

Indian Biotechnology Sector

Biotechnology deals with the application of biological knowledge and techniques pertaining to molecular, cellular and genetic processes to develop significantly improved products and services. The applications of biotechnology range from agriculture, industrial and medical biotechnology.

The Indian Biotechnology sector can be divided into the segments of biopharmaceuticals, bioservices, bioagriculture, bioindustrial and bioinformatics.

Nearly 40 percent of the biotech companies operate in the biopharma sector, followed by the bioservices (21 percent), bioagri (19 percent), bioinformatics (14 percent) and lastly the bioindustrial sector (5 percent).

Biopharmaceuticals: This constitutes the largest segment of the Indian biotech industry both in terms of domestic and export revenues. About 70 percent of the domestic biotech industry comprises of the Biopharma sector. Of the total 325 biotechnology companies in India, more than 40 percent are in the biopharma sector. Vaccines, therapeutics and diagnostics fall into this category.

BioServices: The Bioservices market is the second largest sector of the Indian Biotechnology Industry. The market's growth can be attributed to the fact that India has become a popular destination for clinical trial, contract research and manufacturing activities.

Agricultural Biotechnology: This segment can be segmented into Hybrid seeds and transgenic crops, Biopesticides and Biofertilizers. Genetically modified cotton or commonly known as Bt cotton constitutes approximately 77 percent of the revenue of this sector whereas Biopesticides and biofertilizers together account only for 23 percent of the revenues garnered by agricultural biotechnology.

BioInformatics / BioIT: This sector deals with the creation and maintenance of extensive electronic databases on various biological systems and is probably the smallest part of the current domestic biotechnology industry. However, India is known for its strong IT base and it is due to this that India is sure to become a leading destination for work in the bioinformatics arena.

BioIndustrial: This industry predominantly consists of enzyme manufacturing and marketing companies. These enzymes are used in industries such as detergents, textiles, food, leather, paper and pharmaceuticals. This generates 6 percent of the revenues of the biotechnology industry.

Strengths of the Indian biotechnology sector:

- Large reservoir of scientific human resource, that is, a strong pool of scientists and engineers;
- Cost effective manufacturing capabilities;
- Number of national research laboratories employing thousands of scientists; centers of academic excellence in biosciences; several medical colleges, educational and training institutes offering degrees and diplomas in biotechnology, bio-informatics and biological sciences;
- Presence of a well-defined and vibrant drugs and pharmaceutical industry;
- Rich Biodiversity: India's human gene pools offer an exciting opportunity for genomics;
- Fast developing clinical capabilities with the country becoming a popular destination for clinical trial, contract research and manufacturing activities

Weaknesses of the Indian biotechnology sector:

- Lack of venture capital
- Relatively low R&D expenditure by industry
- Missing link between research and commercialization
- Doubts about the ability of Indian products to meet International standards of quality

Regulatory Regime:

Department of Biotechnology (DBT): This department which is under the Ministry of Science and Technology is the apex authority for the development of biotechnology sector in India. It has been set up for the purpose of planning, promoting and coordinating various biotechnological programmes and activities in the country. It is the nodal agency for providing grant-in-aid support to national research laboratories, universities and research foundations for biotechnology related activities in different sectors like health care, agriculture, environment and industry. The main responsibilities of the Department are to:-

- Promote large scale use of biotechnology
- Identify and set up centres of excellence for R&D in biotechnology and related manufacturing fields
- Establishment of infrastructure facilities to support R&D and production

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- Act as an agent of the Government for import of new recombinant DNA based biotechnological processes, products and technology
- Evolve bio-safety guidelines for laboratory research, production and applications
- Initiate scientific and technical efforts related to biotechnology
- Develop integrated programmes for human resource development
- Promote international collaborations for expanding knowledge base of biotech sector
- Serve as a nodal agency for collection and dissemination of information relating to biotechnology.

