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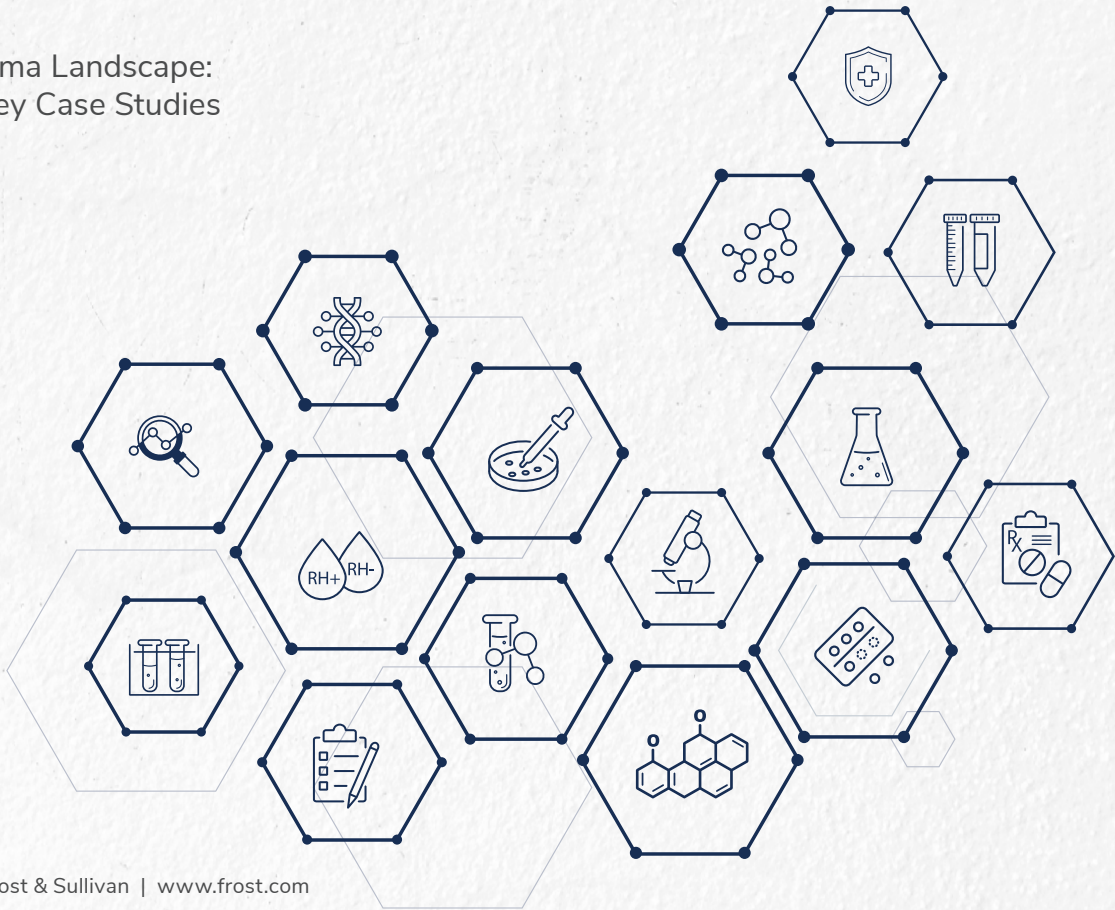
BIOPHARMA CONCLAVE

CONTENTS



Overview of the Global Biologics Landscape

Frost & Sullivan estimates that biologics will be a key growth driver and will grow from 34.1% in 2024 to 38.5% of the global pharmaceutical industry by 2028. The key leading global biologics are Merck's Keytruda, a recombinant antibody for oncology; Novo Nordisk's Ozempic, a glucagon-like peptide 1(GLP-1) inhibitor for diabetes; and Sanofi's Dupixent, a monoclonal antibody (mAB) for allergies. The development of new therapeutic modalities, like messenger RNA (mRNA), CGT, and ADCs, have fueled precision medicine advances which will likely drive the overall growth of the sector. Strategic collaboration between innovators and large pharma companies or bio-CMOs will enable optimized scaling of new biologics formulations across the global biopharmaceutical landscape.

