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BIOTECHNOLOGY

SCIENCE THAT SHAPES GROWTH

BIOTECHNOLOGY SECTOR OVERVIEW

CURRENT SCENARIO

CURRENT MARKET SIZE:
USD 51 Bn (2018)

INDIA'S RANKING

- India is the **3rd largest** biotech destination in the Asia Pacific Region
- India has the **second highest** number of US Food & Drug Administration (USFDA)-approved manufacturing plants outside the US
- India is among the **top 12 destinations** for biotechnology in the world, with approximately 3% share in the global Biotechnology industry
- Biotechnology revenues reached **USD 11.6 Bn** in 2017
- India has **2600+** DPIIT recognized biotechnology startups

MAJOR SEGMENTS

- Bio-pharmaceuticals, Bio-services, Bio-agri
- The Department of Biotechnology launched the first ever Industry-Academia mission to accelerate bio-pharmaceutical development in India under the 'National Biopharma Mission' in June 2017

FUTURE POTENTIAL

- By 2025, the Indian biotechnology industry is expected to reach **USD 100 Bn**
- **Focus states:** Gujarat, Telangana, Andhra Pradesh, Karnataka, and Himachal Pradesh

ADVANTAGE INDIA

ACCESSIBILITY

- Over **USD 200 Bn** to be spent on medical infrastructure in the next decade
- Over **1,60,000 hospital beds** expected to be added each year in the next decade

AFFORDABILITY

- Rising income could drive **73 Mn** households to the middle class over the next 10 years
- Over **650 Mn** people are expected to be covered by health insurance by 2020
- The National Health Protection Scheme is the largest government funded healthcare program in the world, which is expected to benefit **100 Mn poor families** in the country by providing a cover of up to INR 5 lakh (~USD 6900) per family per year for secondary and tertiary care
- Availability of affordable medicines under the **Pradhan Mantri Bhartiya Janaushadhi Pariyojana(PMBJP)** has led to savings worth INR 1000 Cr (~USD 138 Mn) for Indian citizens till date

ADVANTAGE INDIA

SKILLED HUMAN CAPITAL

- India has a population of **1.3 Bn** with 50% under the age of 25 which contributes to a young and affordable high-quality skilled workforce
- Recent development of several life-science clusters builds collaborations between research institutes and the private sector, growing the R&D capabilities
- The government has come up with an industry-academia collaboration with the World Bank for accelerating Discovery research for early-development of biopharmaceuticals

INFRASTRUCTURE FACILITIES

- Central and state governments have worked to set up several incubators and life-science clusters across India
- **9** DBT-supported Biotech Parks
  41 BIRAC-supported Bio-incubators

EPIDEMIOLOGICAL FACTORS

- Patient pool expected to increase over 20% in the next **10 years,** mainly due to rise in population
- New diseases & lifestyle changes to boost demand for drugs and devices

POLICY SUPPORT & INCENTIVES

FDI POLICY

- 100% under automatic route for greenfield projects
- 100% under government route for brownfield investments
- 74% under automatic route for brownfield investments

SKILL DEVELOPMENT

- Setting up of the Life Sciences Sector Skill Development Council (LSSSDC) under National Skill Development Corporation (NSDC) to promote skill development in the life sciences sector

STATE-SPECIFIC POLICIES

- **Andhra Pradesh** launched its Biotechnology Policy 2015-2020, which has enabled the development of multiple infrastructure projects and industrial parks and has helped the state to become a top biotech destination in India
- **Gujarat** ts draft Biotechnology Policy 2016-2021 with the aim to develop a robust biotechnology ecosystem in the state
- **Rajasthan** launched Biotechnology Policy 2015 with the aim to establish world class research institutes and biomanufacturing infrastructure
- **Telangana** launched the Life Sciences Policy 2015-2020, which has helped Telangana develop suitable infrastructure to attract global life science companies and become a leading invesment destination in the field
- **Uttarakhand** launched its Biotechnology Policy 2018-2023 with the aim to attract new investments worth INR 5000 Cr in the sector as well as generate employment opportunities for 5000 people by 2023
- **Himachal Pradesh** launched its Biotechnology Policy 2014 with the aim to make Himachal a globally competitive destination for the development of biotechnology products, processes and services
- **Assam** Biotechnology Policy 2018-2022 was recently launched to develop the biotechnology industry in Assam, which currently has an emerging BioAgri segment