The Department has the following autonomous institutions which work on various aspects of medical, agriculture and industrial biotechnology:

- National Institute of Immunology, New Delhi
- National Centre for Cell Science, Pune
- Centre for DNA Fingerprinting and Diagnostics, Hyderabad
- National Brain Research Centre, Manesar, Haryana
- National Centre for Plant Genome Research, New Delhi
- Institute of Bioresources and Sustainable Development, Imphal
- Institute of Life Sciences, Bhubaneswar

The following are the public sector undertakings in the Department which work for the development of biotech sector:

- Bharat Immunologicals and Biologicals Corporation Limited, Bulandshahar
- Indian Vaccines Corporation limited, Gurgaon

Genetic Engineering Approval Committee (GEAC): Constituted under the Ministry of Environment and Forest (MOEF), this is another leading regulatory body in the area of Biotechnology in India. GEAC is responsible for monitoring the large scale and commercial use of transgenic materials. This is the nodal agency responsible for implementing the Biotech Rules of 1989 under the EPA Act 1986.

Central Drugs Standard Control Organization (CDSCO): The CDSCO constituted under the Directorate General of Health Services, Ministry of Health and Family Welfare, is headed by the Drugs Controller General of India. It is mainly responsible for coordinating the activities of the State Drugs Control Organization, laying down policies, and ensuring uniform implementation of the Drugs and Cosmetic Act throughout India.

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The Biotechnology industry in India is governed by the following enactments, regulations and guidelines:

- Environment Protection Act, 1986;
- EXIM Policy;
- Foreign Exchange Management Act, 1999;
- Laws pertaining to Intellectual Property Rights;
- Rules for the Manufacture, Use/Import/Export and Storage of Hazardous; Micro Organisms/Genetically Engineered Organisms or Cells, 1989; notified by Ministry of Environment & Forests on December 5, 1989 under Environment and Protection Act, 1986;
- Revised Recombinant DNA Safety Guidelines;
- Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998;
- National Seed Policy, 2002;
- Seeds Act, 1966;
- The Plants, Fruits and Seeds [Regulation of import in India] Order 1989 issued under the Destructive Insects and Pests Act, 1914;
- Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics, 1999;
- Drugs & Cosmetic Act 1940 along with Drugs and Cosmetic Rules;
- Drug Policy, 2002;
- Biological Diversity Act.

Market Trends:

India is ranked among the top 12 biotech destinations in the world and the Indian biotech sector is the third largest in the Asian region after Australia and China. The Indian biotechnology sector has excellent potential and is expected to touch five billion-dollar mark by 2010.

The biotechnology sector in India is growing rapidly at a rate of over 40 percent annually. India is the largest producer of recombinant Hepatitis B vaccine in the world. In addition, Indian vaccine market, which is over \$100 million, is growing at over 20 percent annually. The Indian market of Contract Research Organizations is growing at the rate of 30% to 40%.

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India occupies a significant position in the world pharma market, 8% by volume (fourth largest in the world) and 1% by value. The pharma industry ranks 17th in terms of export value. India accounts for 22% of the global generics market

Biotech Industry in 2006-07 and 2005-06

(Revenues in Rs Crore)

	2006-07	2005-06	% Change
BioPharma	5973.00	4708.00	26.87
BioServices	1102.00	720.00	53.06
BioAgri	926.00	598.00	54.85
BioIndustrial	395.00	375.00	5.33
Bioinformatics	145.00	120.00	20.83
TOTAL	8541.00	6521.00	30.98

Biotech Industry in 2007-08

During 2007-08, the biotech industry crossed \$2.5 billion (Rs.103 billion) in revenues, recording 20 percent growth over the previous fiscal at \$2.1 billion.

The global biotech industry in 2007 grew at about 8 percent, while the Asia-Pacific region registered a growth of 21 percent.

The biopharma segment recorded sales in excess of \$1.72 billion (Rs 6,899 crore) and accounted for 67 percent of the total industry revenues, registering 16 percent growth.