Oncology, infectious diseases, immunology and central nervous system diseases will be the key focus areas for biologic therapies. Keytruda will continue to be one of the fastest-growing treatments in the market. Novo Nordisk's GLP-based drugs for type 2 diabetes and obesity will generate approximately $28 billion in 2025 and may surpass Keytruda. Alzheimer's disease will be a prime focus area, with promising upcoming candidates, including Eli Lilly's donanemab. The global biologics pipeline will move towards advanced therapeutic modalities, like antibody-drug conjugates (ADCs), cell and gene therapies, and bispecific antibodies, creating transformative precision medicine opportunities for the global biopharma industry.

Overview of the Indian Pharmaceutical Landscape

The Indian pharmaceutical industry is the world's third largest contributor to global pharmaceutical production and globally leads the supply of low-cost vaccines such as measles, DPT and BCG to the world. The country is the leading global supplier of generics. India also has the greatest number of United States Food and Drug Administration (USFDA) compliant pharmaceutical manufacturing centers outside of the USA . The country has more than 2,000 WHO-GMP approved facilities, which cater to demands from over 150 countries using more than 10,500 manufacturing facilities. The Indian government's ongoing Production Linked Incentive (PLI) scheme intends to decrease India's reliance on China for API and boost local API production, resulting in 21 projects with an installed capacity of 33,895 tonnes. In 2023, 55 out of the 271 applications received approval in the pharmaceutical sector, which brought more than 2.04 billion USD in investments, with support for a wide range of products, including CGTs and phytopharmaceuticals, generating approximately 20,000 direct and 80,000 indirect jobs because of the sector's growth . The Indian pharmaceutical, valued at 49.63 billion USD in 2023, is known to provide high quality of medicines at an affordable price, making it the 'pharmacy of the world'.

While the Indian pharmaceutical industry is an established sector across the global landscape, the Indian biopharmaceutical segment is still largely an emerging industry. However, India is also rapidly transforming from a generics leader to a center for high-value biopharmaceuticals, including biosimilars. For instance, India-based Enzene Biosciences will add a 5,000-square-meter facility for continuous biomanufacturing in US which will have 500-L and 2-KL bioreactors for GMP drug-substance production. Aragen Lifesciences also intends to invest $30 million in a cell-culture biomanufacturing facility in Bengaluru, India.

The Indian bioeconomy was valued at $151 billion in 2023 and accounted for about 4.25% of India's Gross Domestic Product (GDP) at a 10% growth rate. The biopharma segment accounted for about the 35.65% share of the total Indian bioeconomy, which was valued at $53.8 billion[3].

[1] Department of Pharmaceuticals, Government of India, Annual Report 2023-2024

[2] Pharmaceuticals.gov.in

[3] The India BioEconomy Report (IBER 2024)

The Indian pharmaceutical sector intends to grow to 130 USD billion by 2030 and to 450 USD billion by 2047. There is a strategic shift which is needed to drive this growth, which can be achieved by pivoting towards a value-drive bioeconomy as opposed to the current volume-driven trends. There is also a rising need to make India a global biopharma hub. To sustain continued growth in this sector, there is a rising need for creating an environment that offers streamlined regulatory policies, fosters biologics and small molecule therapy innovations, enables cost-effective biomanufacturing, and encourages industry-relevant skill development and training.

The strategic transition can be achieved by directed and structured regulatory reforms, and the rising innovations landscape across biologics, biosimilars, cell and gene therapies which will be fueled by infrastructure development and close collaborations industry-academic collaborations.