STATE-SPECIFIC POLICIES

- **Karnataka** Biotechnology Policy 2017-2022 lays emphasis on strengthening the ecosystem required to boost startups, providing access to funds for R&D and product development, developing attractive incentives for investors, and providing mentorship for further growth of the biotechnology sector in Karnataka
- **Odisha** Biotechnology Policy 2018 was launched with the aim of making Odisha one of the top biotech investment and innovation destinations in the country
- **Madhya Pradesh** Biotechnology Policy 2003 looks at the conservation and sustainable utilization of bio-resources to promote socio-economic growth in the state

BIRAC

- Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit set up by Department of Biotechnology (DBT), Government of India as an interface agency to strengthen and empower the emerging biotechnology enterprises to undertake strategic research and innovation
- Biotechnology Industry Facilitation Cell for Make in India at BIRAC

MAJOR BIOTECH INITIATIVES

- Regulations and guidelines on biosafety of recombinant DNA research & biocontainment released (2017)
- The Lok Sabha has passed the DNA Technology (Use and Application) Regulation Bill, 2018 that allows regulated use of DNA
- Innovate in India" (2017) - a DBT and World Bank program, with a funding of USD 250Mn- aims to bring together industry and academia to promote entrepreneurship and indigenous manufacturing in bio-pharma

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019

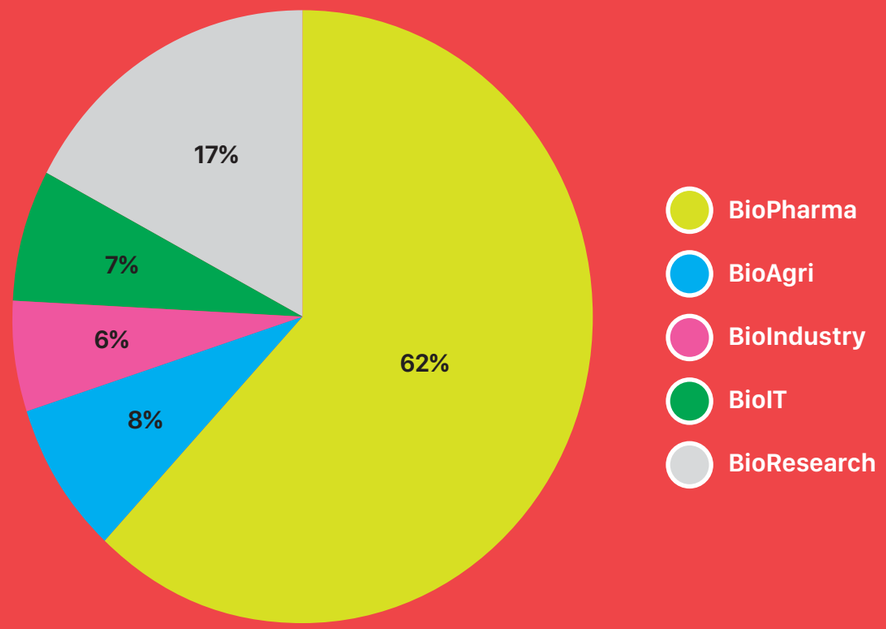
- The Ministry of Health and Family welfare released the new rule to promote clinical research in the country
- Under it, drug approval outcomes must be shared within 30 days for a clinical trial done within India, and 90 days for clinical trials of drugs developed outside India
- Earlier, approval durations were a challenge as it could take anywhere from 6-12 months

