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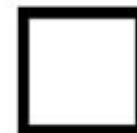
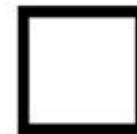
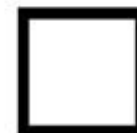
BIOTECHNOLOGY

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November 2020

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Global position

- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific. The country is also the biggest producer of recombinant Hepatitis B vaccine and BT cotton
- In 2019, India was among the top suppliers of DPT, BCG and measles vaccines worldwide

Strong start-up ecosystem

- India has a strong start-up ecosystem, originating from gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favourable government policies
- The biotechnology industry in India comprises >2700 biotech start-ups and is estimated to reach 10,000 by 2024

Strong growth in Biopharmaceuticals

- The biopharmaceutical is the largest segment that contributes ~62% to the Indian biotechnology market
- In June 2017, Department of Biotechnology, under the 'National Biopharma Mission', launched 'Industry-Academia Mission' to accelerate biopharmaceutical development in India

Leading destination for clinical trials

- Bio-services, which account for 16% of the biotechnology industry in India, is becoming a leading sector for clinical trials, contract research and manufacturing activities in the country
- The New Drugs and Clinical Trials Rules, 2019 were developed to create a streamlined legal framework for the biopharmaceutical market to reduce costs, approval timelines and cut bureaucratic red tape

Notes: BT Cotton: Genetically modified pest resistant plant cotton, DPT: diphtheria, pertussis, tetanus, BCG: Bacille Calmette-Guerin

Source: Global Bio-India 2019, Biotechnology Industry Research Assistance Council

ADVANTAGE INDIA



- With a total population of 1.3 billion, 50% being under the age of 25, India has large pool of young and skilled workforce
- The government has come up with an industry-academia collaboration with the World Bank to accelerate discoveries and research for early-development of biopharmaceuticals

Skilled human capital

- Central and state governments have worked to set up several incubators and life science clusters across India
- 9 DBT-supported biotech parks and 50 BIRAC-supported bio-incubators

Infrastructure facilities

ADVANTAGE INDIA

- 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

Epidemiological factors

- 100% under automatic route for greenfield projects for pharmaceuticals
- While 74% is permitted under automatic route for brownfield projects, 100% under government route is permitted for brownfield investments

Policy support & initiatives

- 100% under automatic route is allowed for the manufacturing of medical devices
- Setting up of the Life Sciences Sector Skill Development Council (LSSSDC), under National Skill Development Corporation (NSDC), will promote skill development in the life sciences sector

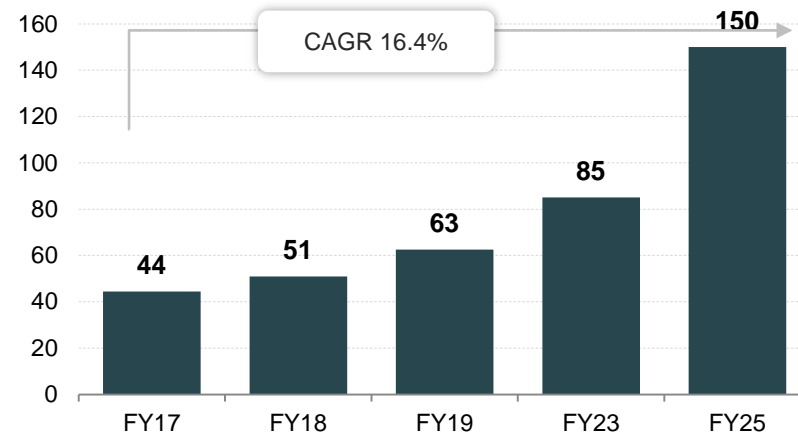
Source: Department of Biotechnology

MARKET OVERVIEW



- The biotechnology sector in India is witnessing a strong growth trajectory and has proved to be highly inventive
- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific
- The Indian biotechnology industry is likely to register a CAGR of 16.4% to reach US\$ 150 billion in 2025
- By 2025, contribution of the Indian biotechnology industry in the global biotechnology market is expected to increase to 19% from 3% in 2017
- The biotechnology sector, mainly due to its multidisciplinary approach holds the potential to provide an array of solutions for challenges in sectors such as health, agriculture, environment, energy and industrial processes.
- The biotechnology industry consists of 2700+ biotech start-ups and is expected to grow to 10,000 by 2024. There are >2500+ biotech companies in India
- India has 665, the highest number, of FDA-approved plants outside of the US; 44% global abbreviated new drug applications (ANDA) and >1400 manufacturing plants, which comply with WHO requirements

Indian biotechnology industry valuation (US\$ billion)



Indian bioeconomy at a glance (2019)