The Evolving Indian Drug Regulatory and Manufacturing Landscape

Biologicals in India are regulated under the provisions of Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945. The Central Drugs Standard Control Organization (CDSCO) is the key regulatory body and Drugs Controller General of India (DCGI) is the central licensing authority that provide new drug approvals before licensing and manufacturing grants can be provided by State Licensing Authorities (SLAs). The Indian Council of Medical Research (ICMR) is responsible for new drug research and development. The ICMR also evaluates new therapies and diagnostics for diseases that are of national health priority while ensuring the compliance with the National Ethical Guidelines during research and development. There is a need to streamline all these regulatory bodies to ensure optimal biologic development outcomes, while ensuring the guidelines and regulations are in sync with international regulatory authorities such as UK Medicines and Healthcare products Regulatory Agency (MHRA), US Food and Drug Administration (FDA), and The European Medicines Agency (EMA). While there is a need for handholding government agencies for ensuring improved biologics regulatory guidelines and practices, government regulatory bodies are ready for change and gearing to eradicate outdated practices such as animal testing for drug development.

There are several regulatory developments and government initiatives that will boost the Indian biologics sector. For instance, the Department of Biotechnology (DBT) has launched BioE3 Policy for encouraging the Indian biomanufacturing through program components such as the Bio-Foundry, Bio-Enabler Hubs and Biomanufacturing Hubs for scaling operations. The DBT also restructured 14 autonomous institutes into the Biotechnology Research and Innovation Council (BRIC) to streamline governance and the launch of the Biological Research

Regulatory Approval Portal (BioRRAP) portal will help streamline regulatory approvals for biologics research. The DBT also introduced IP reforms for commercialization of public-funded research by enabling flexible licensing options and protection mechanisms like March-in Rights to ensure socio-economic benefits. The Indian government also released draft guidelines for clinical trials of CAR-T cell products in 2019 in collaboration with the Indian Council of Medical Research (ICMR) that helped in securing the approval of ImmunoACT's NexCAR19, India's first CAR-T cell therapy. However, there's still room for improvement from clinical, patent and regulatory perspectives for the Indian biologics sector. There is also an urgent need for subject matter experts in the Indian biologics regulatory landscape.

India continues to be a key manufacturing hub for the global pharmaceutical industry as it provides 30%–35% cost saving when compared to US or Europe and R&D costs are around 85% less than that of developed economies. The Government of India has announced the "Strengthening of Pharmaceutical Industry (SPI)" scheme that promises a total financial outlay of 60.9 million USD to extend support to pharma clusters and MSMEs in India. Additionally, now up to 100% FDI is allowed for Greenfield pharmaceuticals projects and up to 74% for Brownfield pharmaceuticals projects through the automatic route. This is likely to encourage a favorable growth environment for the Indian pharmaceutical sector.

Recently, the CDSCO announced in August 2024 that drugs and vaccines that fall in the category of orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes, and new drugs having significant therapeutic advances over the current standard care – will be considered for clinical trial waivers if the drugs are approved in the United States, United Kingdom, Japan, Australia, Canada, and European Union. This is likely to improve patient access to global innovative therapies which will help address certain unmet clinical needs. However, it is critical that the Indian Government has checks and balances to ensure that the waivers are not abused at the cost of patient's health and safety.

India as an Emerging Innovation Hub for Biologics and Biosimilars

India is fast emerging as a leading innovations hub for biologics and biosimilars. India has over 95 biosimilars approved by the CDSCO, whereas Europe has over a 100 biosimilars approved by the EMA. The US FDA has approved over 60 biosimilars compared to about 30 biosimilar approvals in China and Japan. Hence, India is one of the leading manufacturing hubs for biosimilars. The biosimilar potential is likely to grow significantly as several biologics will fall of the patent cliff during from 2025-2030, including blockbuster drugs such as Opdivo (Nivolumab, patent expiry in 2028) and Keytruda (Pembrolizumab, patent expiry in 2028). While the biologics approaching the patent cliff present a great growth opportunity for biosimilar drugs in India, there is also a need to create a strong perception of Indian patent protection laws, especially for innovators and start-up companies. While patent enforcement laws are stringent and cannot be violated even by large, established pharma or biopharma companies, India is still perceived as a region that lacks IP protection and enforcement. The Indian judiciary system is largely viewed to prolong decisions due to complex judiciary processes. The fact remains that the Indian Patent Office (IPO) reached a milestone with over 75,000 patents granted in the fiscal year 2023, and the year witnessed about 247 patent applications every day. Educational and scientific institutes such as the Indian Institute of Technology, Madras, dominated the patent landscape. While IT and computer engineering were the predominant technology areas of patent interest, India also witnessed significant patent proliferation across biotechnology, pharmaceuticals, AI, and renewable energy, underscoring India's rising technology innovation and capabilities across these sectors[4].