STARTUP ECOSYSTEM

CURRENT SCENARIO

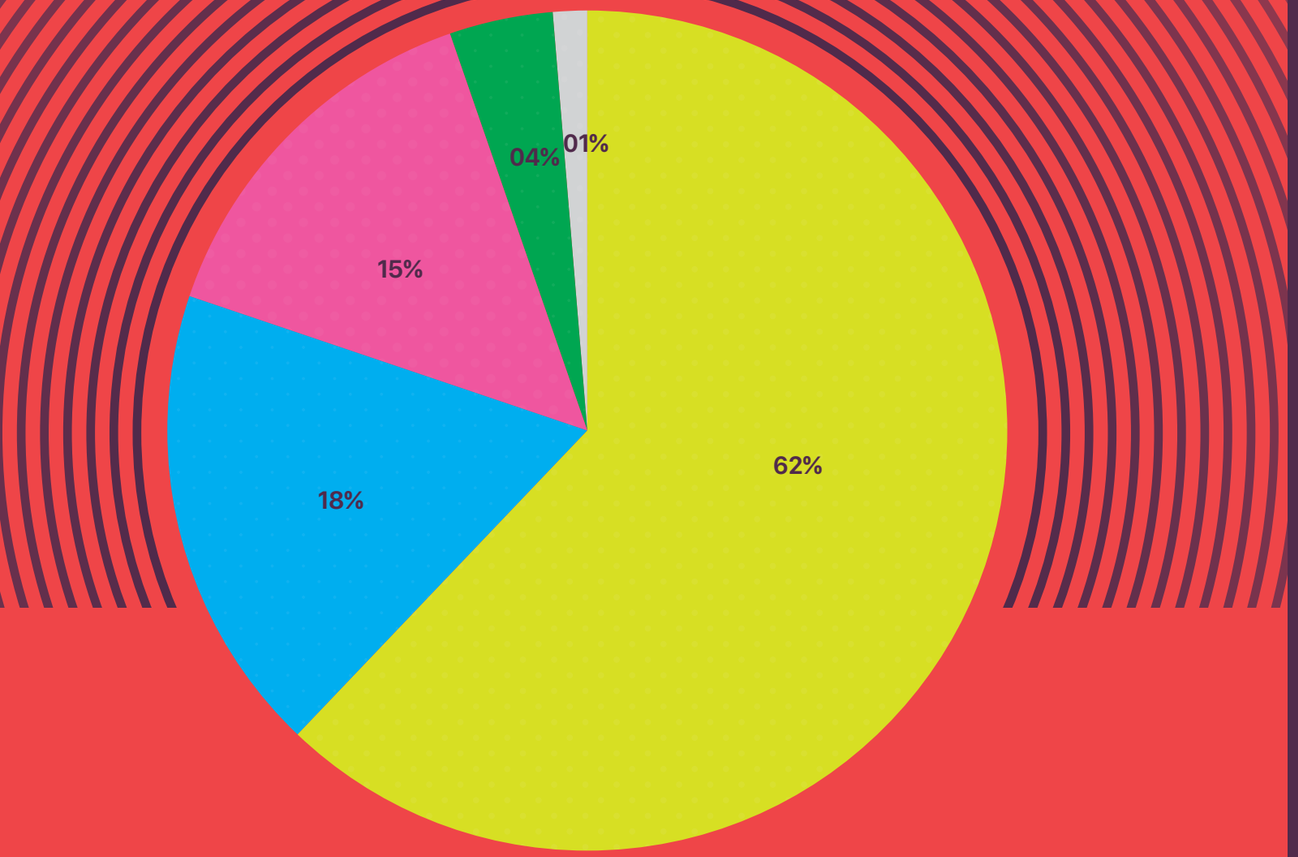
- India has robust startup ecosystem which comes from gradual improvements in the ease of doing business, proof-of-concept funds for startups and favorable government policies
- BIRAC will continue to grow its partnerships with innovative foundations and universities to focus on Make in India and Startup India programs