BioServices remained the second largest contributor to the industry with 15% share of the industry and contributing Rs 10 billion (\$250 million).

BioAgri sector recorded sales of about Rs 11 billion accounting for 12 percent of the total industry revenues.

Bioindustrial sector accounted for 4% of the total industry revenues generating Rs 4 billion.

Bio-informatics sector accounted for 2% of the total industry revenues generating Rs 1.3 billion.

Exports:

During 2007-08, the biotech exports grew to Rs 5,733.7 crore in revenues. Exports account for 56% share of the total biotech sector. Exports from biopharma alone accounted for over 70 percent of the total industry (Rs 3,999 crore), while the bioservices sector had 26 percent share in exports (Rs 1,502 crore). The bioservices sector registered 53 percent growth. The bioagri sector grew by 30 percent to Rs 1,202 crore, the bioindustrial sector by 4 percent to Rs 410, and the bioinformatics sector by 31 percent to clock Rs 190 crore in revenues.

Government Initiatives:

The Central government as well as the State governments have taken various initiatives to boost the biotechnology sector in India. Some of the key steps taken include the following:

- Commercial cultivation of BT cotton was approved by the government in early 2002 which today accounts for about 70 per cent of the total area under cotton cultivation and thus makes agri-biotech the fastest growing biotech industry.
- National Biotechnology Policy: The government has announced a National Biotechnology Policy as recognition of the importance of the sector as a key growth area. The key elements of strategy include:
 - (i) A National Biotechnology Regulatory Authority would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes.
 - (ii) A high-powered Inter-ministerial Committee is to be set up under the chairmanship of secretary, DBT, to effectively coordinate the development of the sector by addressing cross cutting issues.
 - (iii) 30 percent of DBT's Budget to be spent on public-private partnership programs.
 - (iv) A Biotechnology Industry Partnership Programme (BIPP) for Advanced Technology would be launched.
 - (v) The existing Small Business Innovation Research Industry (SBIRI) scheme to promote innovation in SMEs has been a success. Approval has been accorded for the expansion of SBIRI during the 11th Plan.

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- (vi) A Biotechnology Industry Research Assistance Council (BIRAC) is to be launched to act as an interface between academic and private sector, particularly SMEs and startups; nurture and catalyze R&D and innovation in biotechnology in the private sector and promote public-private partnerships.
- State Biotechnology Policies: Karnataka was the first state in the country to announce a “millennium” biotechnology policy as early as 2001 to promote the nascent biotech sector. Maharashtra, Tamil Nadu, Himachal Pradesh and Andhra Pradesh followed it with their own biotechnology policies during the year. Later other states like Haryana (2002), Punjab, Kerala, Madhya Pradesh (2003), Uttar Pradesh, Rajasthan (2004) and Gujarat (2005) joined the ranks by announcing their respective state policies.
 - Biotech Parks: The government has set up exclusive Biotech Parks such as Shapoorji Pallonji Biotech Park, Hyderabad; ICICI Knowledge Park, Hyderabad; International Biotech Park, Pune. These biotechnology parks are acting as bioclusters - where companies, universities and R&D institutes are all located in one place. These parks have emerged as a focal point of some of the leading biotech clusters such as Genome Valley in Hyderabad and Hinjewadi in Pune. States such as Andhra Pradesh, Kerala, Maharashtra, Punjab, Tamil Nadu and Uttar Pradesh have made substantial progress in establishing biotech parks, whereas Himachal Pradesh, Karnataka, Madhya Pradesh, Rajasthan and Uttaranchal are in development stage. The state governments too are supporting the industry players who are looking at setting up their units at the parks by offering incubation facilities, tax holidays and incentive packages, venture funding initiatives and so on.
 - The government has approved the National Policy on Biofuels along with setting up of an empowered National Biofuel Coordination Committee and a Biofuel Steering Committee.
 - The government has initiated a project to conduct genome-wide research on a range of agronomically important crops.
 - Nanoelectronics Centres have been launched by the government.
 - The Patent Act (Third Amendment), 2005: India amended its Patent Act in 2005 to usher in a new product patent regime. Provisions in the amended Act which relate specifically to biotechnology include the following:

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- (i) Plants and animals, seeds, including essentially biological processes used for propagating plants and animals are not patentable. The area of patentability in relation to microorganisms is not clear. Going by the US and European precedents, it would appear that only such microorganisms that are the result of human intervention would be patentable.
- (ii) Synthetic genes (as distinct from naturally occurring gene segments) too would now be the subject matter of patentability.
- (iii) Genetic inventions will include SNP (single nucleotide polymorphism), vectors, recombinant products such as vaccines, enzymes, hormones, etc.
- (iv) In order to get a patent, the Act requires the deposit of biological material with the International Depository Authority (IDA). IMT, Chandigarh, is the IDA in India for some of biological materials such as bacteria and plasmids.

Tax Incentives (Budget 2008-09):

- Excise duty on all goods produced in the pharmaceutical sector reduced from 16 per cent to 8 per cent.
- A reduction in Customs duty from 10 per cent to 5 per cent on certain specified life saving drugs and on the bulk drugs used for the manufacture of such drugs.
- Reduction in Central Sales Tax from 3 percent to 2 percent.
- A total exemption of excise duty on certain specified life-saving drugs and bulk-drugs.
- Amounts spent in R&D eligible for a 125 per cent weighted deduction.
- Increase in healthcare allocation by 15 percent to Rs 16,354 crore.
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Biotech Parks:

- Concessions to biotech companies located in biotech parks
- Duty free import of equipment, instruments and consumables

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- Tax holiday granted under the Income Tax Act which provides such a special provision in respect of newly established industrial undertakings in free trade zones and newly established hundred per cent export-oriented undertakings.
- Biotech companies located in biotech parks to be allowed a five-year time frame to meet the export obligation norms under the Special Economic Zone scheme.

Foreign Direct Investment Policy:

FDI up to 100% is permitted through the automatic route for the manufacture of drugs and pharmaceuticals provided the activity does not attract compulsory licensing or involve the use of recombinant DNA technology and specific cell/tissue targeted formulations

FDI proposals for the manufacture of licensable drugs and pharmaceuticals and bulk drugs produced by recombinant DNA technology, and specific cell / tissue targeted formulations will require prior Government approval

Localization of the Industry:

The biotech companies have developed in three major clusters across the country. The largest in terms of revenue generated is the Western cluster (Ahmedabad, Aurangabad, Mumbai and Pune), followed by the Southern cluster (Bangalore, Chennai and Hyderabad) and the Northern cluster (Delhi, Gurgaon and Noida).

The biotech cluster in Bangalore makes the city the leading biotech destination in the country.

The Knowledge Park, the Biotech Park, Genome Valley and other projects in Hyderabad make it another very preferred destination having operations of over 53 international biotech companies in the Genome Valley over the last one year. Additionally, two biotech special economic zones (SEZs) and three biotech parks will be developed in the city in the next couple of years.

A genomics centre is being set up at Tidel Park in Chennai and three more biotech parks and a biotech SEZ will be developed in the coming years.

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In addition to the above, cities like Vadodara, Coimbatore, Goa, Mysore, Madurai, Kolkata, Gurgaon, Thrissur, Nagpur and Tiruchirapalli have immense potential to attract investments and emerge as biotech destinations.

