.

4. Market Entry & Opportunities

The Government of India allows Biotechnology imports under “Open General” category. Reduced import duty and simplified import procedures encourage imports of capital goods and raw materials.

Price, quality and after-sales service support are major factors in purchase decisions. A letter of credit is the usual payment mechanism for imports. Importers are required to find foreign exchange from their export earnings, or to buy foreign exchange from government approved foreign exchange dealers. U.S. manufacturers and exporters are advised to

identify competent local partners who offer strong sales and after-sales service support. The U.S. Commercial Service can assist in this search.

The buyers of biotechnology products and bio molecules are the research institutes and pharmaceutical companies. U.S. Companies could export process equipment, quality testing equipment, analyzers, filters and raw materials such as chemicals. Opportunities exist for companies to offer consultancy services and build infrastructure for Indian biotech companies as well as offer consultancy services for water treatment facilities. Many companies seek assistance on certifications, regulatory and FDA clearances.

Opportunities

Biopharma: It is the largest component of biotech industry which is estimated to reach \$2.5 billion by 2015. A front runner in biosimilars, India is extensively investing in improving the R&D capabilities and bio-manufacturing infrastructure. The market will gain momentum as the market is fuelled by overall GDP growth and increasing prosperity especially the growth of the middle class who can afford medicine and the changing profile of disease prevalence. Majority of multinationals collaborate with major bio-pharma companies for early stage clinical trials as well as to sell the finished product for better market penetration.

Vaccines and recombinant therapeutics are the leading sectors driving the biotechnology industry's growth in India. Protein and antibody production and the fabrication of diagnostic protein chips are a promising area for investment.

Bio Agri: The biotechnology agriculture methods for grain production can address the daunting challenge of widening demand-supply gap in food grain production. Technology provides methods to improve the effectiveness of agriculture inputs bring down input costs and increase output. Bio agriculture is estimated at \$7.8 billion which is growing steadily. However, there is a need to educate public about the benefits of Bio-agriculture methods. The country holds immense potential to become a major producer of transgenic rice and several modified or engineered vegetables.

Others: Some other potential areas of development include biosimilars, stem cells, medicinal and aromatic plants, animal biotechnology, aquaculture and marine biotechnology, genome analysis and others.

Key Biotechnology Parks and Research Institute in India

Biotechnology Parks

Shapoorji Pallonji Biotech Park in Hyderabad, ICICI knowledge Park in Hyderabad, International Biotech Park in Pune, Lucknow Biotech Park in Lucknow, Golden Jubilee Biotech Park in Chennai, Tical Bio Park in Chennai

Research Institutes

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Center for Cellular & Molecular Biology (Hyderabad), Indian Institute of Chemical Biology (Kolkata), Institute of Genomics and integrative Biology (New Delhi), Institute of Microbial Technology (Chandigarh), National Center for Biological Sciences (Bengaluru), Jawaharlal Nehru Center for Advanced Scientific Research (Bengaluru), Indian Institute of Science (Bengaluru)

5. Barriers

- India maintains a very permissive patent opposition system with 11 grounds for opposition and the same parties can file serial oppositions citing the same grounds. India is one of the world's biodiversity hotspots and passed a separate Biological Diversity Act (BDA) which came into effect in 2002. However, the enhanced scrutiny by the Indian Patent Office (IPO) of applications involving Indian bioresources or traditional knowledge and the narrow scope of patent eligible subject matter has resulted in a loss of confidence in the Indian IP system and U.S. agricultural and biotechnology companies remain seriously concerned about widespread product piracy and rebranding in India.
- Cumbersome regulatory process with multiple agencies hinders innovation due to several cumulative procedural delays.
- High tariff duties on high end equipment, manufacturers to establish cutting edge Bio-analytical facilities.
- Cumbersome regulatory process for importing biological samples and non-participation in negotiating government-to-government treaties for handling biologics.
- Insufficient cold storage facilities in important airports such as Hyderabad, Delhi, Pune and Chennai.
- Poor infrastructures such as uninterrupted power and water supply and poor roads also a challenge for Bio Pharma companies. Research and development in biopharma requires highly specialized skill sets which are not abundant in India.