Sector-wise representation of startups



KEY SEGMENTS

Biotechnology Segments



- BIOPHARMACEUTICALS
- BIO-SERVICE
- BIO-AGRICULTURE
- BIO-INDUSTRIALS
- BIO INFORMATICS, SYSTEM BIOLOGY

1 BIOPHARMACEUTICALS

1.1 BIO-SIMILARS

Biologics are expected to contribute approximately
27%
to global prescription sales by 2020. Given the immense growth of Biologics, the opportunity for biosimilars is evident- and has attracted high investments. The size of the global biosimilar market is predicted to reach
USD 25 Bn
by 2020

India Opportunity:

India has 50+ approved biosimilar products, with a market size of USD 0.92 Bn in 2016. The Indian market for biosimilars is expected to reach
USD 2.2 Bn
by 2025

Approximately
USD 70 Bn
biologics drugs will go off- patent between 2016 and 2020, presenting a significant opportunity for exports

1.2 VACCINES

Globally, vaccines are a
USD 30 Bn
market. The Indian vaccine market is valued close to USD 3 Bn, with two-thirds of this exported. With a projected growth rate of 10-15% over the next decade, the Indian vaccine market has the potential to become a USD 8-12 Bn industry by 2025

India Opportunity:

India currently exports vaccines to about
150 countries

India meets
40-70%
of the World Health Organisation (WHO) demand for the DPT (diphtheria, pertussis or whooping cough, and tetanus) and BCG (Bacille Calmette-guérin) vaccines against tuberculosis, as well as almost 90% of its demand for the measles vaccine

1.3 INSULIN

Globally diabetes is one of the most prevalent disorders. India has the largest pool of diabetic patients, with more than 41 Mn people suffering from the disease. It is estimated that India will have more than

100 Mn

diabetics by 2030

India Opportunity:

The direct and indirect costs of treating such patients are currently about US$420 per person per year. If these costs remained the same as they are now, India's total bill for diabetes would be about

USD 30 Bn

by 2025

The global anti-diabetes market is worth more than USD 50 Bn growing at approximately 15% of which insulin is close to USD 30 Bn and is expected to reach

USD 57 Bn

by 2025

1.4 REGENERATIVE MEDICINE

The regenerative medicine market can be categorized into three major categories: tissue engineering, biomaterials/ biomolecules, and stem cell therapy. Rise in the prevalence of chronic disease is driving the demand for regenerative medicine

India Opportunity:

Several major research institutes, such as the National Centre for Biological Sciences in Bangalore, the Centre for Cellular and Molecular Biology in Hyderabad the National Centre for Cell Sciences in Pune and the National Brain Research Centre near Delhi, are investigating the use of stem cells to regenerate nerve, heart and adult muscle cells, and repair damaged bone tissue

The Indian Council of Medical Research has issued National Guideline for Stem Cell Research (2017) to promote clinical applications of stem cell research in ophthalmology, cardiology and spinal cord repair, and build links between scientists and doctors

2 BIO-SERVICES

2.1 CONTRACT MANUFACTURING

The global market for Contract Manufacturing is estimated at USD 4 Bn and is expected to reach USD 8.8 Bn by 2025. India has been a major player in contract manufacturing with USD 1.3 Bn market. Indian Contract Manufacturing market is expected to grow to

USD 4 Bn

by 2025

India Opportunity:

India has a far superior edge, due to resources including manpower, technically knowledgeable work force, WHO-GMP approved production premises and a substantial 40% lower cost of operation and production

2.2 CLINICAL RESEARCH

Global contract research market is estimated at approximately USD 340 Bn and is expected to reach

USD 45 Bn

by 2025

India Opportunity:

50%

public funding through a public private partnership (PPP) model to harness India's innovation capability

Vision 2020 to catapult India into one of the

top five

Pharma innovation hubs by 2020 with one out of every 5 to 10 drugs discovered worldwide, coming from India

3 BIO-AGRICULTURE

The global market for Bio-Agriculture is expected to grow from USD 20 Bn to
USD 59 Bn
by 2025 with USD 43 Bn contributed by genomic based products. Bio-Agriculture in India at USD 11 Bn (2018) forms the third largest and fastest growing segment within the industry. The segment comprises primarily of hybrid seeds, GM crops, bio-fertilizers and bio-pesticides

