

A female scientist with dark hair, wearing safety glasses and a white lab coat, is focused on using a pipette to transfer a purple liquid into a test tube. In the foreground, a rack of several test tubes with blue caps is visible, some containing the same purple liquid. The background is a clean, bright laboratory environment.

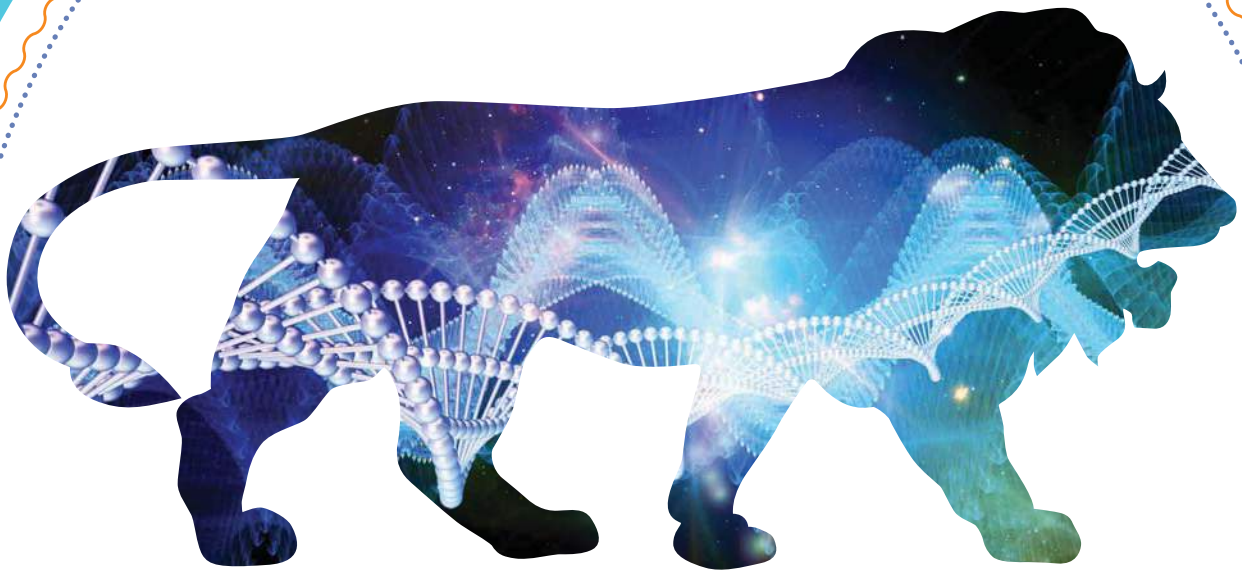
Making Global Impact through Affordable Innovation

We are driven by our vision to develop high quality, yet affordable biopharmaceuticals that address the global need for effective, safe and affordable biologics to treat critical chronic diseases such as diabetes, cancer and autoimmune disorders.

We have used complex technology platforms to develop a rich portfolio of novel biologics and biosimilars including monoclonal antibodies, rh-Insulin and analogs. Our disruptively innovative process engineering has enabled us to deliver affordable pricing and make a difference to global health. Our patient-centric approach and commitment to world-class quality have earned us the reputation of a credibly capable biopharmaceutical organization.

As the world's fourth largest insulins player and a leading provider of affordable cancer care, we are passionately pursuing a mission of developing transformative therapies that can benefit a billion patients across the world.

MAKE IN INDIA



BIOTECH HANDBOOK 2016

IN ASSOCIATION WITH



Confederation of Indian Industry



WHAT WE DO

EMPOWER, ENABLE & ACCELERATE
THE INNOVATION ECOSYSTEM

SUPPORTING EARLY AND LATE STAGE INNOVATION RESEARCH

- ✓ Ignite new ideas - Biotech ignition grant (BIG)
- ✓ Support early stage research for proof of concept validation (SBIRI)
- ✓ Partnership with industry for high risk discovery led innovation (BIPP)
- ✓ Facilitating technology validation and development (CRS)

ENABLING SERVICES FOR PROMOTING THE INNOVATION ECOSYSTEM

- ✓ IP Management
- ✓ Technology Transfer and Acquisition
- ✓ Access to research Resources
- ✓ Bio-incubation Space
- ✓ Mentorship & Capacity Building

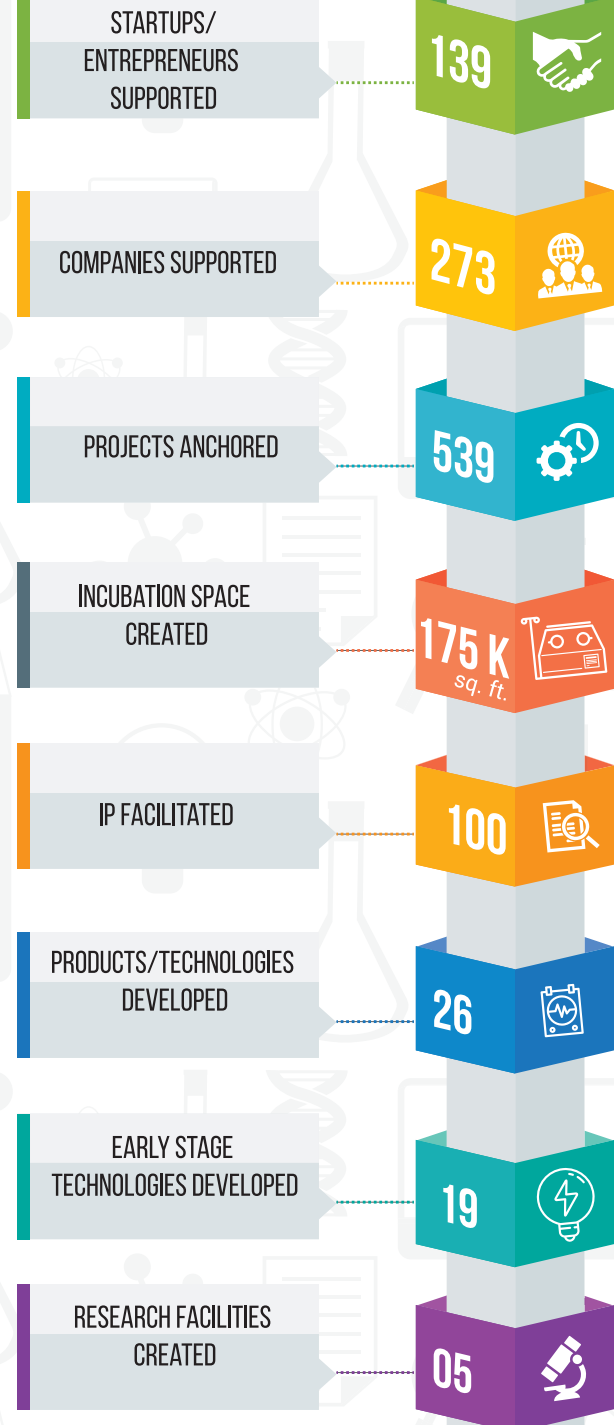
PRODUCT INNOVATION & COMMERCIALIZATION THROUGH PARTNERSHIPS

- ✓ Grand Challenges India
- ✓ Wellcome Trust
- ✓ Hort Innovation Australia
- ✓ Nesta
- ✓ Tekes
- ✓ SPARSH Social Innovation

About BIRAC

A not-for-profit Section 8, Schedule B, Public Sector Enterprise, under the aegis of Department of Biotechnology (DBT), Government of India, mandated as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

OUR IMPACT



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India has a robust and unique life sciences ecosystem. Industry is growing over 9% CAGR. Biotech companies today have a strong product pipeline; India has a national

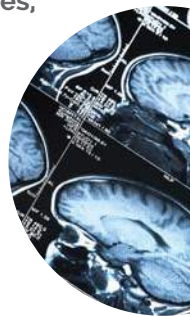
biotech development strategy, enabling environment to empower start-ups and incubation centers, and ever cooperating bioclusters. The sentiment is positive.

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ACKNOWLEDGEMENTS

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- Bioprocess Development & Characterization

Manufacturing Capabilities

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- HPAPIs



Quality
Innovation
Confidentiality
Science



Dr Harsh Vardhan

UNION MINISTER GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY & EARTH SCIENCES
ANUSANDHAN BHAWAN, RAFI MARG , NEW DELHI 110001
INDIA

NEW DELHI
JUNE 2016

INVITATION

It gives me great pleasure to note that INDIA is participating at BIO International Convention, San Francisco, in June 2016.

Over the past two years, India has witnessed several changes, led by our energetic Prime Minister Shri Narendra Modi to connect with several countries to boost business and trade relationships. The “MAKE IN INDIA” drive has been the central theme that we feel is the key to a more prosperous future for all our trade partners and for India.

India is a leading exporter of affordable generics to many countries including the developing and developed nations and we will continue to discharge our responsibilities. We intend to continue formulating plans that are based on sound science, technology, business sense and ethics. We will strive to increase the ease of doing business in India for which several measures have already been announced and many others will follow.

Laboratories should start brainstorming with youngsters to generate fresh ideas which can help the country. Providing affordable healthcare solutions to the common man is a big challenge before scientists and technologists. And experienced scientists should start afresh out-of-the-box process of brainstorming with our young scientists.

As part of the Start-up India initiative of the government, an amount of \$1500 million has been kept aside only to support the young people in the country who have bright and brilliant ideas, and I think this is where the country needs to use the young people.

India needs more affordable medicines and technology and there are lots of advancements taking place in healthcare sector. Every advancement takes the healthcare delivery system a little distance away from the common man because of the cost. The challenge before scientists, technologists and others is to make it affordable for people.

India is destined to increase its economic growth rate to match with the best in the world and we invite all stakeholders to consider and make India an important partner in their planning. I wish the Organizers all the best for organizing the events and appreciate them for inviting India to be a part of the exhibition and conference meetings.

With regards

Sd/-

Dr. Harsh Vardhan



Prof K VijayRaghavan

SECRETARY, DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE & TECHNOLOGY
GOVERNMENT OF INDIA
NEW DELHI

NEW DELHI
JUNE 2016

MESSAGE

I am happy that INDIA is participating at BIO International Conference June 6-9, 2016 in San Francisco. The presence of several Government of India Departments, Organizations and officials along with many private Industry companies and leaders is testimony to the fact that India lays a great importance on such an International Event and is open to dialogue on important issues.

India is known to be the 'Pharmacy of the World' and with a thriving and rapidly growing pharmaceuticals, biologics, medical devices and CRAMS industry, it is poised to grow at a faster rate than most economies.

Over the past year, the dynamic leadership of our Hon'ble Prime Minister, Shri Narendra Modi and his cabinet colleagues has infused the entire country with a new spirit and zeal. Several policy measures have been taken at a macro level that are leading to an increased ease of doing business in India. The The MAKE IN INDIA programme aims to make the country the world's favourite destination for manufacturing a wide range of goods and biotechnology products have a pride of place in the scheme of things.

Health is a priority for the Indian Government and access to good medicines of high quality at affordable prices is the underlying driver. India is one of the largest suppliers of reasonably priced medicines all over the globe and has over 600 USFDA approved plants that is the largest number outside the USA. India is the largest supplier of life-saving Vaccines through the WHO system.

With such a large manufacturing infrastructure India provides a unique opportunity for International stake-holders to source their requirements from India and to consider setting up their manufacturing base in India. These projects could be in Generics, Biologics, Medical Devices, Contract Research & Manufacturing Services (CRAMS), etc.

India provides a large market opportunity for companies and welcomes interested International stakeholders to research, develop, manufacture, market in India as well as export from India.

I invite you to consider India as your next business and manufacturing destination.

KIRAN MAZUMDAR SHAW
CHAIRMAN

PM MURALI
PRESIDENT

NEW DELHI
JUNE 2016

RESEARCH, DEVELOP & MANUFACTURE IN INDIA

The Global Pharmaceuticals industry is almost \$1000 billion and will continue to grow at a rapid pace as the population increases. The costs of drug development have gone up steadily and will continue to increase unless a new paradigm is found. Most developing nations including India have yet to develop a New Chemical Entity or New Biological Entity (NCE or NBE) that remains an issue of concern.

India is one of the largest suppliers of Generics around the globe that has kept medicines within the reach of common citizens in many countries including those in the US. Most economies including the developed ones are struggling to keep their medical costs under check. One way forward is to use relatively less-expensive countries for outsourcing R&D and manufacturing activities.

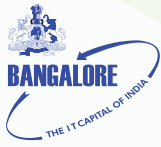
India has the wherewithal to research, develop and manufacture Generics, Biologics and medical devices in a cost-efficient manner. Over the past year the Government of India has taken several measures to increase the ease of doing business in India that has led to several International stakeholders entering into business deals. With its high quality human resources matched with the existing and improving infrastructure, India is now the place to be. India has one of the largest engineering and IT skills base and is destined to do exceedingly well in the High Technology space including Medical Devices, Health IT and CRAMS.

In a recent International survey 25% of those interviewed thought India was one of the five most promising markets for medical devices.

Since 2009 Indian companies and their foreign subsidiaries have accounted for 30 to 40% of the market authorizations issued by the USFDA. As of March 31, 2015 the total number of ANDAs stands at 3030.

India has a large public and private R&D network of world class laboratories doing excellent work in various fields. The Government of India supports Innovation in Science & Technology, the results of which will become evident soon.

We welcome all International stakeholders to join us in India to realize their vision.