Key Methods Of Doing Business In India

A new entrant to the Indian market should consider one of the following options, depending on the expected volume of business, the nature of business (whether it's an active pharma ingredient/generic bulk drug or a pharma product), market potential and its long term strategy in the Indian market.

A foreign company may appoint a distributor as this is the ideal entry option which does not require as many resources. But the selection of the right distributor is essential. For most industrial products, one exclusive indenting agent or distributor is the most common arrangement.

A foreign company may open its liaison office in India. However, a liaison office is not allowed to transact any business. It could only undertake market development activities. Expenses of this type of office must be met through inward remittances from the head office abroad. The Reserve Bank of India (RBI) grants approval for the opening of such offices.

Opening of a Branch Office by foreign companies engaged in manufacturing and trading
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activities abroad is another option available to undertake buying and selling activities in India. A branch office may render technical support and professional consultancy services but it is not allowed to undertake manufacturing activities. Permission from the RBI is required to set up this type of office.

Joint Venture/Wholly Owned Subsidiary: A foreign company can commence operations in India through incorporation of a company under the provisions of the Indian Companies Act (2013).

6. Competition in the Market

The Indian biotech industry is fairly competitive. Karnataka is the major hub providing base to almost half of the country's biotechnology companies. Apart from Karnataka, states such as Andhra Pradesh, Maharashtra, Tamil Nadu and Kerala have been proactive in supporting the biotech sector by establishing world-class biotech parks and clusters.

India has approximately 350 companies operating in the biotechnology sector. Some of the major biotechnology companies in India are:

Biocon,
Serum Institute of India,
Panacea Biotech,
Nuziveedu Seeds,
Reliance Life Sciences,
Quintiles,
Rasi Seeds,
Novo Nordisk,
Shantha Biotechnics,
Venkateshwara Hatcheries,
Indian Immunologicals,
TransAsia Biomedics and
Mahyco.

7. Success Stories

Last one decade witnessed a change in biotech industry with major merger and acquisitions deals. Some of the examples are:

- a) Matrix lab acquired by US Based Mylan Inc
- b) Piramal Healthcare acquired by US based Abbot Laboratories
- c) Biocon has entered into an agreement with Mylan for the global development and commercialization of biocon's generic insulin analog products (Long lasting insulins), which has a global addressable market of US \$ 11.5 billion.

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- d) Shantha Biotech took over by France based Sanofi Aventis

8. Trade Events / Associations

- [Bangalore-India BIO](#)
Feb 10-12, 2014 Bangalore, India
The three-day event comprises of multi-track conferences, international trade show, bio-partnering, CEO conclave, bio excellence award and a host of other events.
Website: www.bangaloreindiabio.in
- [First Annual BIO India International Partnering Conference](#)
September 21 - 22, 2010 Hyderabad, India
This conference will bring together biotechnology and pharmaceutical companies from North America, Europe and Asia to meet and explore business opportunities with India's emerging biotech sector.
- [BioAsia - The Global Bio Business Forum](#)
February 21 - 24, 2011 Hyderabad, India
The conference aims to provide an interdisciplinary forum for discussing new approaches in the field of biotechnology, integrating innovative developments with engineering applications, and converting technologies into industrial products.

9. Useful Web Links

- [Official Website of Department of Biotechnology](#) (DBT)
- [Association of Biotechnology led Enterprises](#) (ABLE)
- [All India Biotech Association](#) (AIBA)
- [National Biotechnology Development Strategy](#)
- [Confederation of Indian Industries](#) (CII)
- [Federation of Indian Chambers of Commerce & Industry](#) (FICCI)
- [Biotech Consortium of India](#)
- [Institute of Bioinformatics](#)
- [Genome Valley](#)
- [IKP Knowledge Park](#)
- [Planning Commission India](#)
- [Pharmabiz](#)

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