India Opportunity:

India ranks
5th
in global cultivation of GM crops

4 BIO-INDUSTRIALS

4.1 BIO-FUELS

Globally, biofuels have caught the attention in last decade and it is imperative to keep up with the pace of developments in the field of biofuels. Bio-fuels are of strategic importance for India. It can help meet multiple objectives viz., energy security, oil import substitution, cleaner environment and rural employment

India Opportunity:

India has largest arable land after US which makes raw material availability relatively easy. Need of the hour is to create and commercialize cost efficient, carbon neutral technologies which can leverage the natural resources available

National Policy on Biofuels, 2018, indicates a viability gap funding scheme for Second Generation ethanol Bio refineries of
INR 5000 Cr
in 6 years in addition to additional tax incentives, higher purchase price as compared to First Generation biofuels

4.2 Enzymes (Industrial + Specialty)

Globally North America and Europe together form more than 60% of the Enzymes' market. Indian market is relatively small and contributes approximately 2% of the overall enzymes market

India Opportunity:

India imports about
70%
of the total enzyme consumption

The industrial enzymes segment, has an estimated worth of
USD 75 Mn,
and is a quickly growing market in India. Pharmaceutical enzymes are the represents most of the industrial enzyme demands in India and cover almost 50% of the total enzyme demand, followed by detergent enzymes (20%) and textile enzymes (20%)

4.3 BIO-POLYMERS

The global biopolymers market is expected to grow at a CAGR of 16.47% between 2019-2025

India Opportunity:

India generates
33.1 Mn pounds
of plastic waste each day of which only 19.8 Mn pounds is collected and recycled. 18 states including Maharashtra, Karnataka, Andhra Pradesh, Goa, Rajasthan, Tamil Nadu, and now Madhya Pradesh have introduced a ban on disposable plastic

5 BIO-IT

5.1 BIO-INFORMATICS, GENOMICS & PRECISION MEDICINE

- Globally, the bioinformatics market is expected to grow from USD 7.5 Bn in 2018 and is expected to generate around **USD 19.8 Bn** by 2025, at a CAGR of around 14.9% between 2019 and 2025. Major growth drivers include the need for integrated database, increased government initiatives and funding, growing use of bioinformatics in drug discovery and biomarker development and rising interest in genomics and proteomics

India Opportunity:

- Bioinformatics is one of the fastest growing segments in the biotechnology sector of India with over **200 companies** in Bangalore, Delhi, Hyderabad, Pune and Chennai
- Increase in public funding towards research and development along with increasing investments from private companies

5.2 BIG DATA

- Big Data analytics will transform the biopharma industry, reinforcing the promise of big data for the emergence of personalized medicine and genomics, unprecedented levels of data sharing and collaboration, advances in technology and availability of data scientists

India Opportunity:

- The Government of India has helped the development of high-performance computing technology for use in bioinformatic
- India is a leader in IT Outsourcing, with **700,000 graduates** and approximately 300,000 post graduates passing out in science and mathematics. India can address the global big data resource requirement
- As India is home to 1.3 Bn people and consists of more than 4500 anthropologically well-defined populations, the genetic diversity is 4x greater than Europe. This offers a huge opportunity for India to create and mine a rich source of genomic information. India is also rich with regards to genetic resources of medicinal and aromatic plants as it constitutes 11% of total known world flora, bringing a huge IT-enabled data mining advantage

KEY STAKEHOLDER

जैवप्रौद्योगिकी विभाग DEPARTMENT OF BIOTECHNOLOGY	**Department of Biotechnology,** Ministry of Science & Technology
विज्ञान एवं प्रौद्योगिकी विभाग DEPARTMENT OF SCIENCE & TECHNOLOGY	**Department of Science and Technology,** Ministry of Science and Technology
birac Ignite Innovate Incubate	**Biotechnology Industry Research Assistance Council (BIRAC)**
वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH	**Council of Scientific and Industrial Research (CSIR)**
ABLE Association of Biotechnology Led Enterprises ™	**Association of Biotechnology Led Enterprises (ABLE)**
CDSCO	**Central Drugs Standard Control Organization (CDSCO),** Ministry of Health and Family Welfare