KARNATAKA BIOTECHNOLOGY AND INFORMATION TECHNOLOGY SERVICES (KBITS)

Dept of IT, BT and S&T, Government of Karnataka

Creating a World Class Bio - Innovation Megacenter

BANGALORE HELIX BIOTECH PARK A FLAGSHIP PROJECT OF KBITS

INSTITUTIONAL AREA

- ▶ Comprises of two prominent Institutions - Institute of Bioinformatics & Applied Biotechnology (IBAB) & Centre for Human Genetics (CHG)
- ▶ Spread over 20 Acres campus

BANGALORE BIOINNOVATION CENTRE (BBC)

- ▶ A world class Incubation Centre & Central Instrumentation Facility
- ▶ Around 25 Incubation Suites
- ▶ Provides Infrastructural, Mentorship, Branding and Networking Support to Start Ups

AREA FOR BIG / ANCHOR COMPANIES

- ▶ Around 56 Acres Land dedicated for leasing out to Big Biotech / MNCs' to act as Anchor Companies in the Ecosystem
- ▶ Public - Private Partnership



BIOTECHNOLOGY FINISHING SCHOOL (BTFS)*

OBJECTIVES

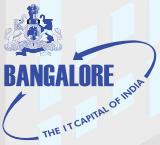
- ▶ Educate & Empower youth to bridge the gap between Industry & Academia
- ▶ Synergize Biotech Industry with well trained Biotech Youth
- ▶ Promote Research activities in Biotech Schools
- ▶ Help Biotech Industry for further growth in the Region

DOMAINS

- ▶ Bioinformatics & Rational Drug Design
- ▶ Cellular & Molecular Diagnostics
- ▶ Fermentation & Bioprocessing
- ▶ Nutraceuticals & Food Processing
- ▶ Plant Genetic Transformation and Analysis
- ▶ Plant Tissue Culture & Micropropagation
- ▶ Clinical research & Data Management
- ▶ Protein Expression & Scale - Up

FEATURES

- ▶ PG Diploma award, 12 BTFS Host Institutions in 7 cities covering 8 Biotech domains
- ▶ **Eligibility:** MSc in any area of Life Sciences / BE / Biotech / MBBS / BDS
- ▶ **Selection:** Online Test & Counseling
- ▶ **Duration:** 6 months Academic Programme followed by 6 months Internship
- ▶ **Support:** 12 months fellowship from DBT, GOI & Infrastructure support from KBITS



KARNATAKA BIOTECHNOLOGY AND INFORMATION TECHNOLOGY SERVICES (KBITS)

Dept of IT, BT and S&T, Government of Karnataka

Creating a World Class Bio - Innovation Megacenter

KARNATAKA A LEADING BIOTECH HUB IN INDIA



Animal BT Park / Vivarium, Bidar

In collaboration with KVAFSU, setting up centres for Innovation and Incubation facility for Disease Diagnosis, Vaccine Production, Embryo Transfer, Bioinformatics and Stem Cells

Agri Biotech Park, Dharwad

In collaboration with UAS – Dharwad Strengthening, Innovation / Incubation in specific areas of Agricultural Biotechnology i.e., Transgenics, Molecular Breeding, Pest/Disease Management, Sustainable Agriculture etc

Marine Biotech Park, Mangaluru

In collaboration with KVAFSU, setting up centres for Innovation and Incubation to explore Marine Ecosystem to develop products relevant to Bio-energy, Pharma, and Nutrition etc

Nutri / Nutraceutical and Phyto-Pharmaceutical Park (N2P2), Mysuru

Being developed in association with prestigious Central Food Technology Research Institute (CFTRI) to innovate products in areas of Phytochemicals and Nutraceuticals and provide Incubation facilities to aspiring entrepreneurs

BANGALORE HELIX - BIOTECH PARK

Consists of Institutional area comprising of Institute of Bioinformatics and Applied Biotechnology (IBAB) and Centre for Human Genetics (CHG), Incubation/ Entrepreneurship area (Bangalore Bioinnovation Centre (BBC)) and large area allocated for MNC's

(Contributes **50%** of Biotech Revenues & home to **60%** of Biotech Companies of the Nation)



INDIA 2025 - A PERFECT TEN!

1400 million consumers (17% of the global population)

Highly skilled young workforce

One of the fastest growing economies

One of the largest high quality R&D talent pools

Important Center for Global Drug Discovery & Development

World's leading producer & exporter of Generics

Significant producer & exporter of Prescription drugs

World's leading supplier of affordable Vaccines

Important supplier of Biologics

Major hub for Medical Devices & Diagnostics



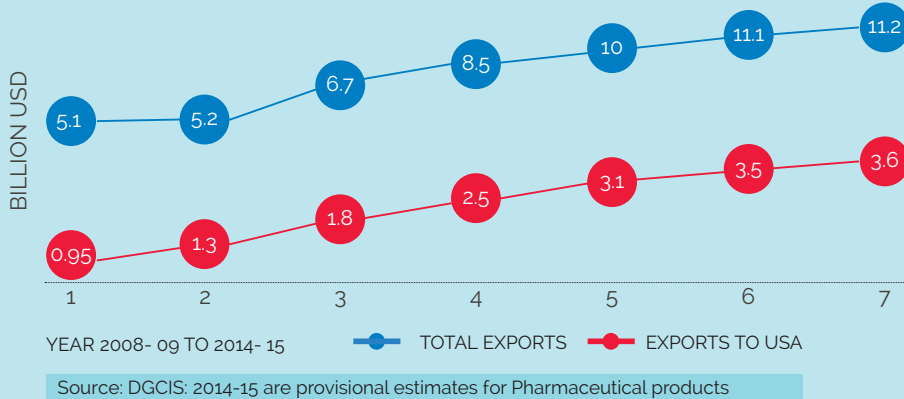
The collective face of the Indian Biotech Industry

www.ableindia.in

PHARMACEUTICALS

India is a major supplier of pharmaceutical products & APIs to the World with approximately \$15 billion exports to over a 150 countries. The trend is likely to increase as the demand for reasonably priced and high quality products increases.

Annual Indian Pharma Exports in USD Billion 2009 - 2015



INDIA'S PHARMA EXPORTS TO US:

Since the year 2000-01, continuously USA has been the largest exporting partner of India's pharmaceuticals year after year. India's exports to USA has gone up from \$105 million in 2001-02 to \$3,963 million in 2013-14 with a CAGR of 35%, while India's global exports have grown by 23% CAGR during the same period.

MARKET AUTHORIZATIONS BY INDIAN COMPANIES IN USA:

As on 31 March 2015, there are over 2900, Drug master filings for supply of APIs from India inclusive of overseas companies spread over 240 companies.

There are 43 Indian companies who have market authorization of USFDA. The total number of authorizations (ANDAs) as on 31 March 2015, is around 3030 (Indian Companies from India & its subsidiaries abroad).

USFDA has granted 476 market authorizations in the calendar year 2012. Out of which India has bagged 178 of them amounting to 37.4 % of the total.

In 2013 USFDA has granted 400 market authorizations and 154 of them are for Indian companies, working out to 38.4% of the total.

In the year 2014 India's companies including its subsidiaries abroad have received 286 market authorizations (Includes Tentative).

Value in USD million

India's Exports to USA (2010-2014)

Category	09-10	10-11	11-12	12-13	13-14	growth rate 2013-14	CAGR 2004-13	CARG 2008-13
Bulk drugs	667	635	703	498	435	-12.7	11.71	0.91
Formulations	1236	1786	2481	3016	3429	13.7	33.03	33.65
Herbals	43	54	70	108	79	-27	21.08	18.59
Ayush	8	23	13	28	20	-28	4.85	41.86
Total Exports	1954	2497	3268	3729	3963	6.3	25.97	24.28

Source: DGCIS

GENERICS ON A FAST TRACK

ESTABLISHED QUALITY SUPPLIER TO THE WORLD

600 + USFDA approved manufacturing plants – highest for any country outside the USA
 50%: Pharmaceuticals produced in India exported to over 150 countries. Exports at \$15 Billion.

Indian companies have 10% -12% share of US' generic drug & OTC market. Significant scope for increase.

LEADING EXPORTERS INCLUDE SUN PHARMA, CIPLA, GLENMARK, LUPIN, DR REDDY'S, CADILA HEALTH, TORRENT, ALEMBIC

ONE OF THE LARGEST CENTERS FOR GLOBAL MANUFACTURING & SUPPLY

CAGR OF PHARMA EXPORTS FROM INDIA AT 25% FOR PAST 10 YEARS

~ 10,500 PHARMA

MANUFACTURING UNITS OVER 350,000 SKILLED

MANPOWER. POISED FOR HUGE EXPANSION

MAJOR GLOBAL PHARMA PLAYERS PRESENT IN INDIA

100% FOREIGN DIRECT INVESTMENT PERMITTED IN GREENFIELD PROJECTS

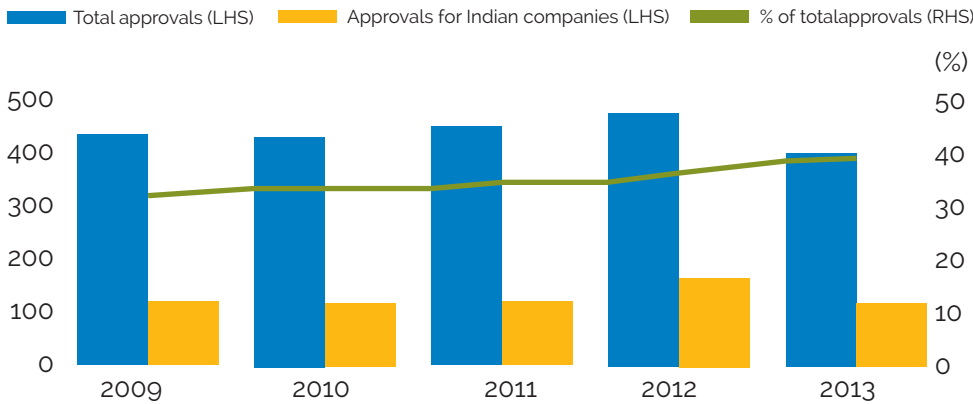
SUPPORT TO INDUSTRY AT CENTER & STATE LEVEL

NET PROFIT % OF LEADING INDIAN GENERICS

MANUFACTURERS

SIGNIFICANTLY HIGHER COMPARED TO OTHER COUNTRIES

INCREASING SHARE OF PRODUCT APPROVALS



Source: CMIE

As on February 28, 2015 India has 603 manufacturing (both API and FORMULATIONS) sites inspected and approved in India.

Top Pharmaceuticals Exporters to the US

Countries' Share of US Phamaceut icals Imports (%)	2008	2009	2010	2011	2012	2013	5yrs CAGR
Total US Pharmaceut ical imports (USDbn)	78.91	81.48	85.45	91.77	87.25	84.02	1.26
Ireland	23.9	21.4	26.5	30.3	24.9	22.3	-0.15
Germany	11.8	10/7	9.1	9.9	12.3	13.7	4.40
Switzerland	5.1	5.9	7.3	8.3	9.7	11.1	18.36
United Kingdom	14.0	14.5	10.2	7.9	7.1	5.5	-15.97
Israel	4.9	4.7	6.2	6.3	6.4	6.5	7.27
India	2.5	2.7	3.7	4.2	5.6	6.1	20.95

Source: United States Census Bureau

Reference for the two tables: India Ratings & Fitch Group: Special report May 7 . 2014

BIOPHARMACEUTICALS

Biopharmaceuticals is a \$250-300 billion Global Opportunity. Requires a higher skills set and tighter Quality control High level of biology / process development / engineering skills

KEY PLAYERS		
Company	Marketed products	Pipeline
Biocon	Streptokinase, insulin, EPO filgrastim, monoclonal antibodies (mAbs)	mAbs (bevacizumab), etanercept, pegfilgrastim
Cadila	Insulin, streptokinase, filgrastim	17 biosimilars in pipeline consisting of interferon beta 1 B and other undisclosed assets including 5 monoclonal antibodies
Dr Reddy's	Rituximab, filgrastim, darbepoetin alfa	Covers all top products coming off patent
Intas Pharma	EPO, filgrastim, pegfilgrastim, follistim, interferon alpha	mAb (ranbizumab), etanercept, Peg-interferon
Lupin	EGFR, abciximab	Currently 10 biosimilars in pipeline including insulin, interferon, mAbs
Ranbaxy	EPO filgrastim, interferon, infliximab	
Wockhardt	Insulin, EPO, insulin glargine	

WHY INDIA?

- FAST CLEARANCES FOR GREEN / BROWNFIELD PROJECTS
- CLEARCUT REGULATORY GUIDELINES FOR BIOLOGICS
- HIGHLY SKILLED WORKFORCE IN FERMENTATION
- R & D CAPABILITIES & FACILITIES AT PAR WITH THE BEST
- LEADING PUBLIC INSTITUTES AND UNIVERSITIES
- SOME LEADING BIOPHARMA PLAYERS BIOCON, LUPIN, INTAS, DR. REDDY'S KEMWELL, CADILLA, STEMPEUTICS STATE- OF-THE ART MANUFACTURING FACILITIES
- EXCELLENT ANCILLARY UNITS TO SUPPORT LARGE SCALE MANUFACTURING

INDIA LEADS THE WORLD IN AFFORDABLE VACCINES

- Indian Vaccines industry at \$1 Billion. Growing at 25%
- Fulfills 60% demand of UNICEF, GAVI and PAHO for low income companies
- Made in India Oral polio vaccines made India polio-free & eliminated Measles and Rubella Syndrome in South Americas
- MenAfriVac (Meningococcal A conjugate vaccine) developed for
- Sub-Saharan African belt, supplied at US \$ 0.50 per dose
- Rotavac to be available at US \$ 1.00 per dose

PRODUCE YOUR VACCINES IN INDIA!

- PROVEN LEADER IN VACCINES DEVELOPMENT & SUPPLY
- CAPACITY TO PRODUCE AT LOW COST
- REASONABLE R&D EXPENDITURE
- SERUM INSTITUTE OF INDIA, INDIAN IMMUNOLOGICALS, BHARAT BIOTECH, BIOLOGICAL E, PANACEA BIOTEC, HAFKINE BIOPHARMACEUTICALS, ZYDUS CADILA
- LEADING EDGE TECHNOLOGY/COMBINATION VACCINES
- LOW COST OF DEVELOPMENT
- ABILITY TO UPSCALE QUICKLY

CONTRACT RESEARCH AND MANUFACTURING SERVICES (CRAMS)

India, due to its strong chemistry skills and large base of pharmaceutical manufacturing, was quick to garner a good market share of global CRAMS market. The Indian Contract Research and Manufacturing Services (CRAMS) industry is expected to touch \$18 billion in size by 2018, according to a report by CARE Ratings. The report said the Indian local industry's share will increase to around 8-9% of global CRAMS market by 2018 from about 6% in 2013.

CRAMS industry has two main segments. Contract Manufacturing Services (CMS) accounts for more than 60% of the industry and Contract Research Services (CRS) accounts for the rest. Indian Contract Research Organizations (CROs) have earned global reputation over the past 2 decades. The CROs support Biopharma industry in the "Development" part of R&D that comprises medicinal chemistry and biology (discovery), Drug Substance and Drug Product Development and clinical supplies, pharm-tox services (nonclinical development) and Clinical development.

