BIOTECHNOLOGY
SCIENCE THAT SHAPES GROWTH
BIOTECHNOLOGY
SECTOR OVERVIEW

CURRENT SCENARIO

MARKET SIZE:
USD 51 Bn (2018)

INDIA’S RANKING

- 3rd largest biotech destination in the Asia Pacific Region
- Among the top 12 destinations for biotechnology in the world with approximately 3% share in the global biotechnology industry
- 2nd highest number of US Food & Drug Administration (USFDA)-approved manufacturing plants outside the US
- Largest producer of BT Cotton in the world
- Home to 1730+ Biotechnology start-ups

MAJOR SEGMENTS

- Bio-pharmaceuticals, Bio-services, Bio-agri

FUTURE POTENTIAL

BY 2025, THE INDIAN BIOTECHNOLOGY INDUSTRY IS EXPECTED TO REACH USD 100 Bn

FOCUS STATES
GUJARAT, TELANGANA, ANDHRA PRADESH, KARNATAKA & HIMACHAL PRADESH

START-UP ECOSYSTEM

CURRENT SCENARIO

India ranks high in the start-up ecosystem. Currently, 1730+ start-ups exist in the country, which have been incorporated since 2012. ~61% of these are focused on BioPharma. This is a result of the gradual improvement in ease of doing business norms, proof-of concept funds for start-ups and favourable government policies.

FUTURE SCENARIO

- Association of Biotechnology Led Enterprises (ABLE) is targeting 2020 start-ups by 2020
- BIRAC will continue to grow its partnerships with innovation foundations and universities, to focus on the Make in India and Startup India programs

In June 2017, the Department of Biotechnology launched “National Biopharma Mission” the 1st ever Industry-Academia mission to accelerate biopharmaceutical development in India.
ADVANTAGE INDIA

ACCESSIBILITY
- Over USD 200 Bn to be spent on medical infrastructure in the next decade
- Over 160,000 hospital beds expected to be added each year in the next decade

AFFORDABILITY
- Rising incomes could result in the addition of 73 Mn households to the middle class over the next 10 years
- Over 650 Mn people are expected to have health insurance by 2020
- Announced in the Union Budget 2018-19, National Health Protection Scheme is the largest government funded healthcare program in the world. It is expected to benefit 100 Mn poor families in the country by providing medical cover of up to INR 5 L (USD 7,723.2) per family per year for secondary and tertiary care hospitalisation
- Affordable medicines under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) have led to savings of INR 600 Cr (USD 85.49 Mn) for Indian citizens in FY19 (up to October 2018)
- The government plans to provide free generic medicines to half the country’s population at an estimated cost of USD 5.4 Bn

INFRASTRUCTURE FACILITIES
- Central and state governments have worked to set up several incubators and life-science clusters across the country
- There are currently 8 DBT-supported Biotech Parks, 35 BIRAC-supported Bio-incubators, as well as 17 Centers of Excellence—with plans for more in the near future

SKILLED HUMAN CAPITAL
- India has a population of 1.3 Bn, 50% of which is under the age of 25. This results in a young and high-quality skilled workforce
- The recent development of several life-science clusters has resulted in collaborations between research institutes and the private sector, thus growing India’s R&D capabilities
- The government has introduced an industry-academia collaboration with the World Bank, to accelerate discovery research for early development of biopharmaceuticals

EPIDEMIOLOGICAL FACTORS
- Patient pool expected to increase over 20% in the next 10 years, mainly due to the rise in population
- New diseases & lifestyle changes are expected to increase the 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 Life Sciences Sector Skill Development Council (LSSSSC) under National Skill Development Corporation (NSDC) to promote skill development in the biotechnology sector

STATE-SPECIFIC POLICIES
- Andhra Pradesh launched its Biotechnology Policy 2015-2020, with an aim to attract new investments worth INR 6,000 Cr by 2020- as well as create 5000 additional employment opportunities for skilled personnel by 2020
- Gujarat launched its draft Biotechnology Policy for 2016-2021, with special emphasis on the Biotech sector
- Rajasthan launched its Biotechnology Policy 2015, with an aim to establish world-class research institutes and biomanufacturing infrastructure
- Telangana launched its Life Sciences Policy (2015-2020), with an aim to make the state the most preferred destination for life science activities- as well as attract new investments worth INR 20,000 Cr by 2020
- Uttarakhand launched its 2018-2023 Biotechnology Policy, aimed at attracting new investments worth INR 5000 Cr- as well as generate employment opportunities for 5000 people by 2023