INDUSTRY CLUSTERS/ZONES

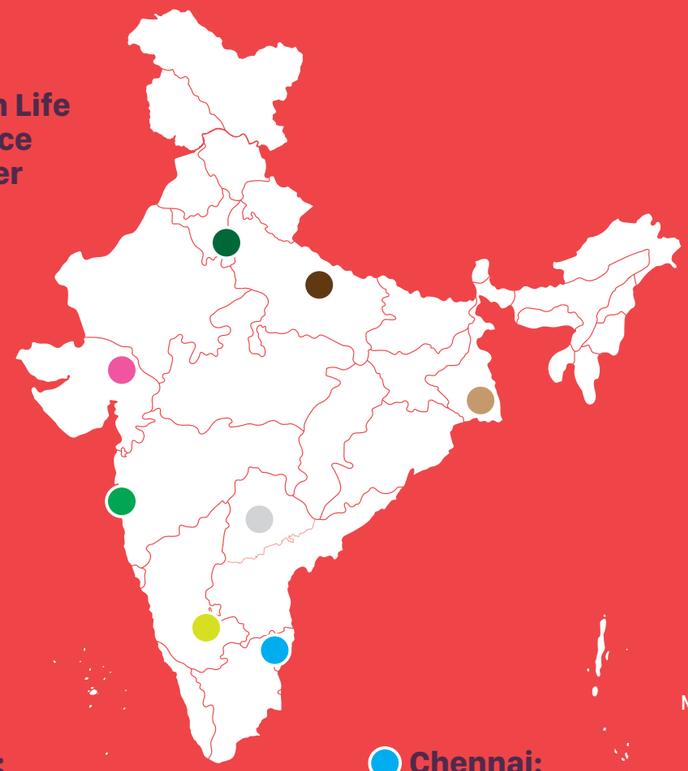
DBT supported biotechnology parks and incubation centers located in different states for the promotion of Biotech start-up companies and the promotion of Public Private Partnerships

- Biotech Park, Lucknow, Uttar Pradesh
- Biotechnology Incubation Centre, Hyderabad, Telangana
- Tidco Centre For Life Sciences (TICEL) Biotech Park, Chennai, Tamil Nadu
- The Golden Jubilee Biotech Park For Women, Chennai, Tamil Nadu;
- Biotech Park Technology Incubation Centre, Guwahati, Assam;
- Biotechnology Incubation Centre, Cochin, Kerala;
- Biotechnology Park, Bangalore, Karnataka;
- Industrial Biotechnology Parks (IBTPs), Jammu & Kashmir; and
- Chhattisgarh Biotech Park, Naya Raipur, Chhattisgarh

Operational Biotech Parks

Map not to scale

Indian Life Science Cluster Map



Map not to scale

Lucknow:

- CDRI, IITR, CIMAP, NBRI
- Lucknow Biotech Park

New Delhi:

- DBT, DST, CSIR, DP, ICMR, ICAR
- Translational Health Sciences Cluster
- National Institute of Immunology
- ICGEB
- Institute of Genomics & Integrative Biology
- National Brain Research Center
- JNU, Delhi University

Kolkata:

- Indian Inst. of Chemical Technology
- Centre for Cellular & Molecular Biology
- Centre of DNA Fingerprinting & Diag.
- National Institute of Nutrition, ICRISAT
- University of Hyderabad, Osmania
- IKP Knowledge Park, SP Biotech Park
- AIBA, FABA

Bengaluru:

- Indian Institute of Science
- National Center for Biological Sciences
- JN Center for Advanced Scientific Research
- University of Agriculture Sciences
- Stem Cell Institute
- IBAB, ABLE