\$12 billion

India's Biotech Industry Revenue

1 million

India's Biotech Workforce

2,500+

Biotech Companies in India

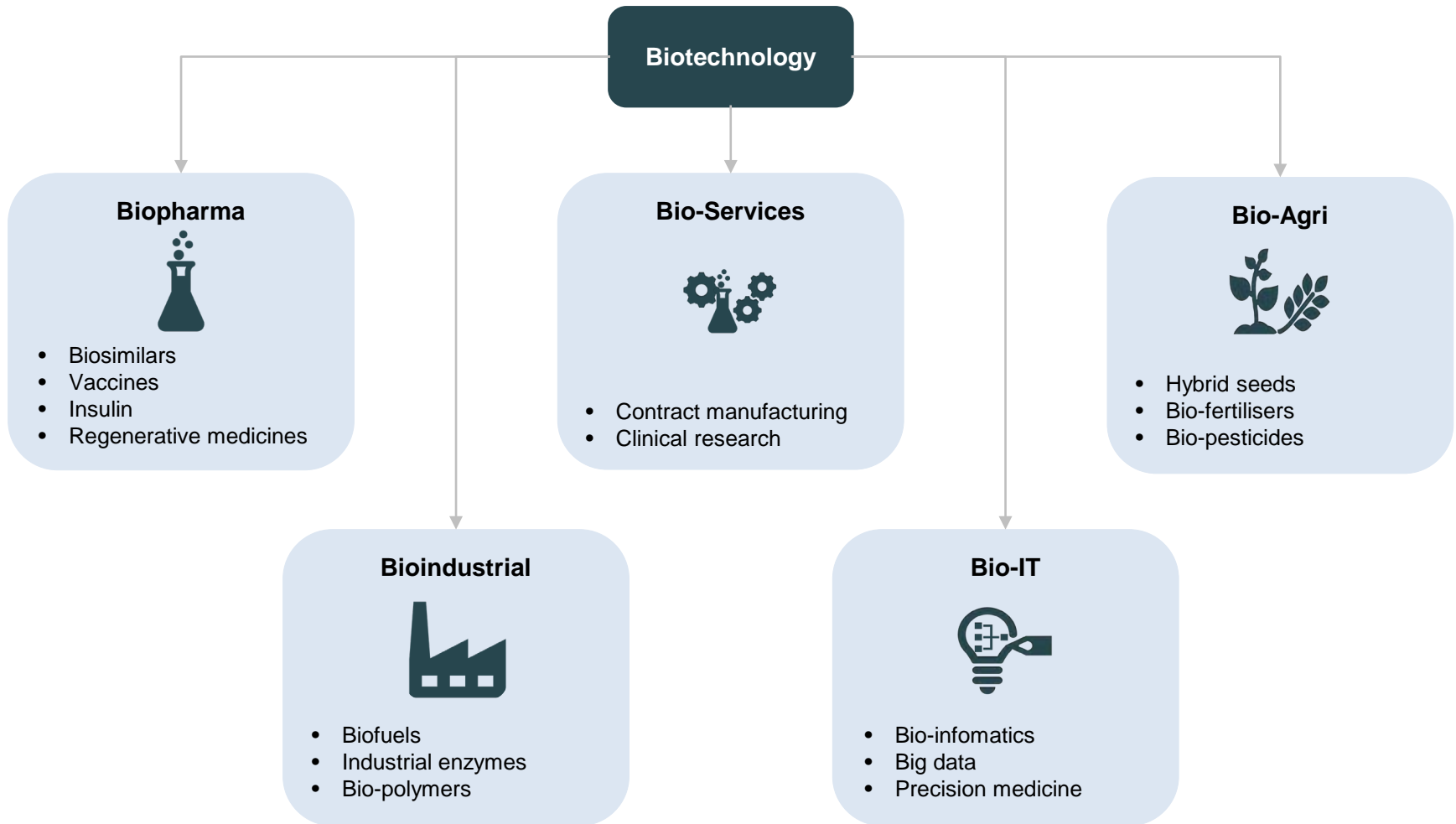
15,500+

Biotech Graduates Every Year






Notes: FDA: Food and Drug Administration

Source: DPT-BIRAC, Association of Biotechnology Led Enterprises (ABLE)

INDIAN BIOTECHNOLOGY SECTOR IS DIVIDED INTO FIVE SEGMENTS



Source: Association of Biotechnology Led Enterprises (ABLE)

	Biocon	<p>Indian pharmaceutical company based in Bangalore that manufactures generic active pharmaceutical ingredients</p>
	Serum Institute of India	<p>Manufacturer of immuno-biologicals, which include Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines</p>
	Panacea Biotec Limited	<p>Innovation-driven biotechnology company, undertaking research and development, manufacturing, sales, distribution and marketing of pharmaceuticals, vaccines and biosimilars</p>
	Dr Reddy's Laboratory Limited	<p>Integrated pharmaceutical company, providing affordable and innovative medicines</p>
	Wockhardt	<p>Global pharmaceutical and biotechnology organisation, manufacturing pharmaceuticals, biopharmaceutical formulations and active pharmaceutical ingredients</p>
	Jubilant Life Sciences Co	<p>Integrated global pharmaceutical and life sciences company, engaged in pharmaceuticals, life science ingredients, drug discovery solutions and India-branded pharmaceuticals</p>
	Bharat Serums and Vaccines Limited	<p>Indian pharmaceutical company based in Mumbai that develops, manufactures and markets plasma derivatives, monoclonals, fertility hormones, antitoxins, antifungals, anaesthetics, cardiovascular drugs and diagnostic products</p>
	Indian Immunologicals Limited	<p>Indian biopharmaceutical company based in Hyderabad that manufactures animal and human vaccine including rabies, Hepatitis B, Diphtheria and Influenza vaccines</p>

Note: News articles

RECENT TRENDS AND STRATEGIES



NATIONAL AND INTERNATIONAL PARTNERSHIPS

Dr. Reddy's partners with BIRAC for Sputnik V vaccine clinical trials

In October 2020, Dr. Reddy's Laboratories Ltd. announced partnership with BIRAC, Department of Biotechnology (DBT), Government of India, for advisory support on clinical trials of Sputnik V vaccine in India.

The partnership will allow Dr. Reddy's to identify and use some of BIRAC's clinical trial centres for the vaccine; the centres are funded under the National Biopharma Mission (NBM), implemented by the Project Management Unit-NBM at BIRAC.