Location of Biotech Parks in India:

- Andhra Pradesh - Development and scale-up of bioprocesses and technologies
- Karnataka - Drugs and Pharma
- Punjab - Agribusiness and Certification of Export Goods
- Kerala - Traditional Medicines
- Himachal Pradesh - Medicinal and Aromatic Plants, Horticulture

Key Indian Biotech Companies:

- Biocon
- Shantha Biotechnics
- Bharat Biotech
- Wockhardt
- Dr. Reddy's Laboratories
- Serum Institute of India
- Zydus Cadila
- Aventis Pharma
- Reliance Life Sciences
- Panacea Biotec
- Ranbaxy Laboratories Ltd.
- Sun Pharmaceuticals Industries Ltd.
- GVK Biosciences Pvt. Ltd.
- Nuziveedu Seeds
- Rasi Seeds
- Novo Nordisk
- Novozymes South Asia
- Indian Immunologicals
- Mahyco
- Jubilant
- Themis Medicare

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- Haffkine Biopharma
- Rossari Biotech
- GlaxoSmithKline
- Biological E

International Biotech Companies in India:

- Monsanto
- Pfizer
- Astra Zeneca
- Unilever
- Dupont
- Bayer
- Eli Lilly
- Hoechst Roussel Vet
- Millipore
- Novozymes

Major Opportunities in the Biotechnology Sector:

Biotechnology is expected to offer investment opportunities of Rs. 9-10 billion in the next 5 years and the growth is expected in the following areas:

Vaccines: Vaccines and recombinant therapeutics are the leading sectors driving the growth of the biotechnology industry in India. It is estimated to reach \$20 billion in 2012. The next few years will also witness launch of newer therapies, prominent among these would be the monoclonal antibodies products, stem cell therapies, growth factors and others. India's huge population makes it among the world's largest markets for vaccines.

Bioactive Therapeutic Proteins: Production of proteins and antibodies and fabrication of diagnostic protein chips would be a promising area for investment. Stem cell research, cell engineering and cell based therapeutics could be another area where India could cash in its expertise. Up to 25% growth is expected in this field.

Agriculture sector: India has the potential to become a major producer of transgenic rice and several genetically modified (GM) or engineered vegetables by 2010. There is an increasing use of molecular markers in crop breeding and a growing realization that some of these new technologies could lead to future

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growth in the productivity and quality of crops such as rice, wheat, eggplant (brinjal), tomato and lady's finger.

Therefore hybrid seeds, including genetically modified seeds represent new business opportunities in India based on yield improvement, and development of a production base in biopesticides and biofertilisers would facilitate India's entry into the growing organic or natural foods market.

Contract Research: The R&D Sector has got huge potential and with the number of foreign companies stepping in India it has opened doors of opportunities to this sector. The cutting edge of the biotech sector is development of new products. Indian pharma companies possess competitive skills in chemical synthesis and process engineering, which they can leverage to develop new chemical entities, and with the application of bioinformatics tools, tap into the high-potential biogenerics segment.

Clinical Trials and outsourcing: India offers a suitable population for clinical trials because of its diverse gene pools covering a large number of diseases. Due to the rising costs of R&D abroad, many global companies are looking for contract research in India especially US and European companies. Cost-effectiveness, competition and the increased confidence on capabilities and skill sets have propelled many global pharmaceutical players to expand their own clinical research investment in India. Contract research supported by IT skills has led to promising outsourcing business in various other segments including Clinical trial data management, statistical analysis, and electronic data capture.

Bioinformatics: Indian bioinformatics companies can play a significant role in critical areas such as data mining, mapping and DNA sequencing, besides functional genomics, proteomics and molecule design simulation in the US\$ 2 billion world market for bioinformatics services. The IT skill of Indian manpower also offers services in bioinformatics and data mining.

Besides the above, the following thrust areas offer tremendous scope for potential investment in the Biotechnology sector:

- Medicinal and Aromatic plants
- Animal Biotechnology
- Aquaculture and Marine Biotechnology
- Serology biotechnology
- Stem Cell Biology
- Human Genetics and Genome Analysis
- Environmental Biotechnology



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- Microbial and Industrial Biotechnology
- Agriculture and Plant Biotechnology
- Healthcare
- Bio-Fuels
- Bio Pesticides
- Bio-Informatics
- Software Support