[4] Intellectual Property India, Annual report 2022-23

[5] https://doi.org/10.1111/bcp.14216

The Central Government of India has set up a new bio-incubator in Noida through BIRAC to accelerate biologics development and manufacturing, but there is low awareness about such public initiatives across the industry. Biocon has Central Government-funded bio-incubator facilities for biotech start-ups but that also has been underutilized, as there is little awareness about this initiative. The National Biopharma Mission (NBM) is also underutilized from a start-up perspective. Hence, there is a need to promote awareness about the public initiatives that are fueling the development of biotech innovations.

Indian Biopharma Landscape: Summary of Key Case Studies

CASE STUDY 1: Emphasizing the Need for Clinical Studies in India

Clinical studies continue to be crucial determinants for evaluating the efficacy of biosimilars and generics through bio-equivalence studies and clinical trial waivers should be considered after detailed evaluation of the innovator's clinical studies.

For example, retrospective clinical bio-equivalence studies of 3 approved generic L-asparaginase formulations for pediatric leukemia were not within the 90–110% of the label claim whereas the innovator was. Moreover, none of the 8 Indian generic formulations tested were able to consistently achieve a clinically defined threshold of 100 IU/L . However, a 2020 clinical bioequivalence study of the first generic of pegaspargase (Hamsyl) approved in India for second line of treatment for acute lymphoblastic leukemia (ALL) was found to be clinically as effective as the reference product (Oncaspar) and continues to be used for ALL treatment in children. Thus, clinical trials waiver for biosimilars and generic formulations should be scrutinized as they are critical to establish the efficacy and safety of the treatment.

CASE STUDY 2: Developing an Innovative Hybridoma Platform for Manufacturing Monoclonal Antibody Cocktails