- There are more than 150 CROs operating in India, operating across fields from discovery chemistry, biology, clinical supplies, toxicology to BA/BE and clinical trials. There are nearly 100 + CROs (including MNC CROs) operating in India in the area of Clinical trials and associated laboratory services.
- Some of the leading Indian CROs provide services across entire spectrum of drug development.
- Clinical research segment has grown exponentially over the past decade in India because of faster recruitment rates, well established hospital infrastructure, qualified & GCP-trained physicians, and cost advantage.

RECENT DEVELOPMENTS & TRENDS

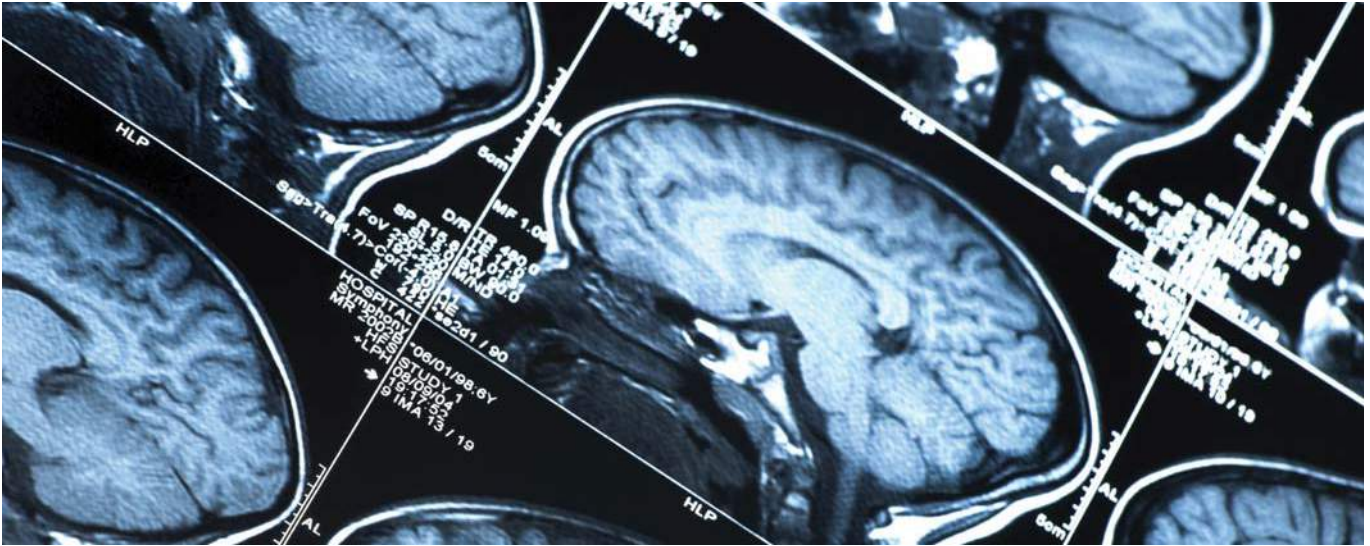
Outsourcing to India has shown high growth in medicinal chemistry, biology, API development and formulation development. Newer areas such as biologics, ADCs, oligonucleotides, peptides are on the rise.

- Many MNC pharmaceutical companies have established strategic partnerships and research collaborations in India.
 - Bristol Myers Squibb (BMS) has recently extended its research collaboration with Syngene for another 5 years up to 2019. Syngene has established a dedicated R & D Center for BMS in 2007.
 - Syngene has collaborated with Abbott to establish a nutraceuticals-focused R&D center in 2012.
 - Syngene has collaborated with Baxter to establish Baxter Global Research Center in 2013
- Some of the leading Indian CROs have chosen inorganic path to expand their capabilities. For example, GVK Bio has acquired Vanta Bioscience, a preclinical CRO operating out of Chennai, and Aragen Biosciences, a biologics CRO based in California, USA.
- There is a trend towards integrated discovery (combining chemistry and biology capabilities) or integrated development (combining Drug Substance and Drug Product development along with clinical supplies).
- Strong process skills, GMP manufacturing experience and a robust experience with IP protection is encouraging research oriented biotechs and Big Pharma to collaborate with Indian CROs and CDMOs (Contract Development and Manufacturing Organizations) for discovery and early development projects.
- The Clinical research segment has gone through turbulence in 2012-13. In the wake of controversies related to some clinical trials that are conducted with deficient informed consent process, Indian regulatory agency (viz. DCGI) has initiated complete overhaul of clinical trial related regulations. The sheer number of new regulations and contents of some regulations gave rise to concern among global biopharma community. However, after a few iterations, the regulations governing clinical trials in India are a lot simpler now and balance the delicate need between appropriate patient safeguards and the need to generate clinical data for advancing new therapies.
 - All clinical trials in patients must be registered with Clinical Trial Registry of India (CTRI) before the enrollment of first patient in the study
 - Audio-visual recording of the informed consent process is now mandatory to make the process more transparent and maintaining confidentiality.
 - Accreditation of Ethics committees and Phase-1 clinics is made mandatory. Draft regulation for accreditation of hospital sites involved in phase-2 and 3 trials is released.
 - Financial compensation based on no-fault principle calculated as per defined formula has been made the mandatory responsibility of the sponsor for trial related injuries or death.

Early signs of recovery in clinical research segment are already visible. The number of new trials approved has jumped by 40% in 2014. In addition to capacity expansion by Indian CROs, few MNC CROs like Quintiles and Parexel have set up large centers in India to provide Risk-based monitoring, data management and pharmacovigilance services to their global clientele.

MEDICAL DEVICES & DIAGNOSTICS

A \$400 billion Global Industry
 INDIAN INDUSTRY TO REACH \$50 BILLION BY 2025
 INDIA – AN ATTRACTIVE DESTINATION IN 2015!



JANUARY 2015 2015 Medical Device Industry Outlook

19

When you think about **YOUR COMPANY**, which markets do you expect to have the strongest growth in 2015?

Market >	BRAZIL	CHINA	EUROPE	INDIA	USA
Among device executives at companies with 250+ employees	29%	44%	37%	25%	43%

Even though economic growth in China is slowing, it still is extremely robust (at 7%) compared to every other major market worldwide. The Chinese government continues to pour money into improving access to healthcare, and with that investment and rising standards of living comes a need for medical devices. This will continue and is one reason executives are bullish on China.

The US continues to surprise many with its sustained economic performance and rosy outlook for 2015. Even though US healthcare spending growth has slowed and pricing pressures continue, executives still see good potential for revenue growth.

Based on 334 responses from senior medical device executives in companies with 250+ employees

EMERGO

EMERGO - Medical Device Regulatory Consultants

INDIA OFFERS

- LARGEST POOL OF ENGINEERING TALENT IN THE WORLD
- YOUNGEST WORKFORCE WITH A HIGH INNOVATION QUOTIENT
- COST EFFECTIVE R&D and MANUFACTURING
- UNPARALLED INFORMATION TECHNOLOGY EXPERTISE IN ELECTRONICS and SOFTWARE DEVELOPMENT
- 100% FOREIGN DIRECT INVESTMENT PERMITTED
- WELL ESTABLISHED INTELLECTUAL PROPERTY REGIME
- A LARGE MICRO SMALL MEDIUM ENTREPRISES (MSME) NETWORK
- SEVERAL GOVERNMENT SCHEMES TO SUPPORT INNOVATION & STARTUPS
- MEDICAL DEVICES TECHNICAL ADVISORY BOARD (MDTAB) BEING ESTABLISHED
- BUSINESS FRIENDLY ENVIRONMENT HAS ATTRACTED WORLD CLASS MNCs

India's BioEconomy touches \$35 billion

Biotechnological activities started in India more than three decades ago when various vaccines and enzymes production facilities came up in a small way. Subsequently, India's entrepreneurs have scaled up with innovative techniques and research to launch a wide variety of products in the field of medicine, agriculture, healthcare, industrial goods and also introduced a range of diagnostic services, set up contract research firms that deal with biomolecules and garnered the power of computer software to provide a host of healthcare and associated services.

With sustained efforts in the past decade, biotech ingredients have become the core of wide range of products and services. It has been the endeavor of the Association of Biotechnology-Led Enterprises (ABLE) to keep track of the widening footprint of biotechnology and in an exercise, the first of its kind attempted in the country, the size of BioEconomy has been estimated to be a little over \$35 billion. Some snapshots from the quick estimates ...

INDIAN BIOECONOMY

India's BioEconomy is estimated to be \$35 billion

INDUSTRY	\$ Billion
BIOPHARMA & DIAGNOSTICS	18.9
BIOAGRI	9.0
BIOIT / IT SERVICES TO BIOSCIENCE COMPANIES	4.4
BIOINDUSTRIAL / BIOFUELS	1.9
BIOSERVICES	0.9
TOTAL BIOECONOMY	35.1

Source: ABLE.

This table has been compiled by ABLE, collecting data from various publicly available reports, published information, and using industry estimates.



INDIAN BIOECONOMY

SEGMENT	SUB-SEGMENT	RETAIL VALUE IN \$BILLION
BIOPHARMA		18.9
	Therapeutics	2.2
	Vaccines	3.8
	Diagnostics & Diagnostic services	12.9
BIOAGRI		9.015
	Bt Cotton	9
	Pesticides / Fertilizers	0.015
BIOIT / IT SERVICES TO BIOSCIENCE COMPANIES		4.4
	Informatics / Genomics	0.05
	IT Healthcare	4.35
		1.9
	Enzymes	0.95
	Biofuels	0.95
BIOSERVICES		0.9
		0.9

Source: ABLE.

This table has been compiled by ABLE, collecting data from various publicly available reports, published information, and using industry estimates.

Biotech Products in Pipeline

Indian biotechs are working on over 100 biopharma products which are at various stages of development. Here is a short list of biotech players and their product pipelines.



VACCINE PRODUCTS PIPELINE

COMPANY	PRODUCTS
Bharat Biotech	Vaccines: Rotavirus; Typhoid Conjugate; Japanese Encephalitis; Chikungunya; Malaria PvR II; Staph Aureus MRSA; Human Papilloma Virus; Acellular Pertussis; Tetanus(meat Free)
Biological E	Vaccines: Meningitis vaccine; DTwP-HBV combination; Hemophilus Influenza type B conjugate vaccine; DTwP-HIB combination; Japanese Encephalitis, DTwP-IPV, DTwP-IPV + Hib, DTwP - Hep B - IPV - Hib, Rotavirus, Dengue
Cadila Pharmaceuticals	Vaccines: therapeutic vaccine for pancreatic cancer; endemic influenza; seasonal influenza; novel malaria vaccine
Indian Immunologicals	*Human Vaccines: Human Vaccines; Oral Cancer vaccines ; Pediatric vaccines; Flaviviral vaccines; Alphaviral vaccines; Picornaviral vaccines; Veterinary Vaccines: Toxoid vaccines; Contraceptive vaccines; Parasitic vaccines; Viral vaccines; Glyco-conjugate vaccines*
Panacea Biotec	H1N1 pandemic influenza vaccine; 13-valent Pneumococcal conjugate vaccine; Recombinant Dengue vaccine; Japanese encephalitis vaccine
Serum Institute of India	Vaccines: Meningococcal I A conjugate vaccine; Meningitis A, Y, C, W-135 Quadrivalent Vaccine; Bladder Cancer Vaccine; Pneumococcal Polysaccharide & Conjugate Vaccine; Monoclonal antibodies against H1N1; HPV Vaccine
Shantha Biotechnics	Shan 5, Hexavalent Vaccine (Pentavalent +Polio); Rotavirus; Typhoid Conjugate; Hepatitis A; HPV
Tergene Biotech	CRM 197 protein conjugate Vaccine
Virchow Biotech	Novel mucosal vaccine for HPV / Rasburicase-Recombinant uricase
Zydus Cadila Healthcare	Influenza Vaccine; Typhoid Vaccine; DPT-HiB; Hepatitis-B, Hepatitis-A; Hepatitis-E; Japanese Encephalitis; HPV vaccine; Malaria Vaccine; Kala-Azar Vaccine Drug Delivery: Oral delivery of Insulin; Oral delivery of mAbs; Oral Delivery of HIV drug

THERAPEUTIC PRODUCTS PIPELINE

COMPANY	PRODUCTS
Advinus Therapeutics	"Pipeline - Early Discovery: JAK 1 selective for RA; BTK inhibitors for Autoimmune/Inflammation/ Cancer; FAAH inhibitor for chemotherapy induced neuropathic pain; GPR40/GPR120 dual agonist for T2D; GPR91 antagonist for retinal angiogenesis/liver fibrosis; GPR40 antagonist for obesity; ROR antagonist for Psoriasis; Target X for Leishmaniasis; GKM001: an activator of glucokinase Pipeline - Late Discovery: ; Development candidate: GKM for T2D;; Partnered program for T2D; Ado A-2B antagonist for SCD/COPD; Ado A-2B antagonist for IBD; Ado A-2A antagonist for PD; JAK 3/1 inhibitors for RA;"
ARA Healthcare	scFV Antibody; ARA I, ARA II and ARA III- Cancer drug molecules
Bharat Biotech	Therapeutics: THR-100; Lysostaphin(USFDA); r Human Serum Albumin
Bharat Serums	Foligraf, recombinant follicle stimulating hormone
Biocon	"Novel: Oral Insulin, Anti-CD6, mAb Fusion Proteins, Anti CD20; Anti-EGFR Biosimilars: Biosimilar mAbs; Transtuzumab; Adalimumab; Pegfilgrastim; Bevacizumab; Etanercept; Insulin Analogs – Lisprol; Aspart Recombinant Human Insulin; Glargine; GCSF; EPO;"
Cellworks	"Immunology: CWG92 (RA); CWG940 (AR) Oncology: CWG89 (KRAS Cancer); CWG71a (KRAS Cancer); CWG71b (KRAS Cancer); CWG59f (KRAS Cancer) Anti-Infective: CWGNC4_1 (TB)"
Clonz Biotech	Ranibizumab , recombinant humanized Anti-VEGF monoclonal antibody fragment
Gennova Biopharmaceuticals	Recombinant Human Papillomavirus vaccine
Indian Immunologicals	Monoclonal Antibody Technologies; Recombinant monoclonal antibodies and its fragments.
Jupiter Bioscience	Therapeutic anti-cancer agents
Mitra Biotech and Anthem Biosciences, Bangalore	PAT-1102, , a novel HDAC inhibitor
Navya Life Sciences	Recombinant blood protein ; Recombinant peptide hormone; Recombinant ESA ; Recombinant Enzyme; Recombinant 3G clot buster; Recombinant mAb - AI disorders; Biomaterial - wound mgmt.
Orchids	OCID-2987, a selective PDE4 inhibitor for the treatment of inflammation
Oxygen Healthcare Research	Novel H3 and other GPC receptor ligands
Serum Institute of India	Recombinant Products: Recombinant Granulocyte Colony Stimulating Factor ; Interferon Alpha; Recombinant Erythropoietin
Stempeutics Research, Bangalore	Allogeneic mesenchymal stem cells
Torrent Pharmaceutical	TRC150094, a novel Diiodothyronine (T2) analogue
Transgene Biotek	"Oncology: miRNA AAV for metastatic liver cancer; shRNA for metastatic breast cancer; Humanized mAb for colon cancer; Humanized mAb for multiple Myeloma; Humanized mAb for Non Hodgkins Lymphoma; Humanized mAb for Esophageal Cancer Auto Immunity: r-FP with selective deletion of B cells in HIV; r-FP with selective deletion of B cells in Multiple Sclerosis"
Wockhardt	Recombinant protein therapeutics
Yasham P2D Lifesciences	Tumor necrosis factor - alpha (TNFa)
Zydus Cadila Healthcare	ZYH1 (Saroglitazar), PPAR alpha/gamma agonist for the treatment of dyslipidemia



Policy Framework

The Department of Biotechnology (DBT), under Ministry of Science & Technology, is the organization responsible for formulating policy and promoting biotechnology in the country. It spends nearly \$300-400 million every year to support R&D and innovation. India plans to spend around \$150 million in the next two years, to boost production of biopharmaceutical firms, even as the local industry gears up for a global boom. The government is focusing on developing infrastructure for enhancing drug production, using biotechnology applications. About 30 percent of the total funding goes into the public-private partnerships (PPP).