Aurobindo Pharma partnered with BIRAC to develop COVID-19 vaccine

In September 2020, Aurobindo Pharma announced collaboration with BIRAC to develop COVID-19 vaccine

Aurobindo Pharma is developing the vaccine through its wholly-owned US subsidiary, Auro Vaccines

Advent International acquired majority stake in Bharat Serums and Vaccines

In November 2019, Advent International, a private equity investor, acquired a majority interest in Bharat Serums and Vaccines Limited

This acquisition was aimed to strengthen and expand Bharat Serums offerings in India and the global markets

Glenmark's spin-off Ichnos Sciences launched as biotech company

In October 2019, Glenmark Holdings spun-off, Ichnos Sciences, was launched as a new independent biotechnology company, focussing on oncology and autoimmune diseases

The new company includes two research centres (biologics in Switzerland and small molecules in Mahape, Navi Mumbai, India), a development site (Paramus, New Jersey) and a GMP biologics manufacturing facility (Switzerland)

Biocon buys Pfizer's R&D facility

In September 2019, Biocon Ltd. Acquired a Chennai-based research and development facility from Pfizer Healthcare India Ltd. through its subsidiary Biocon Biologics

This acquisition was aimed to help Biocon accelerate its development of biosimilars from lab to pilot scale

Notes: BIRAC: Biotechnology Industry Research Assistance Council

Source: Company website, news articles

RECENT INVESTMENTS BY KEY PLAYERS

India allows 100% FDI under the automatic route (a non-resident or Indian company will not require any approval from the government) for greenfield pharmaceuticals and manufacturing medical devices.

2020

- **November 2020:** Bharat Biotech plans to produce 10 types of vaccines including malaria and COVID-19 with a total investment of Rs. 300 crore (US\$ 40.54 million) at its upcoming unit in Bhubaneswar, Odisha.

2019

- **September 2019:** German chemical and pharma major, Bayer AG, completed the integration of Monsanto's India business to form Bayer CorpScience Ltd. as a part of the US\$ 63 billion mega deal

2018

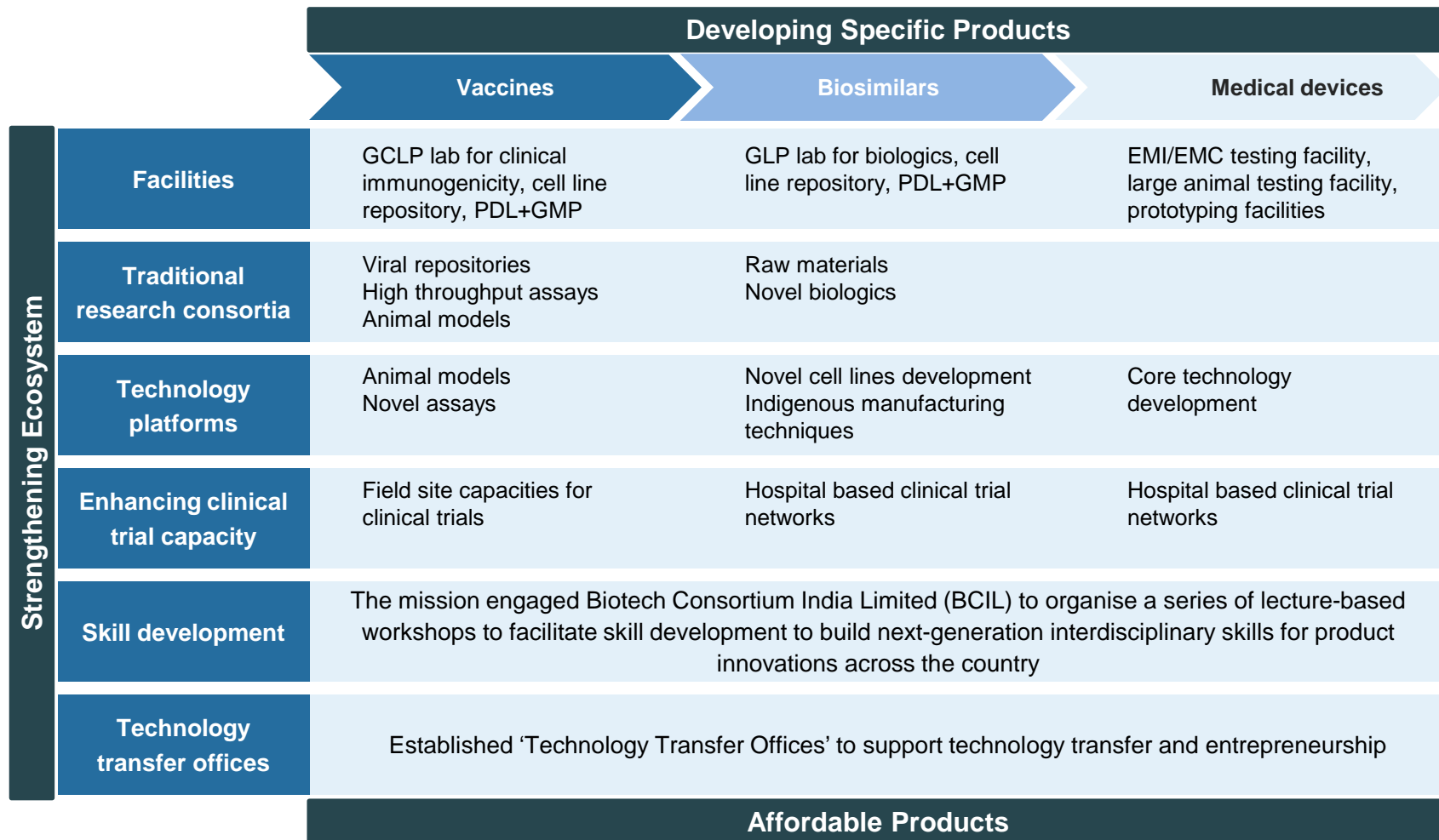
- **November 2018:** Germany-based pharmaceutical group, Merck KGaA, signed a memorandum of understanding with India-based CSIR - Institute of Microbial Technology to open a high-end 'Skill Development Centre' in Chandigarh, India. This centre aimed to accelerate healthcare research and train local students and researchers in the latest life science technologies
- **August 2018:** Siemens Healthineers, which provides medical solutions and operates as a subsidiary of Germany-based Siemens, opened a new diagnostics manufacturing facility in Vadodara, India. The 3150 sq. m. facility is equipped with bench-marked manufacturing equipment, processes and systems; manufactures urine strips and autopak kits