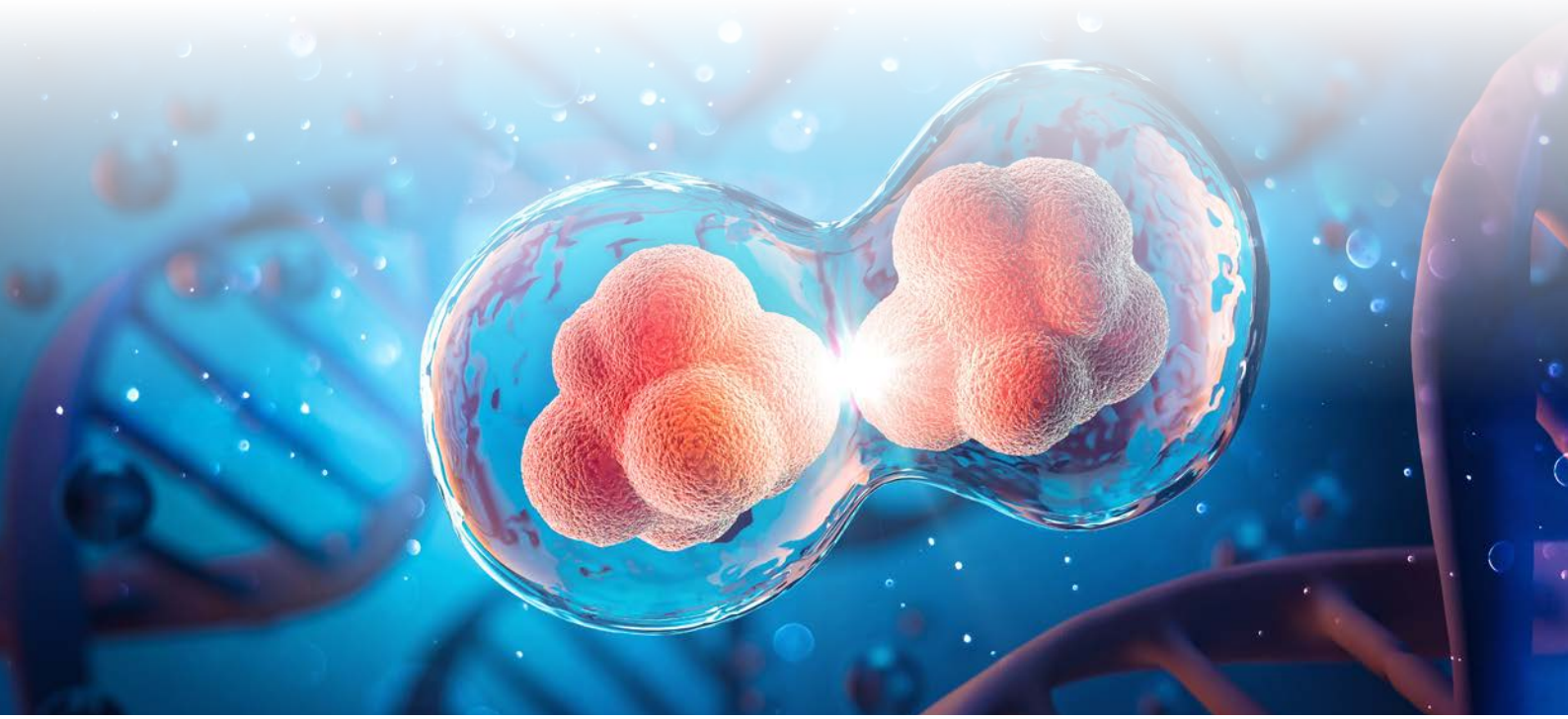
Syngene International Limited, a leading India-based research, development and manufacturing organization, helped a global biotech company develop a unique hybridoma cell line for manufacturing mAb cocktails that can be used in reagent kits for human T cells for immunotherapy applications. The Syngene biologics teams integrated hybridoma cell lines with five ancillary raw materials (ARMs) to create 3 distinct ancillary reagents (ARs) using specified ARM concentrations and combinations. These new reagent kits were successfully launched and will serve as powerful tools for advancement of regenerative medicine.

CASE STUDY 3: Developing a Proprietary Human Antibody Platform INABLR ™

Zumutor is an Indian Immuno-Oncology company founded in 2013 that is developing NK cell therapeutics using their proprietary Human Antibody platform INABLR ™. The platform has enabled the creation of Zumutor's wholly owned, first-in-class therapeutic antibodies targeting innate immunity and regulating the tumor microenvironment. Their lead candidate, ZM008, an anti-LLT1 monoclonal antibody, is in phase 1 clinical studies for the treatment of prostate cancer, B-cell lymphoma and glioma. ZM008 can convert the less immune responsive cancers into highly immune responsive tumors. This helps provide an effective treatment option to patients who are resistant to existing immunotherapy treatments.

Advancing Cell and Gene Therapies in India

Cell and gene therapy research is rapidly evolving in India. The key challenge faced by this sector is the lack of large-scale CGT research and production centers. Hospitals, academic institutes and innovators are collaborating closely to bridge this gap and accelerate CGT research and development. Some of the key academic institutes and hospitals that are advancing CGT research include Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Mumbai, Indian Institute of Technology (BSBE), Mumbai, Centre for Stem Cell Research, Christian Medical College, Vellore, CSIR-Institute for Genomics and Integrative Biology, New Delhi, Narayana Nethralaya Foundation, Bangalore and Tata Memorial Hospital, Mumbai. Private companies such as ImmunoACT, Intas Pharmaceuticals and Reliance Life Sciences are also advancing CGT innovations for several diseases.