The Department of Biotechnology (DBT) announced the National Biotechnology Development Strategy in September 2007. Through the strategy, biotechnology was recognized as a sunrise sector that needed focused attention.

The cornerstone of the strategy was to focus on building coherence and connectivity between disciplines and bring together variegated skills across sectors to enhance synergy.

Necessary guidelines for transgenic plants, recombinant vaccines and drugs, stem cell therapy have been evolved. A strong base of indigenous capabilities has been created. Many innovations and research applications for socio-economic development have

been supported in the areas of medical, agricultural, environmental and industrial biotechnology. PPP models have been successfully implemented and a new section 25 company a Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), was set up to exclusively work on PPP programs in biotechnology. Most of the new initiatives announced in the 2007 Strategy are in place.

The implementation of Biotech Strategy 2007 has provided an insight into the enormous opportunities. Thus, it was felt opportune to take a critical look at the Indian biotech sector as it will likely unfold over the next 5-6 years.

The National Biotechnology Development Strategy 2015-2020 (NBDS 2015-2020) is the direct result of consultations over the past few years with over 300 stakeholders including scientists, educators, policy makers, leaders of industry and civil society, voluntary and non-government organizations, regulators and international experts. The consultations offered an opportunity to discuss and evaluate technological, societal and policy aspirations, critical success factors as well as barriers that will impede growth and put them in newer and broader perspective and action plan.

The new strategy would build on the earlier Strategy to accelerate the pace of growth of biotechnology sector in line with global requirements. Scale up and sustainability are important for novel efforts and approaches to make institutional mechanisms of innovation empowering.

Biotechnology is widely used for producing drug substances and in enhancing food productivity, both of which are for direct public utility. Hence the Department is committed in ensuring safety of the products and processes generated through biotech research so that they are eventually accepted by the end user for whom it is produced, to gain public acceptance

SIMILAR BIOLOGICS GUIDELINES 2016

India's Central Drugs Standard Control Organization (CDSCO) recently released new guidance for biosimilar developers as new biosimilars come to market there before other regions, and as India's regulators look to develop more specific guidance on postmarketing studies. The new document is a slight amendment of previous guidance issued in 2012, but includes several important changes that are now up for discussion through 30 April. India's biosimilars market currently includes eight biosimilars. Among the most major changes, CDSCO now says that if the reference biologic (for which the biosimilar is being developed) is not marketed in India, the reference biologic can be licensed in any ICH country (i.e. EU, Japan, US, Canada and Switzerland). Postmarket Updates One of the biggest differences between the 2012 guidance and the recently issued document is the section on postmarketing studies, which CDSCO says are intended "to further reduce the residual risk of the Similar Biologic" and which now includes a timeline for

such studies. CDSCO is calling for specific postmarketing safety data "through a pre-defined single arm study of generally, more than 200 evaluable patients and compared to historical data of the Reference product. The study should be completed preferably within 2 years of the marketing permission/manufacturing license unless otherwise justified."

The primary aim of the Phase IV study is safety, CDSCO says, noting that the primary endpoint should be safety while the secondary endpoint should be efficacy and immunogenicity. In addition to the new postmarketing guidance, CDSCO says that "if the firm conducts pre-approval studies that included more than 100 patients on the proposed Similar Biologic drug, the number of patients in phase IV study can be reduced accordingly so that the safety data (from both Phase III and IV) is derived from a minimum of 300 patients treated with the Similar Biologics." The regulator also added a new section on non-comparative safety and efficacy studies, noting that if a product is found to be similar "in pre-clinical,

in vitro characterization having established PK [pharmacokinetic] methods and a PD [pharmacodynamic] marker that is surrogate of efficacy, the residual risk is significantly reduced in the Phase I study if equivalence is demonstrated for both PK and PD. Phase III clinical trials of such a Similar Biologics product may be waived...[and] where considered necessary, an appropriate single arm study in at least 100 evaluable subjects may be carried out in the most sensitive indication to address any residual uncertainty." CDSCO also added new information on when a confirmatory clinical safety and efficacy study can be waived, noting: "In case the safety and efficacy study is waived all the indications approved for reference product may be granted based on comparable quality, non clinical as well as convincing PK/PD data. Wherever the phase III trial is waived, the immunogenicity should have been gathered in the PK/PD study and will also need to be generated during post-approval Phase IV study."

Regulation of rDNA products

At present, the Review Committee on Genetic Manipulation (RCGM) functions in DBT to monitor the safety related aspects in respect of all recombinant DNA activities and projects involving genetically engineered organisms/ hazardous micro-organisms and controlled field experiments research in four areas namely human and ani-

mal healthcare, agriculture, industry and environmental management. RCGM has also brought out manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and application.

RCGM reviews and issues the clearance for import/export of etiolog-

ic agents and vectors, germplasm, organelle, etc. needed for experimental work/training and research through a multi-level process of assessment undertaken by scientific experts. The BRAI draft bill prepared by the DBT in 2008 had proposed BRAI, a regulatory body in India for utilization of biotechnology products including genetically modified organisms (GMOs). The regulatory body will be an autonomous and statutory agency to regulate the research, transport, import and manufacture of biotechnology products and organisms. GM crops as food: With the Indian government's approval for field testing of GM crops, the role of the DBT which is part of the RCGM becomes all the more significant. It would encourage and support research on GM crops. To validate GM food, the DBT would establish a toxicological center for testing toxicity, safety and biological contaminants and adulterants.

Encouraging safe processes

The safety of drugs produced through biotechnology rDNA technology are governed and regulated by RCGM. After experimental trials as per RCGM, the products are further reviewed by independent regulatory body for human trials. The current timelines and regulatory steps for the process are not user friendly. A process reform table of current qualitative and quantitative limits, mechanisms and timelines is urgently needed. The Department intends to support regulatory reforms with respect to preclinical and clinical trials for animal and human experiments. The DBT recognizes that it is important to facilitate safe processes and hence would initiate creation of Customised experimental animal resources in strategic locations across the country. Clinical trial infrastructure in diverse demographical settings. Efficient regulatory departments well versed in GCP, GMP and GLP. In addition, discrepancies on therapeutic applications of stem cells have now been clarified in the new

CDSKO

The Central Drugs Standard Control Organization (CDSKO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSKO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control. Major functions of CDSKO: Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licences as Central Licence Approving Authority is exercised by the CDSKO headquarters

regulatory guidelines for research and therapeutic applications of stem cells brought out by DBT in collaboration with ICMR. To ensure environmental safety in the course of manufacturing of bioproducts, the DBT proposes to implement environmental regulation policy.

Biotechnology Patenting in India

Indian patent practice and jurisprudence with respect to the patenting of biological materials are relatively new.

India's National Intellectual Property Rights (IPR) Policy was released in mid-May this year

The National IPR Policy is keenly concerned with generating "awareness" of intellectual property (IP) in the country. The policy calls for nothing less than a new gold rush towards IP — attracting everyone from university professors to people in "rural and remote areas".

The Policy aims to push IPRs as a marketable financial asset, promote innovation and entrepreneurship, while protecting public interest. The plan will be reviewed every five years in consultation with stakeholders and the policy is entirely compliant with the WTO's agreement on TRIPS.

It suggests making the department of industrial policy and promotion (DIPP) the nodal agency for all IPR issues. Copyrights related issues will also come under DIPP's ambit from that of the Human Resource Development (HRD) Ministry.

Trademark offices have been modernized, and the aim is to reduce the time taken for examination and registration to just 1 month by 2017. The government has already hired around 100 new examiners for trademarks. Examination time for trademarks has been reduced from 13 months to 8 months, with the new target being to bring the time down to one month by March 2017.

The Policy also seeks to facilitate domestic IPR filings, for the entire value chain from IPR generation to com-

mercialization. It aims to promote research and development through tax benefits. There is a proposal to create an effective loan guarantee scheme to encourage start-ups.

It also says "India will continue to utilize the legislative space and flexibilities available in international treaties and the TRIPS Agreement." These flexibilities include the sovereign right of countries to use provisions such as Section 3(d) and CLs for ensuring the availability of essential and life-saving drugs at affordable prices.

The policy left the country's patent laws intact and specifically did not open up Section 3(d) of the Patents Act, which sets the standard for what is considered an invention in India, for reinterpretation.

On compulsory licensing (CL), India has issued only CL for a cancer drug. The IPR policy favoured the government considering financial support for a limited period on sale and export of products based on IPRs generated from public-funded research.

Manufacturing

As far as the manufacturing of biosimilars, CDSKO has altered the section on "Fermentation Process Development," which it now calls "Upstream Process Development," though the requirements under the changed name are the same:

"Upstream process should be described in detail including media components used for cell growth: At least three batches of reproducible fermentation data at pilot scale (batch size adequate to give enough purified product to generate preclinical data) Upstream process should be well controlled and monitored," CDSKO says.

The regulator also says manufacturers should include details of "upstream process kinetics data from consistency batches indicating cell growth, product formation, pH, temperature, dissolved oxygen, major nutrient consumption pattern and agitation rate."

Empowering Biotech Enterprises

BIRAC is a unique organization in the Indian context.



The fundamental mandate for BIRAC is to nurture and grow the emerging biotechnology industry in India and catalyze the growth of the industry to global excellence. The biotechnology industry in particular has several challenges unlike many other industrial segments and BIRAC has a good understanding of these issues. It has been focused on de-risking all aspects of novel product development chain. BIRAC's focus has been funding support to SMEs and stimulating SME's R&D behaviour, kickstarting biotech startups in India, providing access to high-end infrastructural requirement, and ensuring new products and technologies emerging from the funded projects.

BIRAC has supported 270 companies through its program such as SBIRI, BIPP, and CRS. The total amount of funding is \$200 million wherein BIRAC's contribution is nearly \$75 million while industry has committed the rest \$125 million. This figure is significant as it alludes to the fact that despite the overall industry being nascent in India, given the right funding tools (such as BIRAC's SBIRI and BIPP) the appetite of the emerging industry for R&D is increasing. As of 2014, BIRAC's programmes (especially SBIRI & BIPP) had fostered 68 collaborations between industry & academia.

The biotech startup scenario in India was changed due to BIRAC's flagship scheme, BIG (Biotechnology Ignition Grant). BIG has supported over 140 entrepreneurial ideas over five calls at pre-proof-of-concept stage. BIG has also encouraged entrepreneurial individuals to establish startups. BIRAC has provided \$6 million to 101 entrepreneurial idea-stage projects.

BIRAC through its bioincubation scheme (BISS) has supported 15 bio-

incubation centers across the nation and has created 124,000sq.ft of incubation space. Within these incubators, around 199 biotech startups are being provided support. In each of the bioincubator, BIRAC has supported a common pool of high end instrumentation that is being used by incubate and other SMEs for R&D.

BIRAC has been instrumental in creation of 17 affordable products and 11 new technologies- developed in India thus highlighting its impetus in Make in India program. These products and technologies are cutting across sector like biopharma, industrial biotech and agribiotechnology. Some of the products are Rotavac (Rotavirus vaccine) that will immunize children against rotaviral diseases and others such as Maxio help in tumor ablation (Maxio has also received a US FDA clearance).

The BIRAC IMPACT



Make in India: Quality, Accessibility Affordability

Affordable Fluorescence Reader
to detect multiple infections simultaneously in remote settings



Fibroheal
for burn wound management. In use at AIIMS, New Delhi



Aina
to measure blood glucose, HbA1C, lipids (HDL, LDL, TrG), Creatinine and Haemoglobin

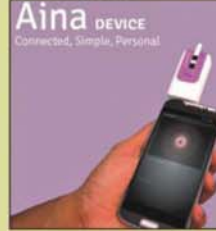


Photo Dynamic Therapy (PDT) Laser System
for cancer treatment



ROTAVAC®
India's first indigenously developed oral Rotavirus Vaccine



Pandyflu®
H1N1 Pandemic influenza vaccine



A rapid POC diagnostic kit
with micro PCR for Diagnoses of Malaria, Dengue & Typhoid



Maxio
Device for tumor ablation. Marketed and secured USFDA clearance



ONCOSCAN
Digital Oncopathology Slide Scanner Offers complete digital pathology solution with ease of operations, scalability, security at an affordable cost



PCR kit for Aquaculture industry
Robust & Economical Indigenous single tube nested PCR kit for WSSV, IHNV & YHV



Albucel - for restoration and maintenance of circulating blood volume



Globucel - plasma protein replacement therapy (IgG) for immune deficient patients



Merkel Haptic - affordable mannequin for effective CPR (Cardiopulmonary Resuscitation) Training



Microfluidics based detection of thyroid disorders, fertility, diabetes and infectious disease



Smartphone based retinal imaging system



Key Biotech Hubs

Incubators, New Hubs

Start-ups are sprouting in various clusters. There are nearly a dozen incubation centers in the academic institutions, a dozen biotech parks, and half a dozen accelerators and mentors, aligning with the overall mandate of Biotechnology Industry Research Assistance Council (BIRAC).