BIRAC
- Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit set up by Department of Biotechnology (DBT), Government of India. It is an interface agency aimed at strengthening and empowering the emerging biotechnology enterprises to undertake strategic research and innovation
- BIRAC hosts an industry-specific Make in India cell for the Biotechnology Sector

MAJOR BIOTECH INITIATIVES
- Regulations and guidelines on biosafety of recombinant DNA research & biocontainment released (2017)
- Lok Sabha has passed the DNA Technology (Use and Application) Regulation Bill 2018, that allows regulated use of DNA
- Launch of National Biopharma Mission's program, "Innovate in India" (2017) – it is a DBT program with USD 250 Mn in funding, that aims to bring together industry and academia in order to promote entrepreneurship and indigenous manufacturing in bio-pharma

THE NEW DRUGS AND CLINICAL TRIALS RULES 2019
- Ministry of Health and Family Welfare released this new rule, to promote clinical research in the country
- Under this rule drug approval outcomes must be shared within 30 days for a clinical trial done in India, and within 90 days for clinical trials of drugs developed outside of India
1

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. India’s 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.

Biotechnology Segments

- 62% BIOPHARMACEUTICALS
- 18% BIO-SERVICE
- 15% BIO-AGRICULTURE
- 04% BIO-INDUSTRIALS
- 01% BIO INFORMATICS, SYSTEM BIOLOGY
1.3 INSULIN
Diabetes is one of the most prevalent disorders globally. 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 cost of treating diabetic patients is currently about USD 420 per person per year. If this cost remains the same, India's total bill for diabetes will be approximately USD 30 Bn by 2025.
- The global anti-diabetes market is valued at more than USD 50 Bn, and is growing at approximately 15%. Of this insulin has a market share of approximately USD 30 Bn and this figure is expected to reach USD 57 Bn by 2025.

1.4 REGENERATIVE MEDICINE
The regenerative medicine market can be divided into 3 major categories: tissue engineering, biomaterials/biomolecules & stem cell therapy. The 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 possibility of using stem cells to regenerate nerve, heart and adult muscle cells - as well as repair damaged bone tissue.
- The Indian Council of Medical Research issued the 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 valued 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 a USD 1.3 Bn market. The Indian Contract Manufacturing market is expected to reach USD 4 Bn by 2025.

India Opportunity:
- India has an edge in contract manufacturing due to resources such as manpower, a technically knowledgeable workforce, WHO-GMP approved production premises and a substantial 40% lower cost of operation and production.

2.2 CLINICAL RESEARCH
The global clinical research market is valued at USD 30 Bn and is expected to reach USD 95 Bn by 2025.

India Opportunity:
- The Indian Council of Medical Research issued the 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.

- Vision 2020 - to make the country one of the top five Pharma innovation hubs by 2020 - with 1 out of every 5 to 10 drugs discovered worldwide coming from India.
Globally, North America and Europe comprise more than 60% of the Enzymes market. The Indian market is relatively smaller, and contributes approximately 2% to the overall enzymes market. India imports about 4.2 Enzymes (Industrial + Specialty). India Opportunity: 70% of its domestic enzyme demand.

The industrial enzymes segment is worth approximately USD 75 Mn, and is a quickly growing market in India. Pharmaceutical enzymes make up most of the industrial enzyme demand in India and cover almost 50% of the total enzyme demand—followed by detergent enzymes (20%), and textile enzymes (20%).

The global biopolymers market is expected to grow at a CAGR of 16.83% during 2017-2021. India annually generates 33.1 Mn pounds of plastic waste, of which only 19.8 Mn pounds are collected and recycled. 25 States— including Delhi, Maharashtra, Karnataka, Andhra Pradesh, Goa, Rajasthan, Kerala, Punjab, and now Madhya Pradesh—have introduced a ban on disposable plastic.