Technological advances in viral vector platforms such as lentivirus and deno-associated virus (AAV) vectors have fueled CGT innovations and has also enabled the launch of the first CGT in India. However, infrastructure challenges, funding and lack of access to structured patient datasets has been an impediment to CGT development in India, due to which the country lags when compared to CGT advances in developed economies such as Europe, Japan and North America. Addressing key bottlenecks related to streamlined regulatory scenarios, increased funding and improved manufacturing infrastructure will help India compete with the rest of the world across the CGT space. The first CAR-T cell therapy launched in India, NexCAR19, costs less than 50,000 USD whereas similar therapies with comparable efficacy in the US can cost up to 530,000 USD, making the Indian CAR-T therapies 10 times more affordable than its global competitors. Thus, India has the potential to emerge as a CGT innovation hub that provides effective CGT therapies that are more accessible to patients.

Key CGT indications across India comprise head and neck cancer, leukemia, haematological diseases, muscular dystrophies, retinal diseases and neurodegenerative disorders. Key CGT technologies being explored in India are CAR-T cell therapies, CRISPR-based gene editing, exon skipping and antisense oligonucleotide (ASO) therapies. AAV vector systems are also being explored in India, but there is a need to establish and increase new clinical-grade AAV production centers. Use of indigenous technologies are predicted to decrease viral vector costs by 50 times when compared to global average viral vector production costs which will provide significant cost savings and improve patient access to advanced therapies.

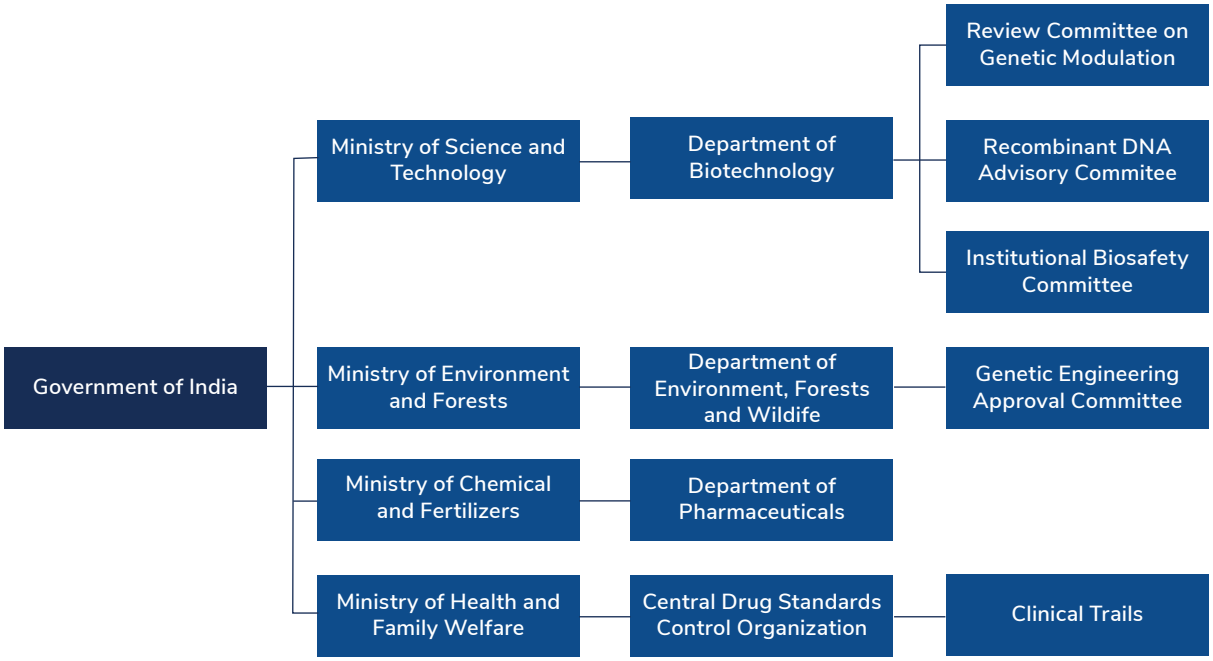
Biomanufacturing practices such as use of modular systems or AI-enabled tools for adjusting batch-sizes to optimize titre values during production processes can help reduce costs. Additionally, use of automated and AI-driven production processes can help save time, improve product quality, reduce manual errors across repetitive tasks and decrease QC costs, creating new opportunities for future growth across the Indian biopharma landscape. It is also important to develop requisite skills at the academic level to ensure that industry training costs for fresh graduates are kept optimal.