2017

- **August 2017:** Capital International Group, a PE equity fund, acquired 3% stake in Intas Pharmaceuticals Ltd. from ChrysCapital for a consideration of US\$ 107 million
- **February 2017:** Aurobindo Pharma Ltd. acquired four biosimilar products from TL Biopharmaceutical AG. Through this acquisition, TL Biopharmaceutical supplied all developmental data for four molecules that were commercialised by Aurobindo Pharma

Notes: As of April 30, 2020

Source: static.investindia.gov.in



Notes: GCLP: Good clinical laboratory practice, GLP: Good laboratory practice, EMI: Electromagnetic interference, EMC: electromagnetic compatibility, PDL: preferred drug list, GMP: Good manufacturing practices

Source: Department of Biotechnology

STATE-SPECIFIC POLICIES

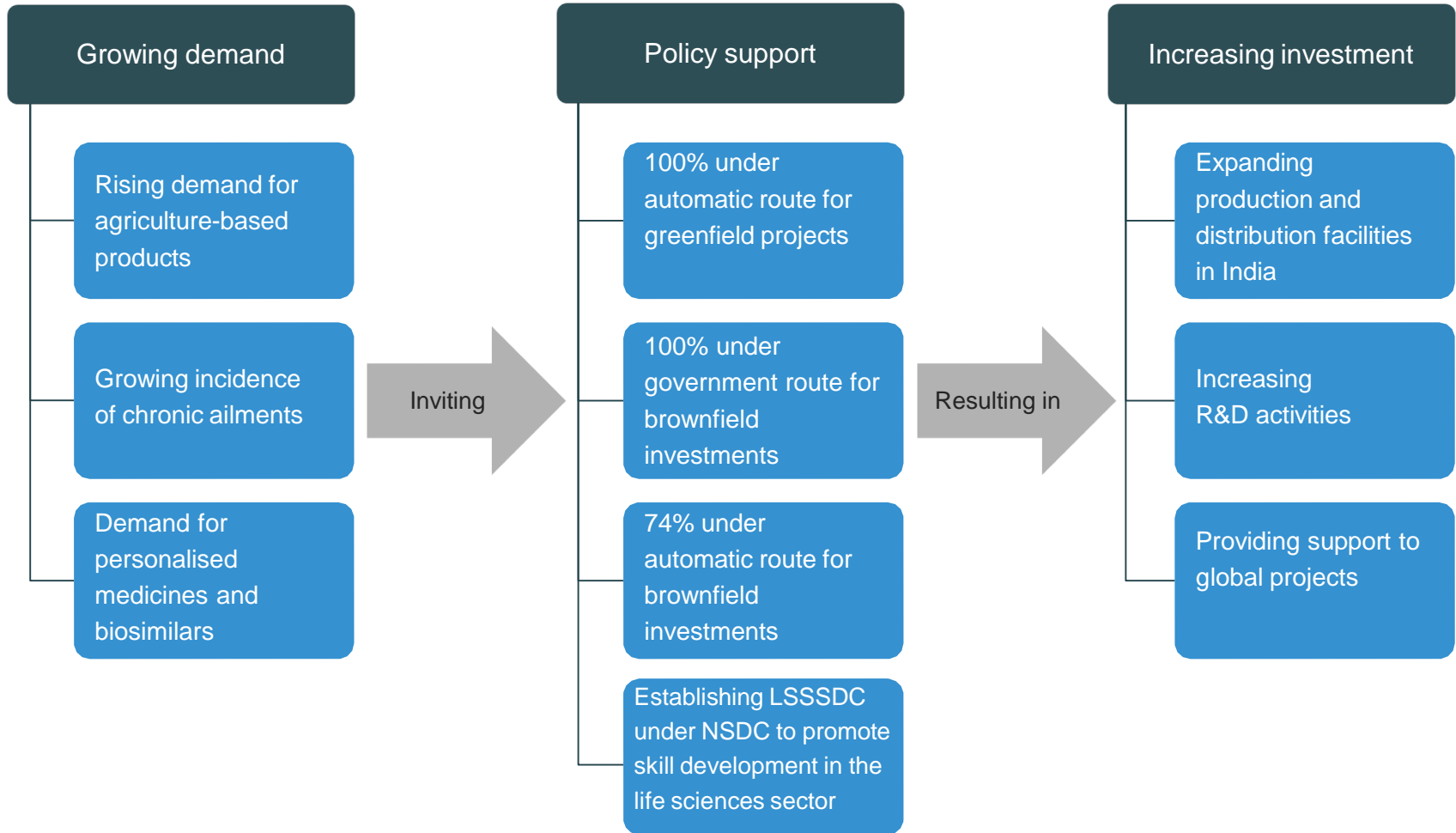
South	
Andhra Pradesh Biotechnology Policy 2015-2020	Development of several infrastructure projects and industrial parks
Karnataka Biotechnology Policy 2017-2022	Strengthening the ecosystem required for boosting start-ups, accessing funds for R&D and product development, developing attractive incentives for investors and providing mentorship for growth
Telangana Life Sciences Policy 2015-2020	Development of suitable infrastructure to attract life science companies and become a leading investment destination in the sector
North	
Uttarakhand Biotechnology Policy 2018-2023	Aims to attract new investments worth US\$709 million in the sector; generate employment opportunities for 5000 people by 2023
Himachal Pradesh Biotechnology Policy 2014	Aims to make Himachal a globally competitive destination for development of biotechnology products, processes and services
West	
Rajasthan Biotechnology Policy 2015	Aims to establish world-class research institutes and biomanufacturing infrastructure
Gujarat Biotechnology Policy 2016-2021	Aims to develop a robust biotechnology ecosystem in the state
East	
Assam Biotechnology Policy 2018-2022	Development of the biotechnology industry in Assam, following the growth of bio-agri segment in the state
Odisha Biotechnology Policy 2018	Aims to make Odisha one of the top biotech investment and innovation destinations in the country
Central	
Madhya Pradesh Biotechnology Policy 2003	Conservation and sustainable utilisation of bio-resources to promote socioeconomic growth in the state