India Opportunity:

The national policy on Biofuels 2018 indicates a viability gap funding scheme of INR 5000 Cr in 6 years for second generation Ethanol Bio-refineries. This is supplemented by additional tax incentives and a higher purchase price compared to First Generation biofuels.
5 BIO-IT

5.1 BIO-INFORMATICS, GENOMICS & PRECISION MEDICINE

The global bioinformatics market is expected to grow from USD 4.11 Bn to USD 12.54 Bn by 2020, with a CAGR of 20.4% during 2014-2020. Major growth drivers include the need for integrated databases, increase in government initiatives and funding, growing use of bioinformatics in drug discovery and biomarker development, and a rising interest in genomics and proteomics.

India Opportunity:
- Bioinformatics is one of the fastest growing segments in India's biotechnology sector, with over 200 companies in Bangalore, Delhi, Hyderabad, Pune, and Chennai
- Increase in public funding towards research and development, along with an increase in investments from private companies.

5.2 BIG DATA

Big Data analytics will transform the biopharma industry. It will reinforce the promise of big data for emergence of personalised medicine and genomics, ensure unprecedented levels of data sharing and collaboration, bring about advances in technology, and result in the increase in availability of data scientists.

India Opportunity:
- The Government of India has aided in the development of high-performance computing technology for use in bioinformatics – C-DAC
- India is a leader in IT Outsourcing, with 700,000 graduates and approximately 300,000 post graduates annually in science and mathematics. With these numbers, India can address global big data resource requirement
- India is home to 1.3 Bn people and comprises more than 4500 anthropologically well-defined populations. Thus, its genetic diversity is 4x greater than that of Europe. This offers a huge opportunity for India to create and mine a rich source of genomic information. India is also rich in genetic resources of medicinal and aromatic plants, as it is home to 11% of the total known flora. This presents a huge IT-enabled data mining advantage.
There are DBT-supported biotechnology parks and incubation centres in different states, designated for the promotion of Biotech start-ups and the Public Private Partnerships:

- Lucknow Biotechnology Park, Uttar Pradesh
- Biotechnology Incubation Centre, Genome Valley, Hyderabad, Andhra Pradesh
- Biotechnology Core Instrumentation Facility (BTCIF) at TIDCO Centre for Life Sciences (TICEL), Chennai
- The Golden Jubilee Biotech Park for Women, Siruseri, Kanchipuram District, Tamil Nadu
- Guwahati Technology Incubation Centre (GBPIC) at Biotech Park, Assam
- Bangalore Biotech Park, Karnataka
- KRIBS BioNest, Kochi, Kerala (previously called KINFRA Biotech Park)
- Punjab Biotechnology Incubator, Mohali, Punjab

• 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

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

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

- Kolkata:
  - Indian Inst. of Chemical Technology
  - Centre for Cellular & Molecular Biology
  - 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
  - IBAD, ABLE

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

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

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

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

- JODHPUR
- GANDHINAGAR
- JAMNAGAR
- ANAND
- VADODARA
- AURANGABAD
- PUNE
- HYDERABAD
- MIDNAPORE
- BHUBANESWAR
- Konark
- VISAKHAPATNAM
- CHENNAI
- PUDUCHERRY
- MADURAI
- KOCHI
- BENGALURU
- KARWAR
- New Delhi:
  - CDRI, IITR, CIMAP, NBRI
  - Lucknow Biotech Park

- Kolkata:
  - Indian Inst. of Chemical Technology
  - Centre for Cellular & Molecular Biology
  - 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
  - IBAD, ABLE

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

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

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

- Vadodhara:
  - PERD, NIPER
  - Savli Biotech Park
  - Proposed Biotech Park in Ahmedabad
  - MS University, Baroda
KEY PLAYERS IN INDIA

TOP INDIAN BIOTECH COMPANIES:
HOW WE HELP INVESTORS

RESEARCH CONTENT PROVIDED
POLICY ADVISORY/REPRESENTATION
STAKEHOLDER MEETING
SITE VISITS
LOCATION ANALYSIS
ISSUE RESOLUTION
REGULATORY CLEARANCE FACILITATION

To find out more
https://www.investindia.gov.in/sector/biotechnology

Phone No: 011 2304 8101
Email ID: biotech@investindia.org.in

First Floor,
Vigyan Bhawan Annexe,
Maulana Azad Road, New Delhi - 110011

@investindia @InvestIndiaOfficial @invest-india