There are many different types of incubators. A few specific types include Business mentoring, branding and funding (e.g., IIM-A, IIT-B, IKP). Some of them focus on infrastructural and specialized facilities/resources support (e.g., C-CAMP, IKP, and Venture Center). A few are focused on techno-commercial mentoring and Proof-of-Concept (POC) funding (e.g.: Accelerators like InnAccel, Venture Center). Then there are others with mix models. Investment needs for

infrastructural and specialized facilities/resources support are the highest. Smaller the incubator, the greater the cost per incubatee since overheads are considerable. A high quality small (under 20,000 sq ft) bioincubator in a top tier city and central location will need around \$650-750 per sq ft per month as set up costs and \$35-40 per sq ft per month in operational costs assuming that there is no in-kind contributions from the host institution. This does not include costs of specialized equipment and instruments needed for the facility.

The universities have begun to create an eco-system to have 10-15 incubatees in the campus. At the moment, DST-NSTEDB, BIRAC and DeitY are supporting setting up of incubation centers, and universities can easi-

ly leverage these funding sources for creating new incubators. One other thing Universities need to do is to formulate suitable policies and set up institutional mechanisms to support incubation activities. Further, BIRAC is doing many things to help incubation for early stage start-ups. It funds almost \$75,000 for 18 months to early stage start-ups through its Biotech Ignition Grant scheme. India is now seeing an increased action in private equity and VC funding, especially in Biomed, Diagnostics, and Bio IT sectors in India

Life Science startups across IITs, IIMs & other incubation centers

- **IIT Delhi:** The Technology Business Incubator (TBI) is active since 2000. It is managed by the Foundation for Innovative and Technology Transfer (FITTT), which is the Industry interface unit of the institute.

Total Incubatees: 30 / Life Sciences: 3

- **IIT Mumbai:** Society for Innovation and Entrepreneurship (SINE) manages a technology business incubator at Indian Institute of Technology (IIT Mumbai). This incubator is a platform to support technology startups founded by IIT Mumbai community or are based on IIT Mumbai technologies.

Total Incubatees: 21 / Life Sciences: 2

■ **IIT Madras:** IIT Madras Incubation Cell (IITM-IC) aims to leverage strengths from various streams to foster innovation and entrepreneurship. Over 30 companies have been incubated. These ventures have been founded by students, faculty, staff and alumni of IITM and external members (R&D partners).

Total Incubatees: 46 / Life Sciences: 8

■ **IIT Hyderabad:** The Center for Innovation and Entrepreneurship (CIE) at IIT-Hyderabad provides an ecosystem for technology commercialization and entrepreneurial action.

Total Incubatees: 16 / Life Sciences: 2

■ **IIT Kharagpur:** Technology Incubation and Entrepreneurship Training Society (TIETS) is a virtual incubation center at IIT Kharagpur (KGP), West Bengal.

Total Incubatees: 26 / Life Sciences: 5

■ **IIT Varanasi (BHU):** Malaviya Center for Innovation, Incubation and Entrepreneurship (MCIEE) is a not-for-profit society at IIT (BHU), aiming to promote innovation and entrepreneurship.

Total Incubatees: 08 / Life Sciences: 1

■ **IIT Guwahati:** The Technology Incubation Centre (IITG-TIC) promotes entrepreneurial initiatives amongst the faculty and alumni of the IITG community in particular. It is the main anchor in the North East India.

Total Incubatees: 6 / Life Sciences: 1

■ **IIT Kanpur:** SIDBI Innovation & Incubation Centre (SIIC) at IIT Kanpur focuses on transforming knowledge into wealth, and creating a generation of zealous entrepreneurs.

Total Incubatees: 24 / Life Sciences: 3

■ **IIM Ahmedabad:** Aarohan Ventures

is an early stage venture fund and incubator focused on building scalable education, healthcare and technology for development solutions. Aarohan supports social enterprises as well.

Total Incubatees: 8 / Life Sciences: 2

■ **IIM Calcutta:** IIM Calcutta Innovation Park (IIP) was set up to incubate and accelerate the growth of start-ups in India.

Total Incubatees: 5 / Life Sciences: 2

■ **IIM Bangalore:** The Nadathur S Raghavan Centre for Entrepreneurial Learning (NSRCEL) facilitates business growth through academic research by scholars and practical learning for entrepreneurs.

Total Incubatees: 40 / Life Sciences: 1

■ **IISc, Bangalore:** The Society for Innovation and Development (SID) was founded in 1991 in collaboration with the Indian Institute of Science (IISc) Bangalore.

Infrastructure Support Incubators

■ **Centre for Cellular and Molecular Platforms (C-CAMP):** This DBT initiative is to be an enabler of bioscience research and entrepreneurship by providing research, development, training and service in state of the art technology platforms. C-CAMP has funded (via BIRAC) and mentors around 50 life science start-ups/spin-offs, of which 11 are incubating at C-CAMP and leveraging the technology platforms and scientific expertise on campus.

■ **IBAB:** The bioinformatics and biotechnology industries are still fledgling in India, and young companies in this sector benefit tremendously from the expertise they can access through the incubation process. This is precisely why IBAB has taken the initiative to incubate several

companies. IBAB has incubated almost 20 start-ups since 2002.

■ **NCL Innovations:** NCL Innovations was founded on as a new resource center of the National Chemical Laboratory, Pune to champion the cause of technology innovations within the organization.

Total Incubatees: 5 / Life Sciences: 2

■ **Venture Center (Pune):** The BioIncubator at Venture Center promotes technology and knowledge-based enterprises in the areas of biotechnology (biopharma, agrobiotech, industrial biotech, and clean technology), biomedical engineering/ devices/ diagnostics, biomass value addition/ renewable fuels/chemicals/materials, bioinformatics, bio/medical services and related disciplines.

Total Incubatees: 24 / Life Sciences: 24

Accelerators

■ **Escape Velocity Accelerator (EVA):** EVA thrives on the passion and drive to spur innovation by hand-holding young and ambitious companies that cater to the broad area of Health-Care and Life Sciences. With emphasis on deep collaboration and synergistic relationships, it helps fundable startups to come into their own.

■ **GSF M-Accelerator:** Started in 2012, India-based GSF M-Accelerator is a specialized accelerator program for mobile start-ups. Functioning as a 'super-accelerator' by design, GSF M-Accelerator offers founders four months to make the kind of progress ordinarily accomplished in six to eight months.

■ **InnAccel:** Bengaluru-based start-up incubator InnAccel plans to support every year at least 12 start-ups that are into medical devices, prosthetics and diagnostics. InnAccel wants to foster the development of at least 50 novel medical devices and diagnostics by 2020, and launch 25 critical medtech products in India by 2025.

Biotech Parks

Southern India

■ **Bangalore Bioinnovation Center (BBC):** This is envisioned to be a state-of-the-art incubation center catering to the needs of start ups in the broad areas of Life Sciences. It is located within Bangalore Helix Biotechnology Park at Electronic City in Karnataka. The center is a modern incubation center with central instrumentation facility in a 10 acre campus with total built up area of above 50,000 sq ft.

■ **Bio360 - Life Science Park:** This is located Southern Indian State of Kerala upcoming lifesciences park, focusing on facilitating the Bio-IT and Nano technology sectors in India.

■ **Genome Valley:** Genome Valley (GV) is a biotech cluster in Hyderabad, southern India. It comprises of knowledge parks, special economic zones (SEZs), multi-tenanted lab space buildings, incubation facilities, office spaces and support facilities. It has an array of companies in the realm of agribiotech, CROs, biopharma, vaccine manufacturing, regulatory and testing. The cluster has over 100 lifescience companies. The multi-tenanted lab space buildings and incubation facilities provide growth to small, medium, and large enterprises, including start-ups. Genome Valley is also known as the 'Vaccine Hub of India', since leading vaccine producers like Biological E, Bharat Biotech and Globion Bio are within the cluster, along with Shantha Biotech and Indian Immunologicals. It has two prominent knowledge parks--Alexandria Knowledge Park and IKP Knowledge Park.

■ **IKP Knowledge Park:** The IKP knowledge park is lifescience park facilitating business-driven R&D for more than a decade now. The facility in Hyderabad is spread across 200 acres in genome valley. The park has ready-to-use multi-tenanted modular wet laboratory blocks (innovation corridors) with in-built flexibility around common, shared facilities and support services, as well as developed land for customized R&D facilities. Over 65 companies have been incubated

in the park. IKP has this year opened a center in Bangalore—EDEN stands for Engineering, Design, and Entrepreneurship Network.

■ **KINFRA Biotech Park:** The Biotechnology Incubation Center (BTIC) set up by Kerala Industrial Infrastructure Development Corporation (KINFRA) in Ernakulum, Kerala, houses labs that are equipped with commercial facilities and six units are under construction. A 20 acre land is available for lease to companies.

■ **TICEL Bio Park:** Located in Tamil Nadu, Chennai, TICEL Bio Park is spread across 5-acre space and is promoted by Tamil Nadu Industrial Development Corporation (TIDCO). The park's co-promoters include Indian Bank, Karur Vysya Bank and Indian Overseas Bank. The park's design and technical parameters were provided by Cornell University, USA.

North / North East / East

■ **Bio Pharma-IT Park:** The facility is being developed at Andharua in Bhubaneswar, in the Eastern part of India in Odisha, on a land parcel of 64.61 acres. The park area has been demarcated and the construction of the building for the incubator is to commence.

■ **Guwahati Biotech Park:** This is in As-

sam (North East) and spread over 17 acres. Facilities include eight modular laboratories, specialized and support facilities. Interim facilities have been created at Indian Institute of Technology (IIT), Guwahati, in a building rented out to the state government for the incubator.

■ **Lucknow Biotech Park (LBP):** The park is located in Uttar Pradesh. Nearly 10 companies have graduated from the incubator and another nine companies are under incubation. The park has National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation for its analytical facilities and provides service to many agro-industries in the region. The plant tissue culture facility is also certified under DBT-BCIL certification program. The park has an extraction unit, a bioinformatics unit and a bio-fuel unit.

■ **Punjab Biotechnology Park:** Located in Dera Bassi at Chandigarh, in the Northern State of Punjab, it focuses on technology transfer, collaborative research, exchange of scientific manpower and company-to-company business relationship in agricultural and environmental biotechnology and bioprocessing.

West

■ **International Biotech Park, Pune:** This is situated just off the Mumbai-Pune Expressway, at Hinjawadi, 10 km from Pune City. The International Biotech Park is a joint venture between Maharashtra Industrial Development Corporation (MIDC) and The Chatterjee Group. This is the first public-private biotechnology park initiative in Maharashtra. It is a 81 acre park dedicated for R&D as well as for manufacturing purposes.

■ **Jalna Biotech Park:** Located in the city of Aurangabad, in the West (Maharashtra), this park was set up by Wockhardt. It has manufacturing facilities for active pharmaceutical ingredients, biopharmaceuticals, R&D center, effluent treatment plant, a corporate office, warehouse and a residential and recreational complex. It provides employment to an estimated 2000 people.

■ **Savli Biotech Park:** Gujarat has set up a Biotechnology Park at Savli Industrial Estate at Vadodara. The Park would be developed as a Public-Private Venture in an area of about 700 acres in three phases.

PROPOSED BIOTECH PARKS

- Biotech Park, Konark, Chandrabhaga, Odisha.
- Marine Biotech Park, Ganjam, Odisha
- Boranda Biotech Park, Jodhpur, Rajasthan.
- Herbal Pharma Biotech Park, Betma, Indore, Madhya Pradesh.
- Ansals API Biotech Park, Lucknow, Uttar Pradesh.
- Pantnagar Biotech Park, Haldi, Uttaranchal.
- Solan Biotech Park, Himachal Pradesh.
- Jogindernagar Biotech Park, Shimla, Himachal Pradesh.

ABLE Association of Biotechnology Led Enterprises

The collective face of the Indian Biotech Industry



Streamlining the
**REGULATORY
PROCESS**



Recommending
union **BUDGET** for
biotech sector



Proposing fiscal
INCENTIVES for
Biotech Sector



Strengthening the
PR REGIME



Recommending
Venture
CAPITAL FUND



Accelerating industry
growth via
ADVOCACY



Kindling & fostering
the fire of
ENTREPRENEURSHIP



Promoting linkage
between
**INDUSTRY-
ACADEMIA**



Catalysing
opportunities for
START-UPS & SMEs



Facilitating
partnership through
COLLABORATION



Encouraging sector
growth through
INVESTMENT



Implementing
member focused
INITIATIVES

New Delhi

309 Mercantile House,
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Telefax: +91 11 2373 1127

Bangalore

#123/C, 16th Main Road, 5th Cross,
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Biologics the core for Biotech Growth

While there are unending possibilities in biosimilar arena, the full realization of its immense potential owing to many factors is about to take off in India

The combined sales potential of more than \$60 billion from several biologics going off the rack of patent shelves in the next few years presents a massive opportunity for India to contribute through biosimilars. Already, the estimated \$850 million biosimilar industry in India is growing at 25%. More than 50 biosimilar products are now available in the Indian market with over 10 pharma players competing in this area for 15 epoetin, eight G-CSF and four insulin biosimilars, besides a few others.

Collaborations play a big role here. Barring a few exceptions, most of the biosimilar manufacturers have entered this space through partnerships. The reason is largely because biosimilar production and commercialization needs many capabilities—biologic product development, manufacturing, regulatory and clini-

cal development, specialized marketing, etc. There were a number of high profile acquisitions and mergers in the biopharma space in 2015. Biosimilars portfolios and capabilities were considerations in several of these deals. This trend is likely to continue in the coming years as companies use licensing and partnerships to achieve in the biosimilars arena what they could not do alone.

While India has been a leading player in the field of generics, it lags behind in the race to make copies of complex biotech drugs expected to generate tens of billions of dollars in sales in the coming years. Indian firms have launched a few such products on the domestic market, where regulatory barriers are relatively low. Three Indian groups—Biocon Ltd, Dr Reddy's Laboratories Ltd, and Intas Pharmaceuticals Ltd—are leading in this space working with partners and keen on entering the global markets in the United States and Europe.