Source: State Government Websites

GROWTH DRIVERS



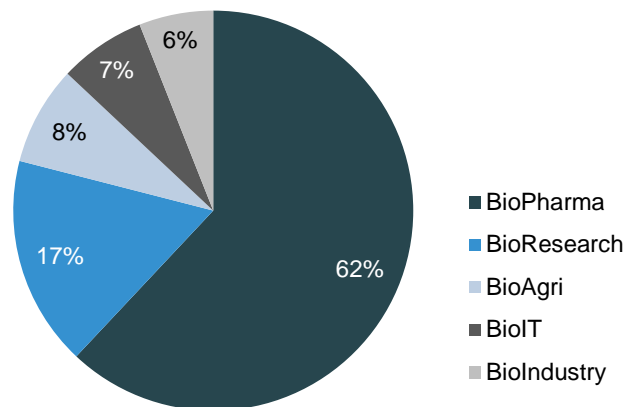
STRONG DEMAND AND POLICY SUPPORT DRIVING INVESTMENTS



Notes: LSSSDC: Life Sciences Sector Skill Development Council, NSDC: National Skill Development Corporation, R&D - Research and Development
Source: Department of Biotechnology, Association of Biotechnology Led Enterprises (ABLE)

- The start-up ecosystem in India is strongly supported on the back of gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favorable government policies
- BIRAC (Biotechnology Industrial Research Assistance Council), a public sector undertaking of DBT, partnered with innovative foundations and universities to focus on 'Make in India' and 'Start-up India' programmes
- BIRAC established several industry-focussed schemes such as SBIRI, BIPP Biotechnology Ignition Grant, BioNEST, SITARE, PACE, SIIP, SEED, LEAP and Fund of Funds-AcE. BIRAC has supported 50 bio-incubators for potential entrepreneurs

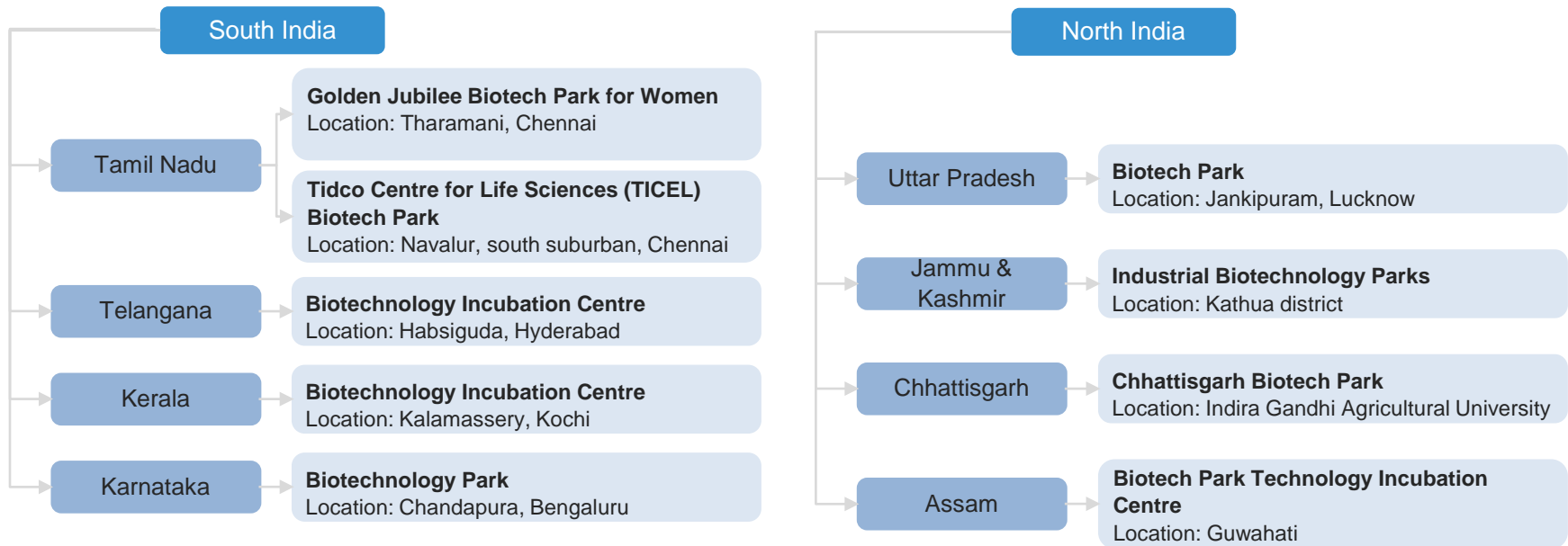
Sector-wise representation of startups-2019 (%)



Source: Investindia.gov.in, BIRAC

BIRAC (Bio-Incubator)

Incubators supported	50
Amount committed for BioNEST	US\$ 30.2 million
Incubation area supported	5,49,219 sq. ft.
Incubatees supported	680
Resident incubatees supported	571
Non-resident incubatees supported	109
Total products/technologies commercialised	200
Total employment generated	3,500
Total IPs generated	250
Total trainings/workshops conducted	1,000



- Biotechnology parks and incubators are established across the country by the Department of Biotechnology (DBT), under the Ministry of Science and Technology, to translate research into products and services by providing necessary infrastructure support
- These biotechnology parks offer facilities to scientists, and small and medium sized enterprises (SMEs) for technology incubation, technology demonstration and pilot plant studies to accelerate commercial development of biotechnology
- The government, at present, supports nine biotechnology parks in various states, with the bulk being in the southern region






“These parks are successfully accelerating the commercialisation of new technologies, nurturing and maintaining emerging ventures and assisting new enterprises to forge appropriate linkages with other stakeholders of biotechnology sector including academia and the government.”