Chennai:

- Anna University
- IIT Madras
- TICEL Biotech Park
- Women's Biotech Park

Vadodhara:

- PERD, NIPER
- Savli Biotech Park
- Proposed Biotech Park in Ahmedabad
- MS University, Baroda

Mumbai:

- TIFR
- IIT Bombay, University of Mumbai
- National Chemical Lab
- National Center for Cell Sciences
- Pune University, IISER
- International Biotech Park

Hyderabad:

- Indian Inst. of Chemical Technology
- Centre for Cellular & Molecular Biology
- Centre of DNA Fingerprinting & Diag.
- National Institute of Nutrition, ICRISAT
- University of Hyderabad, Osmania
- IKP Knowledge Park, SP Biotech Park
- AIBA, FABA

UPCOMING PROJECTS

- Hyderabad Pharma City: One of the biggest Pharma City cluster projects in the world. The cluster aims to create a smart ecosystem, setting a benchmark for sustainable industrial cities worldwide. With plug-n-play facilities, the cluster is designed to become the jump-start platform for companies that make bulk drugs, fermentation products, synthetic drugs, intermediates, vitamins, vaccines, drug formulations, nutraceuticals, herbal products, specialty chemicals and cosmetics

- The Government of Uttar Pradesh is planning on setting up six pharma parks in Noida, Bundelkhand, Ghaziabad, Gorakhpur, Lucknow and Allahabad

- Construction of a new Odisha Biotech Park at Andharua, Bhubaneswar is also underway

KEY PLAYERS IN INDIA

Top Indian Biotech Companies:

Company	CEO	Revenue(USD Mn 2018)
Biocon	Kiran Mazumdar Shaw	590
Serum Institute of India	Cyrus Poonawala	590
Panacea Biotec Limited	Sandeep Jain	65.40
Dr. Reddy's Laboratory Limited	G.V Prasad	2100
Wockhardt	Murtaza Khorakiwala	560
Jubilant Life Sciences Co	Shyam S Bhartia	1053
Bharat Serums and Vaccines Limited	Bharat V. Daftary	98
Indian Immunologicals Limited	K. Anand Kumar	-

RECENT INVESTMENTS

The drugs and pharmaceuticals sector attracted cumulative FDI inflows worth USD 16.73 Bn between April 2000 and June 2019, accounting for 4% of the total FDI inflows into India

Major investments include:

- Piramal Enterprises Ltd acquired a portfolio of spasticity and pain management drugs from UK-based specialty biopharmaceutical company Mallinckrodt Pharmaceuticals, in a deal worth USD 171 Mn (January 2017)

- Aurobindo Pharma Ltd has acquired four biosimilar products from Swiss firm TL Bio-pharmaceutical G which will require TL Biopharmaceutical to supply all the developmental data for four molecules, to be commercialized by Aurobindo pharma (February 2017)

- Capital International Group, a PE equity fund, has acquired 3% stake in Intas Pharmaceuticals Ltd from ChrysCapital Llc for a consideration of USD 107 Mn (August 2017)

- Siemens Healthineers, which provides medical solutions and operates as a subsidiary of Germany-based Siemens, has opened a new diagnostics manufacturing facility in Vadodara, India. The 3150 Sq m facility is equipped with a bench-marked manufacturing facility and globally renowned processes and systems for Indian healthcare industry. The facility will manufacture urine strips and autopak kits (August 2018)

- Germany-based pharmaceutical group Merck KGaA has signed a memorandum of understanding with India-based CSIR-Institute of Microbial Technology to open a 'High-End Skill Development Centre' in Chandigarh, India. The centre will help accelerate healthcare research and train local students and researchers in the latest life science technologies (November 2018)

- German chemical and pharma major, Bayer AG completed the integration of Monsanto's India business to form Bayer CorpScience Ltd as part of a USD 63 Bn mega deal (September 2019)

All information in this brochure was last updated on Apr 30th, 2020.

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& FACILITATION AGENCY

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