Biocon has a tie-up with Mylan Inc and is testing four molecules in global Phase III trials, for which it plans to seek approvals in the United States and Europe starting in fiscal 2017. Dr Reddy's is developing biosimilars such as rituximab and pegfilgrastim for use in cancer treatment under a pact with Germany's Merck KGaA and it plans to launch its first biosimilar in the United States by 2018. Intas has eight biosimilar products in the market, including one monoclonal antibody MABTAS (rituximab). It has also launched its first biosimilar, Filgrastim, in Europe, through its wholly owned subsidiary Accord Healthcare. The product has recently been introduced under the brand Accofil and has already won two prestigious tenders, in Netherlands and the UK respectively.

Evolving landscape of biologics

The growth of the market is also linked to the fast changing rules and regulations. The interchangeabil-



FACTORS THAT COULD SERVE AS CATALYSTS

Local regional hubs

Public private partnerships

Leveraging academic expertise

Policies in sync with industry's needs

Incentivizing technology entrepreneurs

Better cold chain logistics

ity besides naming are two important considerations in the uptake of biosimilars once they are launched. The European Union has approved 21 biosimilars as of November, 2015. All these have been issued under the same non-proprietary name as for the reference product. Recently, the US FDA has issued draft guidance on the subject of non-proprietary naming of biosimilars. The US FDA guidance recommends that all biologicals and biosimilars have not only non-proprietary names but also a four-letter suffix to distinguish them from each other.

The newly interested players apart from the existing ones will have to understand the game fully. To compete in international arena, they will have to understand the complexities from the day one.

Regulatory scenario

Copying chemical-based drugs has been a major strength of pharmaceuticals industry in India. Biotech drugs, however, are more difficult to make and cannot be replicated exactly, which is why regulators have come up with the notion of versions that are similar enough to do the job. The cost and complexity of developing biosimilars will be a deterrent for many Indian players.

Indian regulatory authorities call products which are similar to biologic as "similar biologics". Generally, the granting of regulatory approval for such "similar biologics" requires more data than for a simple generic drug application.

India announced the release of draft regulatory guidelines for 'similar biologics' at the BIO industry conference in Boston, USA, on 19 June 2012. Finalized guidelines were implemented on 15 September 2012. The guidelines outline a simple abridged procedure for evaluation of similar biologics which have been approved and marketed in India, Europe or the US for more than four years. The regulatory bodies responsible for ap-

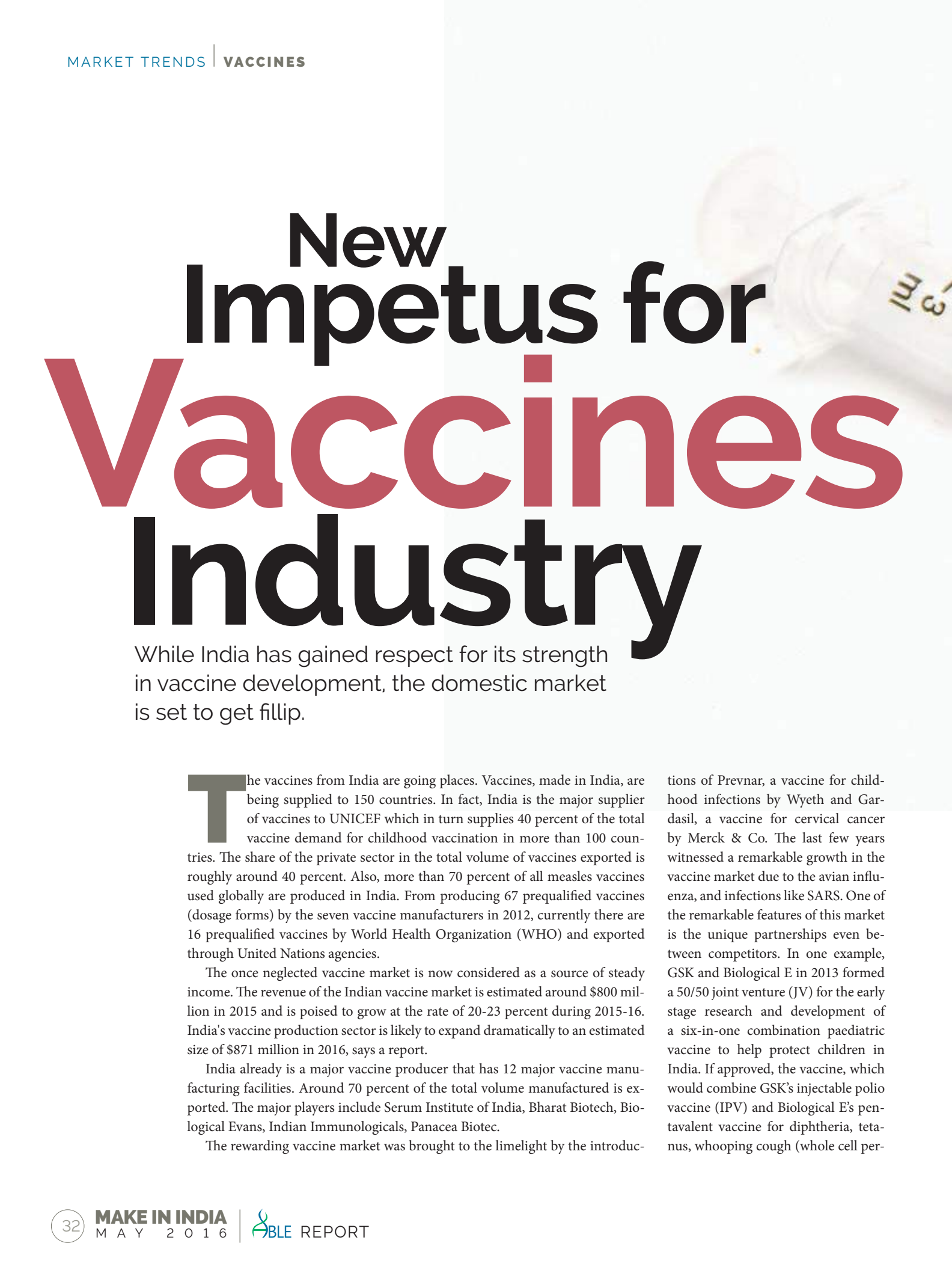
proval of "similar biologics" in India are the Department of Biotechnology (DBT – under the Ministry of Science and Technology), through its Review Committee on Genetic Manipulation (RCGM), and the Central Drugs Standard Control Organization (CDSCO – under the Ministry of Health and Family Welfare).

India has approved more than 50 "similar biologics" till date. According to research at GaBI Online, the first "similar biologic" was approved and marketed in India for a hepatitis B vaccine in 2000. In recent years over 50 biopharmaceutical products have been approved for marketing in India, with more than half of them being 'similar biologics'.

Aligning to global trends

The global biosimilars market is predicted to have sales of \$25 billion by 2020, according to a 2014 Thomson Reuters report. Similarly, according to a report by Frost & Sullivan the global market for biosimilars will rapidly expand more than 20-fold in the next five years and same thing applies to Indian market. Demand is being fuelled by governments around the world turning to biosimilars as a cheaper option to reduce healthcare costs. Government initiatives, strategic collaborations, and increasing incidents of new diseases are also increasing the value of the market. Globally, Western pharmaceutical firms such as Novartis AG; Pfizer Inc, in partnership with South Korea's Celltrion Inc; and Merck & Co with partner Samsung Bioepis, are leading in the race to dominate the Western biosimilars market.

Here in India, the guidelines for biosimilars released in 2012, are in the process of revision currently. These guidelines are expected to be released for stakeholder review shortly. Besides that the host of factors including government funding, infrastructure, resources and regulations are going to decide whether India will continue to matter in this biologics race.



New Impetus for Vaccines Industry

While India has gained respect for its strength in vaccine development, the domestic market is set to get fillip.

The vaccines from India are going places. Vaccines, made in India, are being supplied to 150 countries. In fact, India is the major supplier of vaccines to UNICEF which in turn supplies 40 percent of the total vaccine demand for childhood vaccination in more than 100 countries. The share of the private sector in the total volume of vaccines exported is roughly around 40 percent. Also, more than 70 percent of all measles vaccines used globally are produced in India. From producing 67 prequalified vaccines (dosage forms) by the seven vaccine manufacturers in 2012, currently there are 16 prequalified vaccines by World Health Organization (WHO) and exported through United Nations agencies.

The once neglected vaccine market is now considered as a source of steady income. The revenue of the Indian vaccine market is estimated around \$800 million in 2015 and is poised to grow at the rate of 20-23 percent during 2015-16. India's vaccine production sector is likely to expand dramatically to an estimated size of \$871 million in 2016, says a report.

India already is a major vaccine producer that has 12 major vaccine manufacturing facilities. Around 70 percent of the total volume manufactured is exported. The major players include Serum Institute of India, Bharat Biotech, Biological Evans, Indian Immunologicals, Panacea Biotec.

The rewarding vaccine market was brought to the limelight by the introduc-

tions of Prevnar, a vaccine for childhood infections by Wyeth and Gardasil, a vaccine for cervical cancer by Merck & Co. The last few years witnessed a remarkable growth in the vaccine market due to the avian influenza, and infections like SARS. One of the remarkable features of this market is the unique partnerships even between competitors. In one example, GSK and Biological E in 2013 formed a 50/50 joint venture (JV) for the early stage research and development of a six-in-one combination paediatric vaccine to help protect children in India. If approved, the vaccine, which would combine GSK's injectable polio vaccine (IPV) and Biological E's pentavalent vaccine for diphtheria, tetanus, whooping cough (whole cell per-



KEY VACCINES UNDER DEVELOPMENT IN INDIA

VACCINE	MANUFACTURER
Malaria vaccine	Bharat Biotech
Dengue Vaccine	Biological Evans
HPV Vaccine	Serum Institute of India and Indian Immunologicals
Chikungaya	Indian Immunologicals
Anthrax vaccine	Panacea Biotec
Pneumococcal Conjugate	Serum Institute of India/PATH
Rotavirus	Serum Institute of India
Meningococcal vaccines Includes polysaccharide and conjugate vaccines	Serum Institute of India and Panacea Biotec
Japanese encephalitis vaccine	Indian Immunologicals, Panacea Biotech

tussis), hepatitis B, and Haemophilus influenzae type b, could be the first of its kind.

Key challenges for the vaccine market

Among the host of challenges, most important ones are long timelines, delays, several agencies being involved and lack of harmonization with international regulatory agencies besides the price point pressure.

Currently the seven government listed vaccines are sold at a rate of Re1 to Re 1.5. Considering the import duties on raw materials and of the cost of production, storage and distribution the manufacturers face a grim situation to run their business profitably. The model of low cost high volume

business has created margin pressure for some vaccines to their manufacturers. The supply chain of the vaccines has to be strictly monitored for specific temperature which adds to the costing woes of the manufacturer. A shortfall in the private investments is strongly felt by the vaccine manufacturers. The cost of the institutional loans is high in comparison to the returns. The meek margins realized for certain vaccines strongly impact the relapse of funds into their R&D capabilities. Uncertainty in demand forecasting for the vaccine market may affect the profitability of the manufacturers.

Clear regulatory guidelines are still under development in India. The success of the vaccine depends upon the results of the clinical trials and the prevailing regulatory guidelines. The losses in this high cash intensive market can be mitigated by support from government and international NGOs.

On-going regulatory shake up

With a great potential to emerge as country's key industrial contributor, the vaccine businesses have not been fully able to evolve due to regulatory hiccups. However, under this government, the health ministry is trying to streamline the regulations.

In a step towards that, for the purpose of charting out a new regulatory pathway for vaccines, the Central Drugs Standard Control Organization (CDSCO) constituted three core working groups from within the industry during 2015. One each for strategy, technical operations, and technical post approval each with its designated chairman and member secretary who will take the things forward in a time bound manner. The new initiative was an outcome of the interaction between the vaccine manufacturers and importers in the country with the Drug Controller General of India (DCGI) on January 15, 2015 in New Delhi. The meeting was convened to hold discussions on the current national and international scenarios in vaccine development and its regulations. The

MAJOR PLAYERS IN INDIA IN THE VACCINE MARKET

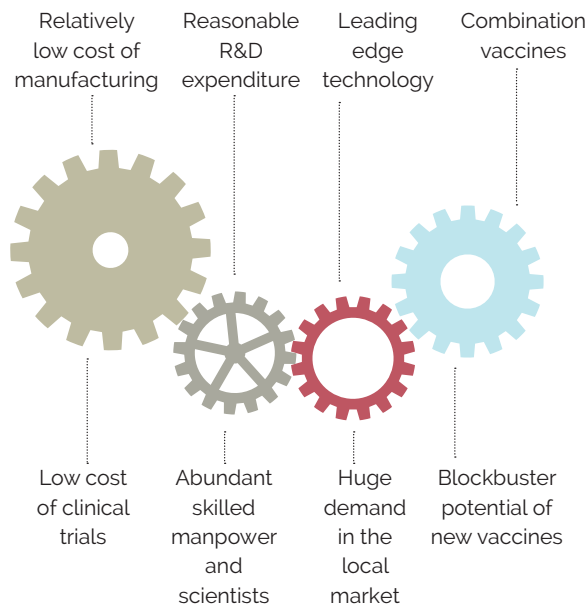
- Serum Institute of India
- Bharat Biotech
- Biological E
- Panacea Biotec
- Indian Immunological
- Aventis Pharma
- Shantha Biotechnics
- Eli Lilly India
- Glaxo Smith Kline Pharmaceuticals
- Haffkine Bio Pharmaceutical Corporation Ltd (HBCL)
- Intervet India
- Lupin
- Wyeth
- Sanofi
- Merck
- Venkateshwara Hatcheries



and international levels.

While the manufacturers go through hiccups, the importers too have to face many issues including taxes and transportation. In case of imported products, these are considered on a case-by case basis; if trials meet the requirements of the National Regulatory Authority (NRA), there is no insistence on clinical trials in the country for registration. The advisory committee that review the information follow published guidelines, directed by a responsible person. External clinical experts may be asked for advice on a case-by-case basis. After licensing, the vaccine manufacturer should undertake a large post-marketing surveillance (Phase IV) to further ensure the safety of their products. Any complaint regarding the safety, efficacy, etc of the licensed vaccine should be directed to NRA. Once the vaccine is licensed in the country, it can be used both by the private as well as the public sector. Generally, all the vaccines recommended by Indian Academy of Paediatrics-Committee on Immunization (IAP-COI) are approved by WHO.