- Secretary, DBT

Source: Association of Biotechnology Led Enterprises (ABLE)

OPPORTUNITIES

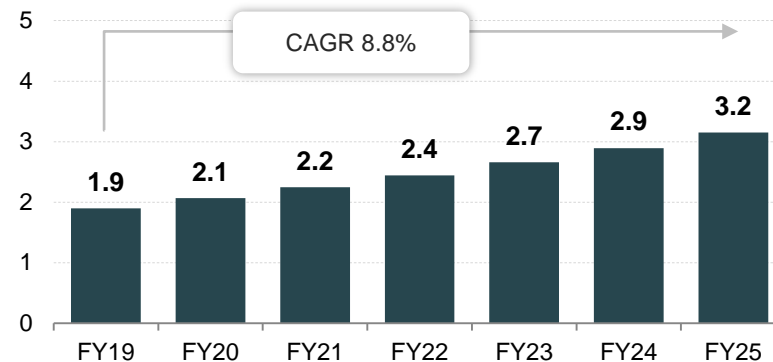


Bio-Services	Bioindustrials	Biopharma	Bio-Agri	Bio-IT
 <ul style="list-style-type: none"> • India has potential for clinical trials due to a large and low-cost market • Clinical trials in India are regulated by the Central Drug Standard Control Organisation, which has reduced approval time to about 30-60 days, giving opportunity for market growth • The country also has the advantage of English-speaking researchers and required medical infrastructure to conduct medical research 	 <ul style="list-style-type: none"> • Biofuels and bioenergy are considered alternative resources and are gaining popularity in India • Rise in energy demand is leading to an increase in dependence on fossil fuel imports • As a result, companies can develop a strategy to reduce import dependence through biofuels and bioenergy 	 <ul style="list-style-type: none"> • The Indian biologics market is expected to register a CAGR of 22% to reach US\$ 12 billion by 2025 • Growth of biologics provides opportunity for biosimilars in the market • With ~12 patented biologics products expected to expire in the US by 2020, there is an opportunity for India biopharmaceutical firms and increased competition is likely 	 <ul style="list-style-type: none"> • India's Union budget states the government's plan to enhance farm productivity and focus on food security • This will likely increase the importance of bio-agriculture, which will enhance efficient food production 	 <ul style="list-style-type: none"> • Biotechnology has immense growth potential in the Bio-IT segment, given the rising need for technology to transform data generated by R&D institutes, clinics, hospitals, etc., into a defined format • India's IT industry is witnessing substantial growth and has the requisite IT infrastructure to cater to the needs of the global Bio-IT industry

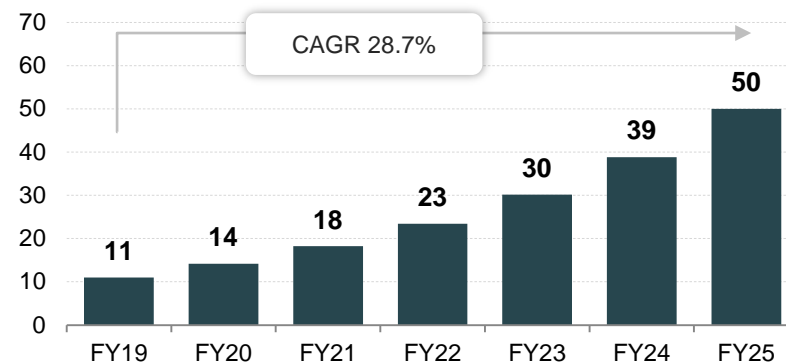
Source: Association of Biotechnology Led Enterprises (ABLE), Institute for Competitiveness

- India is among the preferred destinations for clinical trials owing to a large patient pool, transformation of the healthcare market, well-educated physicians and cost competitiveness
- The Union Ministry for Health and Family Welfare has reported new Drugs and Clinical Trials Rules, 2019, changing the regulatory landscape for approval of new drugs and conducting clinical trials in the country
- The Indian Council of Medical Research (ICMR) has selected 12 institutes for clinical trial of the country's first indigenous COVID-19 vaccine
- In 2020, the ICMR to develop indigenous COVID-19 vaccine (BBV152 COVID) in partnership with Bharat Biotech International Limited
- The Indian medical devices industry consists of MNCs and SMEs are expected to reach US\$ 50 billion by 2025 with domestic manufacturers accounting for ~65%
- India is among the top 20 markets for medical devices in India and 4th largest in Asian markets
- India has six medical device manufacturing clusters where efficient manufacturing is done at lower costs
- In September 2020, Thiruvananthapuram-based Sree Chitra Tirunal Institute for Medical Sciences and Technology announced that it will collaborate with the Kerala government to set up a Rs. 260 crore (US\$ 35.44 million) medical devices park in Thonnakkal (Thiruvanthapuram)

Clinical trials market in India (US\$ billion)



Medical devices market in India (US\$ billion)



Source: News Articles

UPCOMING BIOTECHNOLOGY PROJECTS IN INDIA

Upcoming Biotechnology Projects	State Presence	Cost of the Project (US\$ million)
Mangalapuram Bio 360 Life Sciences Park Project - Phase II	Kerala	56.56
Kupwara Biotechnology	Jammu & Kashmir	4.5

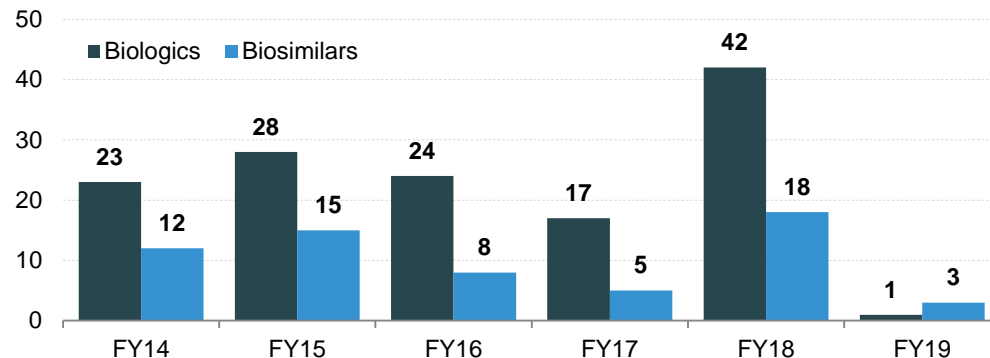
Source: News Articles

INDIA: EMERGING HUB FOR BIOLOGICS AND BIOSIMILARS

The global life sciences industry is shifting from chemical-based drug to biologics and biosimilars; India approved its first biosimilar as early as 2000

- India's first biosimilar was approved in 2000 and has more than 98 biosimilars approved until September 2019
- Biologics economy in India is valued at US\$ 3 billion and is forecast to reach US\$ 7.3 billion by 2025
- In India, the biologics segment is led by Biocon Ltd., and has commercialised the biosimilars Trastuzumab and Pegfilgrastim among others in partnership with Mylan
- Other players in the space include Dr Reddy's Laboratories, Intas Pharmaceuticals, Zydus Cadila and Lupin

Number of biologics and biosimilars approved in India



Drug name	Originator company	Active companies	First launched
bevacizumab	Dr Reddy's Laboratories Ltd.	Dr Reddy's Laboratories Ltd	19-Aug-19
trastuzumab	Dr Reddy's Laboratories Ltd	Dr Reddy's Laboratories Ltd	26-Jul-18
pegfilgrastim	Lupin Ltd	Lupin Ltd	25-Jul-18
pegfilgrastim	Biocon Ltd	Biocon Ltd; Mylan NV	30-Jun-18
adalimumab	Hetero Group	Hetero Group	03-Jan-18
bevacizumab	Biocon Ltd	Biocon Ltd; Mylan NV	23-Nov-17
bevacizumab	Zydus-Cadila Group	Zydus-Cadila Group	30-Sep-17

Source: Biologics Division, CDSCO, Association of Biotechnology Led Enterprises (ABLE)

- India has >50 approved biosimilar products and the market is expected to reach US\$ 2.2 billion by 2025
- Expiry of ~US\$ 70 billion biologics drugs patent by 2020 will provide export opportunities
- Global companies are leveraging both generics to contain healthcare costs and Indian companies such as Biocon are positioning themselves to deliver affordable access to innovative and inclusive healthcare solutions

Biosimilars

Biopharma opportunities for India

Vaccines

- India exports vaccines to about 150 countries
- The country covers 40-70% of the World Health Organisation (WHO) demand for DPT (diphtheria, pertussis or whooping cough, and tetanus) and BCG (Bacille Calmette-guérin) vaccines against tuberculosis, followed by ~90% of its demand for the measles vaccine

- India is likely to witness >100 million diabetics by 2030. With rising number of patients, ~50% are undiagnosed, providing domestic market opportunity to the country
- Indian players are also creating opportunities in the international market. For example, Biologics and its partner Mylan N.V. launched their insulin glargine injection under the brand name Semglee in the US

Insulin

Regenerative medicine

- Several research institutes in India are investigating the use of stem cells to regenerate nerve, heart and adult muscle cells, and repair damaged bone tissues
- Rise in chronic disease incidences is driving the demand for regenerative medicine
- The Indian Council of Medical Research has issued the National Guideline for Stem Cell Research to promote clinical applications of stem cell research in ophthalmology, cardiology and spinal cord repair