KEY DRIVERS FOR THE VACCINE



dialogue between regulator and industry on various issues, challenges, opportunities in respect of manufacturing of priority vaccines including import of vaccines and regulatory pathways i.e to promote a legal, regulatory and administrative framework for the safety of vaccines at national

Playing the big role globally

The rapid growth of the global vaccine market would lead to increased competition and experts say that it would even resemble the pharmaceutical market. There would be a distinct first mover advantage for companies launching their vaccines early in the Indian market with funding from various government agencies. Competition in the market is set to increase with the entry of more traditional companies. India must develop its own national strategies to meet its vaccination needs within its budgetary constraints. However, the new initiatives and new strategic approach by the regulatory bodies can build the industry's confidence. That in turn will be able to bring about positive changes to enable India as an emerging leader in global vaccine industry.

MEDICAL TECHNOLOGY

The Next Sunshine Industry

With huge unmet needs coupled with fast swelling tribes of innovators, the medical devices are piped to be a major contributor to the growth of Indian health sector

The country's strong economic growth and better living standards have given a boost to the India's medical device market. This is also among the top five priority sectors as part 'Make in India' roll out program. Besides that, one of the primary reasons for this rapid growth has been due to large population with huge disease burden. Adding to that is the increased purchasing power due to host of factors such as urbanization and availability of the better job opportunities.

As per a recent report from consulting firm, GlobalData, the medical devices sector will rise from \$10.4 billion in 2014 to reach \$17.6 billion by 2020, representing a robust Compound Annual Growth Rate (CAGR) of 9.4 percent. The increased demand for medical facilities and devices has also been driven by mounting patient awareness of advancements in medical technology through television and other mediums including mobile phones. The aging populations are a huge growth driver for the sector in the longer run. However, despite the strong opportunities, currently there is a mismatch between the technology availability and the unmet needs. Estimated 70 percent of Indian population is dependent on the imported medical devices. Out of that close to 30 percent is said to be supplied by the United States alone. In this case of high import scenario, there is clear inconsistency between the technologies imported and the prevailing clinical conditions as well as the healthcare infrastructure in India.

Presently, medical devices are governed by the Drugs and Cosmetics Act,

1940 and Drugs and Cosmetics Rules, 1945. The current regulatory structure has its own barriers and limitations such as complex rules and guidelines, high capital investment, lack of active participation from the government and low penetration.

Being regulated by similar framework as for drugs, medical devices companies feel restricted and over-regulated. Establishing a separate regulatory body for medical devices will create a clear ownership within the government to push the medical devices agenda as well as promote growth for the sector

Medical tourism boom

The Indian medical devices arena is also profiting from a growing medical tourism market, which is driven

by the comparatively low cost of treatments. The market estimated to be valued at \$ 4.5 billion has close to 1.27 million tourists from countries such as the US, UK, and Canada in addition to visitors from neighbouring countries like Bangladesh, Sri Lanka, and China avail the medical facilities in India. The big corporate hospitals such as Tata, Fortis, Max, Wockhardt, and Apollo Hospitals have made significant investments in setting up modern hospitals and tourism-related services to cater to the new brand of visitors from abroad.

Indigenous push to innovation

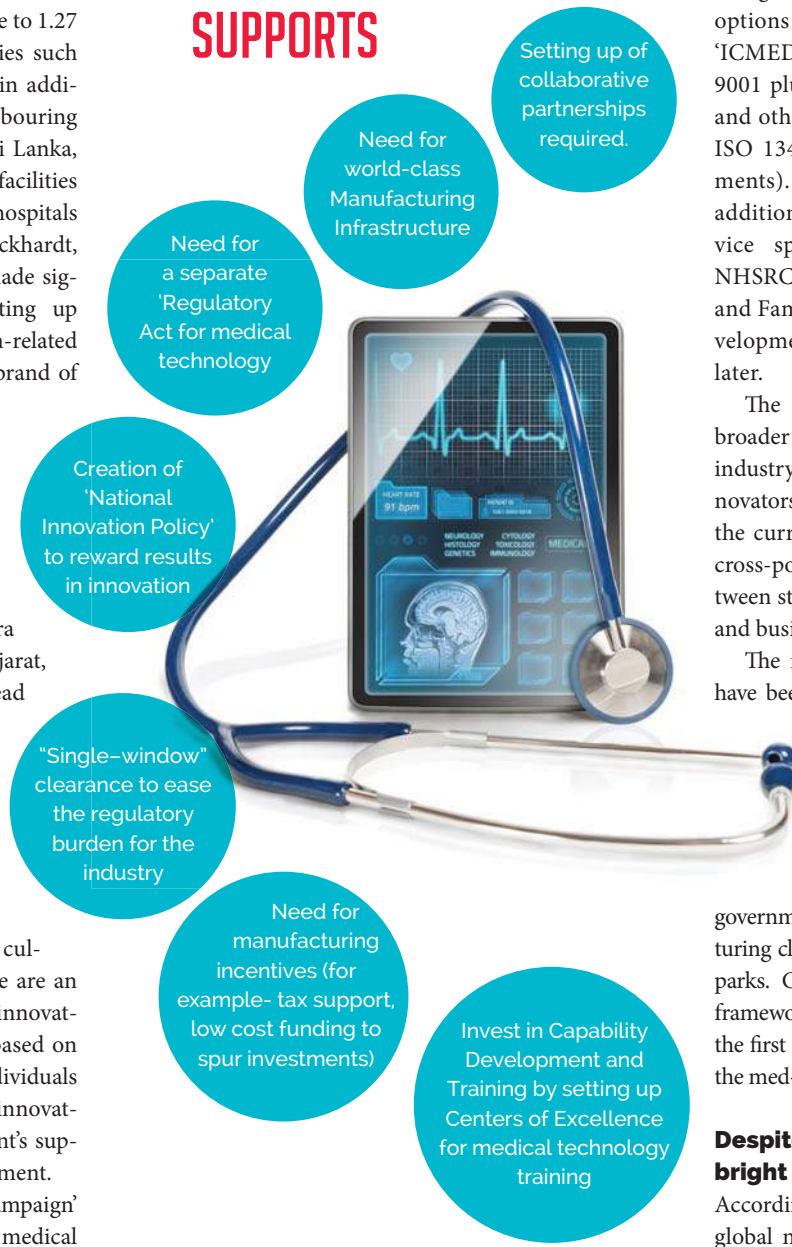
The Indian market has diverse opportunities for the growth of the medical devices sector. While states of Andhra Pradesh, Maharashtra, Gujarat, and Telangana are racing ahead to establish exclusive world class medical device manufacturing parks, the union government has taken some appreciable measures to rekindle domestic manufacturing.

With the dominant startup culture and trend in India, there are an increasing number of people innovating and inventing products based on novel ideas. However, for individuals and companies to continue innovating, they need the government’s support in terms of capital investment.

The ‘Make in India campaign’ has a mandate to boost the medical device-manufacturing sector in India for all types of medical devices and equipment used in manufacturing of Pharmaceuticals. But while the government’s initial approach was to not just promote indigenous manufacturing but also encourage MNCs to come and manufacture in India, a combination of price regulation on medical devices and hiking imports duty would only discourage the latter.

Indian Certification of Medical Devices Scheme (ICMED), country’s first indigenous quality assur-

INDUSTRY SUPPORTS



Setting up of collaborative partnerships required.

Need for world-class Manufacturing Infrastructure

Need for a separate 'Regulatory Act for medical technology

Creation of 'National Innovation Policy' to reward results in innovation

"Single-window" clearance to ease the regulatory burden for the industry

Need for manufacturing incentives (for example- tax support, low cost funding to spur investments)

Invest in Capability Development and Training by setting up Centers of Excellence for medical technology training

tiveness. The Certification Scheme being launched has presently two options for certification, one being ‘ICMED 9000 Certification (an ISO 9001 plus additional requirements)’ and other being ‘ICMED 13485 (An ISO 13485 Plus additional requirements). A third level, which would additionally prescribe medical device specifications developed by NHSRC of the Ministry of Health and Family Welfare is still under development and would be launched later.

The experts say that there is a broader requirement for academia-industry interactions for guiding innovators. They also point towards the curriculum adaptation as well as cross-pollination of knowledge between students of medical technology and business management.

The industry associations in India have been lobbying for a Department for Medical Devices, a separate ministry for health-care products to act as facilitator and regulator and coordinated plan between central government and state governments to aid existing manufacturing clusters and new medical device parks. Creating a separate regulatory framework for medical devices will be the first step in addressing the needs of the med-tech sector.

Despite odds, outlook is bright

According to the CII-BCG report, global medical technology market is expected to be over \$600 billion by 2025 and that India can capture 10 percent of that share if it is provided with adequate support and policy guidance. Some of the steps that the government can take include increasing overall spending on healthcare and per capita spend on medical devices, introducing greater insurance coverage, creating incentives for investment and R&D and undertake and disseminate research on medical devices.

ance system for India manufactured medical devices, was launched on March 15, 2016. ICMED is the first home developed international class certification scheme for the medical devices in the country and aims to eliminate the malpractices of substandard or fraudulent certification or quality audits, thereby ensuring substantial savings, enhanced credibility and increased competi-

Biocon

Delivering Affordable Innovation

Headquartered in Bangalore, India, Biocon has taken the lead in India to harness the power of biotechnology through affordable innovation to find solutions that heal the world. It has successfully taken a range of novel biologics, biosimilars, differentiated small molecules and affordable recombinant human insulin and insulin analogs from “Lab” to “Market”.

Biocon's key innovations in the area of diabetes management include an indigenous recombinant human insulin (rh-insulin) based on proprietary fermentation technology, INSUGEN, insulin analogue Glargine, BASALOG, and INSUPen, a next generation afford-

able insulin delivery device introduced in India.

In the field of anti-cancer therapies, Biocon launched India's first indigenously produced novel monoclonal antibody for head and neck cancer, BIOMAb EGFR. It has launched the world's most affordable biosimilar trastuzumab, CANMAB, for the treatment of HER2-positive breast cancer in India. CANMAB is one of the most successful oncology product launches in India.

In the mission to address autoimmune diseases, Biocon has introduced the world's first novel anti-CD6 monoclonal antibody, ALZUMAb, for the treatment of chronic plaque psoriasis. This molecule also holds promise for

a range of other autoimmune diseases.

Biocon aspires to become a \$1 billion company by FY2018. It has identified five powerful growth accelerators to achieve its goals—Small Molecules, Biosimilars, Branded Formulations, Novel Molecules, and Research Services with a focus on emerging markets.

The Small Molecules vertical consists of statins, immunosuppressants, specialty molecules like Fidaxomicin and other APIs. The Biosimilars portfolio includes generic insulin and analogs for diabetes and biosimilars for oncology and autoimmune indications. The oncology and autoimmune indications portfolio consists of three biosimilar monoclonal antibodies (trastuzumab, bevacizumab and adalimumab) and two biosimilar recombinant proteins (pegylated-filgrastim and eterncept).

Over the years, Biocon has invested in cutting-edge science, key research partnerships and global manufacturing scale to develop products that address the needs of patients through differentiated products in over 100 countries.

For more details, visit:
www.biocon.com

Syngene

International

putting science to work

Biocon has also built a remarkable Research Services business through Syngene International that offers integrated discovery and development solutions for both small and large molecules to 16 of the world's top 20 biopharmaceutical companies, a large number of mid-sized biotech and pharma firms and several small and virtual enterprises. Focus and dedicated services have enabled this Bangalore-

based company to become one of Asia's largest Contract Research Organizations.

Syngene provides discovery and developmental services for new molecular entities across multiple platforms including small molecules, large molecules, antibody - drug conjugates and oligonucleotides. These services are aimed towards bringing novel molecules to the market by supporting the R&D

efforts of organizations across diverse sectors like pharma, biotechnology, nutrition and animal health. Syngene offers an integrated platform for R&D focused organizations to optimize their R&D investments and develop their novel molecules with a distinctive cost advantage. In FY2016, Syngene serviced 256 clients including eight of the top 10 global pharma companies.

Syngene has three business verticals – Dedicated R&D Centers, Discovery Services, and Development & Manufacturing Services. Syngene follows a flexible business model that allows multiple entry points for its clients to engage with it thereby offering forward as well as backward integration opportunities on the discovery, development and manufacturing continuum. Syngene International went public in July 2015 and its IPO was oversubscribed 31 times on the day of listing.

For more details, visit:
www.syngeneintl.com

Karnataka

biotech hub of Asia

The southern state of India—Karnataka—has been at the forefront of biotechnology in India and is rightly known as the Biotech Capital of India. It is home to a large array of biotechnology enterprises and leads the sector in India due to its strong ecosystem and rich tradition of education and biotechnology training. Internationally renowned research institutions like the Indian Institute of Science, National Centre for Biological Sciences, NIMHANS, Jawaharlal Nehru Centre for Advanced Scientific Research, Central Food Technological Research Institute (Mysore), Kidwai Memorial Institute of Oncology, Rajiv Gandhi University of Health Sciences and the University of Agricultural Sciences have

been the anchors for this sector.

The Governments in Karnataka have always supported the growth of biotech industry. Karnataka was one of the first in the country to have a Biotechnology Policy that outlined steps to enhance the development of industry and harness its benefits for the common citizen. The policy offered a number of fiscal incentives and concessions too, besides a dedicated fund in partnership with professional Venture Capital firms. It is ready to announce a third version soon.

Karnataka has undertaken several pioneering steps like setting up a department for fostering the biotechnology (BT), information technology (IT), and science & tech-

nology (S&T) sectors. The department has a dedicated organization, Karnataka Biotechnology and Information Technology Services (KBITS), to help to facilitate and promote the emerging sectors in the state. KBITS provides secretarial services to the state level Single Window Agency and High Level Committee for quick clearance of IT and BT projects in the state. KBITS assists the Directorate of IT & BT, for administering incentives and concessions to companies.

The state has also created a Biotechnology Facilitation Cell (BFC), which under the guidance of KBITS, works closely with the industry and academia. One of pioneering initiatives of BFC has been Biotechnology Finishing Schools (BTFS) program implementation across the state. BTFS program is to equip students with necessary employable skills and make them industry ready. Karnataka is initiating several such strident initiatives to keep the impetus going for sector's growth in the state.