Source: BIRAC

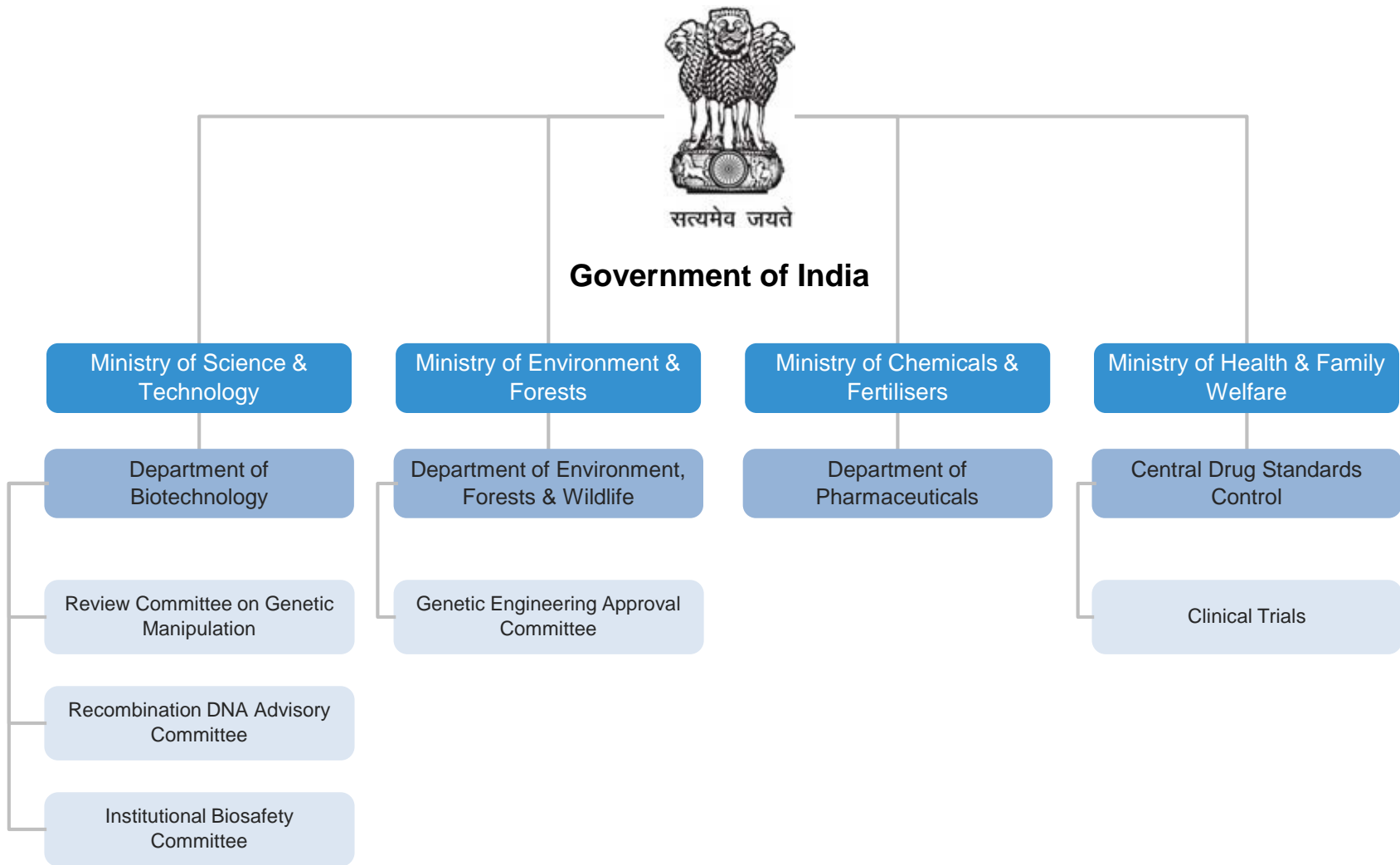
KEY INDUSTRY ORGANISATIONS



KEY INDUSTRY ORGANISATIONS

Agency	Contact Information
Department of Biotechnology, Ministry of Science & Technology	6th-8th Floor, Block 2 CGO Complex, Lodhi Road New Delhi – 110 003.India Phone: 91-11-2436 2950 Website: www.dbtindia.gov.in
Department of Science and Technology, Ministry of Science and Technology	Department of Science & Technology, Technology Bhavan, New Mehrauli Road, New Delhi-110 016 Phone: +91-11-26562122/25/33/44, 26567373, 26962819 Fax +91-11-26863847, 26515637 Website: www.dst.gov.in
Biotechnology Industry Research Assistance Council (BIRAC)	1st Floor ,MTNL Building ,9 , CGO Complex, Lodhi Road, New Delhi-110003 Website: www.birac.nic.in , E-mail address: birac.dbt@nic.in Phone: + 91-11-24389600 Fax: + 91-11-24389611
Council of Scientific and Industrial Research (CSIR)	Council of Scientific and Industrial Research, Anusandhan Bhawan, 2 Rafi Ahmed Kidwai Marg, New Delhi - 110001 Phone: +91-11-23737889 Website: www.csir.res.in
Association of Biotechnology Led Enterprises (ABLE)	# 123/C, 16th Main Road,5th Cross, 4th Block, Near Sony World showroom / Headstart school, Koramangala, Bangalore -560034, India Phone: +91-80-41636853 Fax: +91-80-25633853 Website: www.ableindia.in , E-mail address: info@ableindia.org.in
The Biotech Research Society, India	Biotechnology Division, NIIST, Industrial Estate P.O., Trivandrum 695019 Phone: +91-471-251 5279 Website: https://www.brsi.in/

DEPARTMENTS CONCERNING BIOTECH APPROVALS



USEFUL INFORMATION



- CAGR: Compound Annual Growth Rate
- Capex: Capital Expenditure
- CENVAT: Central Value-added Tax
- EHTP: Electronic Hardware Technology Park
- EPCG: Export Promotion Capital Goods Scheme
- FDI: Foreign Direct Investment
- FY: Indian Financial Year (April to March); So, FY10 implies April 2009 to March 2010
- LCD: Liquid Crystal Display
- R&D: Research and Development
- US\$: US Dollar
- Wherever applicable, numbers have been rounded off to the nearest whole number

EXCHANGE RATES

Exchange Rates (Fiscal Year)

Year	Rs. Equivalent of US\$ 1
2004-05	44.95
2005-06	44.28
2006-07	45.29
2007-08	40.24
2008-09	45.91
2009-10	47.42
2010-11	45.58
2011-12	47.95
2012-13	54.45
2013-14	60.50
2014-15	61.15
2015-16	65.46
2016-17	67.09
2017-18	64.45
2018-19	69.89
2019-20	70.49

Exchange Rates (Calendar Year)

Year	Rs. Equivalent of US\$ 1
2005	44.11
2006	45.33
2007	41.29
2008	43.42
2009	48.35
2010	45.74
2011	46.67
2012	53.49
2013	58.63
2014	61.03
2015	64.15
2016	67.21
2017	65.12
2018	68.36
2019	69.89

Source: Reserve Bank of India, Average for the year

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