For more details,

<http://www.bangaloreitbt.in/>,

<http://www.btfskarnataka.org/>

Bangalore Bioinnovation Centre (BBC)

nurturing and promoting start ups

The Bangalore Bioinnovation Centre (BBC) is a center for nurturing and promoting start ups in Life Sciences. This is a flagship project of KBITS and is envisioned as a state-of-the-art incubation center catering to the needs of start ups in the broad areas of life sciences. It is located within Bangalore Helix Biotechnology Park at Electronic City, Bangalore. BBC is a world class Incubation center with central instrumentation facility in a 10 Acre campus with total built up area of above 50,000 sq ft. The Center is nestled between

thriving academic institutions like Institute of Biotechnology and Applied Biotechnology (IBAB), Centre for Human Genetics and the upcoming area for anchoring Big Companies/MNCs. Thus, the center provides a crucial link within the developing biocluster, the Bangalore Helix Biotech Park. BBC today houses over 19 companies.

BBC is facilitating a unique idea to proof of concept scheme. The scheme called, Idea2PoC, is an initiative of the Department of IT, BT and S&T, Government of Karnataka.

The scheme enables technology innovators and entrepreneurs to pursue a promising technology ideas, and validate proof of concept (PoC). It is expected that innovators and entrepreneurs advance an idea closer to commercialization in the form of creation of start-up companies, technology licenses or become venture ready.

For more details,

<http://www.bioinnovationcentre.com/>

DIRECTORY OF BIOTECH RELATED INDUSTRY ASSOCIATIONS AND AGENCIES

NAME	
Association of Biotechnology Led Enterprises (ABLE)	<p>CONTACT: http://www.ableindia.in</p> <p>DESCRIPTION: ABLE is a not-for-profit national forum that represents the Indian Biotechnology sector.</p>
Association of Contract Research Organizations (ACRO)	<p>CONTACT: http://www.acroindia.org</p> <p>DESCRIPTION: ACRO, founded and registered in India in Feb 2005, has been formed under the aegis of Confederation of Indian Industry (CII) for bringing all CROs operating in India on one common platform.</p>
Association of Diagnostics Manufacturers of India (ADMI)	<p>CONTACT: http://www.admi-india.org</p> <p>DESCRIPTION: The main aim of the Association of Diagnostic Manufacturers of India is to provide a platform for the Indian IVD manufacturers so that they can voice their concerns and resolve issues.</p>
Association of Medical Device Industry (AIMED)	<p>CONTACT: http://www.aimedindia.com</p> <p>DESCRIPTION: AIMED is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of medical devices, representing the interest of over 700 manufacturers of medical devices to cover issues and address the manufacturers' problems.</p>
Biotechnology Industry Research Assistance Council (BIRAC)	<p>CONTACT: http://www.birac.nic.in</p> <p>DESCRIPTION: BIRAC is a not-for-profit, Public Sector Enterprise, set up by Department of Biotechnology (DBT), as an interface agency to strengthen and empower the emerging biotech enterprises to undertake strategic research and innovation, addressing nationally relevant product development needs.</p>
Bulk Drug Manufacturers Association (BDMA)	<p>CONTACT: http://www.bdmai.org</p> <p>DESCRIPTION: BDMA was formed in 1991. This is an all India body representing all the Bulk Drug Manufacturers of India.</p>
Crop Care Federation of India (CCFI)	<p>CONTACT: http://www.cropcarefed.in</p> <p>DESCRIPTION: CCFI is a non-profit, non-commercial organization, endeavoring to build a responsible image for the agrochemical industry.</p>
CropLife India	<p>CONTACT: http://croplifeindia.org</p> <p>DESCRIPTION: CropLife India is the voice and advocacy of the plant science industry in India.</p>

NAME	
Federation of Indian Export Organisations (FIEO)	<p>CONTACT: http://www.fieo.org</p> <p>DESCRIPTION: FIEO is the apex body of Indian export promotion organizations set up jointly by the Ministry of Commerce and private trade and industry in the year 1965. It represents the Indian entrepreneurs spirit of enterprise in the global market.</p>
Federation of Pharma Entrepreneurs (FOPE)	<p>CONTACT: http://fopeindia.org</p> <p>DESCRIPTION: FOPE was started in 2006, with an objective to take up the common issues affecting the Pharma industry at the national level.</p>
Healthcare Federation of India (NATHEALTH)	<p>CONTACT: http://www.nathealthindia.org</p> <p>DESCRIPTION: NATHEALTH, is India's apex healthcare body.</p>
India Pharmacological Society	<p>CONTACT: http://www.indianpharmacology.org</p> <p>DESCRIPTION: It is an apex body promoting need-based research in pharmacology and other allied sciences.</p>
Indian Analytical Industry Association (IAIA)	<p>CONTACT: http://www.iaia.org.in</p> <p>DESCRIPTION: IAIA, an exclusive professional body was formed in 1996 with a vision to promote, encourage and develop the growth of the Analytical Instruments Industry.</p>
Indian Association for Statistics in Clinical Trials (IASCT)	<p>CONTACT: http://www.iasct.net</p> <p>DESCRIPTION: IASCT was founded in the year 2007 with a mission to enhance awareness about the role of statistics in clinical trials.</p>
Indian Chamber of Commerce (ICC)	<p>CONTACT: http://www.indianchamber.org</p> <p>DESCRIPTION: The Indian Chamber of Commerce, or ICC as it is popularly known, is the premier body of business and industry in Eastern and North-Eastern India.</p>
Indian Chemical Council	<p>CONTACT: http://www.indianchemicalcouncil.com</p> <p>DESCRIPTION: Indian chemical council, established in 1938, is dedicated to the growth and promotion of the Chemical Industry in India.</p>
Indian Drug Manufacturers' Association (IDMA)	<p>CONTACT: http://www.idma-assn.org</p> <p>DESCRIPTION: IDMA aims to promote Drug research in all its branches, including the manufacture of Drugs in India."</p>
Indian Industries Association (IIA)	<p>CONTACT: http://www.iiasonline.in</p> <p>DESCRIPTION: IIA is an apex representative body of Micro, Small and Medium Enterprises (MSME) with a strong membership base of about 5000 Micro, Small and Medium Enterprises (MSMEs).</p>
Indian Medical Association (IMA)	<p>CONTACT: http://www.ima-india.org</p> <p>DESCRIPTION: IMA is the organization of Doctors of Modern Scientific System of Medicine, was established in 1928, is a society registered under The Societies Act of India.</p>
Indian Pharma Machinery Manufacturers Association (IPMMA)	<p>CONTACT: http://www.ipmma.org</p> <p>DESCRIPTION: IPMMA was founded on 23rd December, 2001 at New Delhi and was registered as a trade association to represent specifically the Indian pharmaceutical machinery manufacturers.</p>
Indian Pharmaceutical Association (IPA)	<p>CONTACT: http://www.ipapharma.org</p> <p>DESCRIPTION: Indian Pharmaceutical Association (IPA) is the premier professional association of pharmacists in India.</p>
Indian Society for Clinical Research (ISCR)	<p>CONTACT: http://www.iscr.org</p> <p>DESCRIPTION: The Society brings together all those who are engaged in clinical research activities in India.</p>

NAME	
Organization For Rare Diseases India (ORDI)	<p>CONTACT: http://ordindia.org</p> <p>DESCRIPTION: ORDI was founded to address the many challenges in the management of rare disease in India.</p>
Organization of Pharmaceutical Producers of India (OPPI)	<p>CONTACT: http://www.indiaoppi.com</p> <p>DESCRIPTION: Established in 1965, the Organisation of Pharmaceutical Producers of India (OPPI) represents the research-based pharmaceutical companies in India.</p>
Pharmaceuticals Export Promotion Council of India (Pharmexcil)	<p>CONTACT: http://www.pharmexcil.com</p> <p>DESCRIPTION: Pharmexcil is the authorized agency of the government of India for promotion of pharmaceutical exports from India.</p>
Process Plant and Machinery Association of India (PPMAI)	<p>CONTACT: http://www.ppmai.org</p> <p>DESCRIPTION: The association represents a world class pool of talent in engineering and management skills, having proven track record in basic design, multidisciplinary detailed engineering, manufacturing of plant & equipment, transportation, installation, construction at sites, erection and commissioning of process plants.</p>
The Advanced Medical Technology Association (AdvaMed)	<p>CONTACT: http://advamed.org</p> <p>DESCRIPTION: AdvaMed is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world.</p>
The Associated Chambers of Commerce of India (ASSOCHAM)	<p>CONTACT: http://www.assochem.org</p> <p>DESCRIPTION: ASSOCHAM is a not for profit organization, facilitating reach of India to all businesses around the globe, for wanting to do business with India.</p>
The Confederation of Indian Industry (CII)	<p>CONTACT: http://www.cii.in</p> <p>DESCRIPTION: CII works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.</p>
The Federation of Cold Storage Associations of India (FCAOI)	<p>CONTACT: http://www.fcaoi.org</p> <p>DESCRIPTION: FCAOI is an all India association with members in most of the states in the country.</p>
The Federation of Indian Chambers of Commerce and Industry (FICCI)	<p>CONTACT: http://www.ficci.com</p> <p>DESCRIPTION: Established in 1927, FICCI is the largest and oldest apex business organisation in India.</p>
The Fertiliser Association Of India (FAI)	<p>CONTACT: http://www.faidelhi.org</p> <p>DESCRIPTION: FAI is a non-profit and non-trading company representing mainly the fertiliser manufacturers, distributors, importers, equipment manufacturers, research institutes and suppliers of inputs.</p>
The Indian Agricultural Association (IAA)	<p>CONTACT: http://iaacentral.org</p> <p>DESCRIPTION: The Indian Agricultural Association (IAA) is the only National body of Agricultural graduates in India.</p>
The Indian Renewable Energy Development Agency (IREDA)	<p>CONTACT: http://www.ireda.gov.in</p> <p>DESCRIPTION: IREDA is a Public Limited Government Company established in 1987, under the administrative control of Ministry of New and Renewable Energy(MNRE) to promote, develop and extend financial assistance for renewable energy and energy efficiency / conservation projects.</p>

OVERVIEW OF KEY MINISTRIES AND REGULATORS

NAME	WEBSITE
Agricultural and Processed Food Products Export Development Authority (APEDA)	http://apeda.gov.in
Biotech Consortium India Limited (BCIL)	http://www.bcil.nic.in
Central Drugs Standard Control Organization (CDSCO)	http://cdsco.nic.in
Council of Scientific and Industrial Research (CSIR)	http://www.csir.res.in
Delhi Pharmacy Council	http://delhi.gov.in
Department of Agricultural Research and Education (DARE)	http://dare.nic.in
Department of Biotechnology (DBT)	http://www.dbtindia.nic.in
Department of Chemicals and Petrochemicals	http://chemicals.nic.in
Department of Pharmaceuticals (DoP)	http://pharmaceuticals.gov.in
Department of Science and Technology (DST)	http://www.dst.gov.in
Department of Scientific and Industrial Research (DSIR)	http://dsir.csir.res.in
Directorate of Plant Protection, Quarantine & Storage (DPPQS)	http://ppqs.gov.in
Food and Drug Administration, Maharashtra	http://foodlicensing.fssai.gov.in
Food Safety and Standards Authority of India (FSSAI)	http://www.fssai.gov.in
Genetic Engineering Appraisal Committee (GEAC)	http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html
Indian Council of Agricultural Research (ICAR)	http://www.icar.org.in
Indian Council of Medical Research (ICMR)	http://www.icmr.nic.in
Indian Pharmacopoeia Commission (IPC)	http://www.ipc.gov.in
Medical Council of India (MCI)	http://www.mciindia.org
Ministry of Agriculture	http://agricoop.nic.in
Ministry of Chemicals and Fertilizers	http://chemicals.nic.in
Ministry of Commerce and Industry	http://commerce.nic.in
Ministry of Corporate Affairs (MCA)	http://www.mca.gov.in
Ministry of Drinking Water Supply and Sanitation (MDWS)	http://www.mdws.gov.in
Ministry of Environment, Forest and Climate Change (MoEFCC)	http://envfor.nic.in
Ministry of Finance (MoF)	http://finmin.nic.in
Ministry of Health and Family Welfare (MOHFW)	http://www.mohfw.nic.in
Ministry of Micro, Small and Medium Enterprises (MSME)	http://msme.gov.in
Ministry of New and Renewable Energy (MNRE)	http://www.mnre.gov.in
Ministry of Planning	http://planningcommission.gov.in
Ministry of Statistics and Programme Implementation	http://mospi.nic.in
National Accreditation Board for Hospitals & Healthcare Providers (NABH)	http://www.nabh.co
National Accreditation Board for Testing and Calibration Laboratories (NABL)	http://www.nabl-india.org
National Innovation Council (NIC)	http://innovationcouncilarchive.nic.in
National Medicinal Plants Board (NMPB)	http://nmpb.nic.in
National Pharmaceutical Pricing Authority (NPPA)	http://www.nppaindia.nic.in
NITI Aayog	http://niti.gov.in/content
Pharmacy Council Of India (PCI)	http://www.pci.nic.in
The Clinical Trials Registry- India (CTRI)	http://ctri.nic.in
Veterinary Council of India (VCI)	http://www.vci.nic.in



BANGALORE BIOINNOVATION CENTRE (BBC)

Dept of IT, BT and S & T, Government of Karnataka, India

- State of the art incubation centre catering to the needs of start ups in the broad areas of Life Sciences i.e, Healthcare (MedTech/ Pharma/ Bio-Pharma), Agriculture, Food/ Nutrition, Industrial Biotechnology and Environmental Biotechnology.
- Structured as a section 8 not-for-profit company set up by the Dept of IT, BT and S & T, Government of Karnataka.
- Funding support by the Department of Biotechnology (DBT), Government of India.
- Located within Bangalore Helix Biotechnology Park at Electronic City, in a 10 acre campus with total built up area of above 50,000 sq ft.
- Nestled between a vibrant academic ecosystem and an upcoming Bio - Industrial Cluster, the centre aspires to nucleate and spur a robust Bio-Innovation Ecosystem.



LAB SPACE/ EQUIPMENT/ FACILITY AVAILABLE IN THE CENTRE

Lab Spaces with DG & UPS Backup

Plant & Animal Tissue Culture Labs

Microscopy Facility

Molecular Biology Facility

Histology Lab

Proteomics Lab

Fermentation Facility

Microbiology Labs

Lab Support

Flow Cytometry Facility

Companies interested in availing Lab Space or Equipment/ Facility may contact the undersigned.

RESIDENT COMPANIES



CONTACT

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