Summary of Overall Recommendations

India needs to simplify regulations, enable infrastructure development, empower India's skilled task force and enhance funding initiatives to foster an optimal environment for biologics innovation. Some of the key recommendations that will ensure India's global dominance in the biomanufacturing and biologics innovation sectors have been discussed below.

Regulatory Simplification

- The regulatory systems for biotechnology in India are controlled by multiple bodies, here's an overview of the biotechnology regulatory environment in India:



- In India, The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945 control biologics manufacturing and import. The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body that monitors the quality, efficacy and the safety of drugs in India. There is also a need to define timelines for regulatory processes and milestones. For instance, in US, if innovators do not hear back from US FDA after IND filing for 30 days, then they can start clinical trials. The timelines initially can be longer than international guidelines, but they need to be defined clearly at the start. There is a need for recruiting biologics subject matter experts or training the relevant people for drafting regulatory guidelines and helping innovators with the necessary regulatory filings.
- Real-time stability assessments and its stability in actual containers should be evaluated stringently to ensure optimal drug shelf-life and storage.
- There are several policies such as the BioE3 and the National Biopharma Mission (NBM) that are designed to accelerate the development and commercialization of biotech and biopharma hubs in India. However, these policies and regulatory bodies tend to work in silos and do not communicate with each other, which makes policy implementation time-consuming and tedious. Hence, it is extremely important that the policies and regulatory bodies designing the policies talk to each other and create realistic implementation timelines based on ground realities across the Indian biopharma and biomanufacturing industries. This will aid to reduce delays and build trust and strong collaborations for taking the innovations to the next level. It is also very important to change perception about the Indian regulatory landscapes and create international trust so that Indian innovations across biologics can be taken to other countries. For instance, China started with a biosimilar innovation-based economy but within 10 years, they have become a biologics innovation hub which is now considered at par with US biopharma standards. India is also capable of such a change, if biologics start-up receives better funding from the government, adopt cost-effective biomanufacturing practices and are given guidance from larger Indian biotech firms.

- There is need to insist on clinical bioequivalence studies for newly developed biosimilars and generics to ensure they meet the safety and efficacy standards of the innovators.
- While Indian patent enforcement allows for strong IP protection, there is a need to work closely with clinical experts to build trust and provide streamlined guidance for patent filings and grants processes.

Enabling Infrastructure Development for Manufacturing at Scale

- AI-based tools should be used across biologics design, discovery, development and manufacturing value chain for optimizing process efficiency, titre values, product quality and costs. For instance, there are several AI-powered algorithms that are available for accurate antibody structure predictions that can accelerate discovery of several new antibody-based biologics. Automated pipetting techniques will eliminate manual errors in biomanufacturing and testing process. AI can also optimize clinical development and manufacturing practices and help de-risk or reduce the risk of failures during biologics development. Use of digital twin in the biomanufacturing landscape can help accelerate biologics development at an unprecedented scale in the future.
- Improved clinical trial design using RWE will improve probability of success.
- The use of local data and global data analytics with real-world patient feedback with the help of AI will improve clinical trial design and outcomes.
- There should be focused efforts to improve country-wide awareness for public initiatives that are launched to help support biologics innovators.
- There is a need to create more bio-incubation facilities, especially in tier 2 cities for fostering bioinnovations. DBT/BIRAC has created 5,69,000 sq. ft. incubation facilities with advanced instrumentation a in 52 incubation centres and plans to increase it to 10,00,000+ sq ft in 125 incubators by 2025. Implementation of this plan will accelerate biomanufacturing in India.

Empowering India's Skilled Biologics Workforce

- The Life Sciences Sector Skill Development Council (LSSSDC) in India is working to help address academic and industry skill gaps to improve employability of fresh graduates across the biologics sector. There are about 2000 people hired every month across the Indian pharmaceutical and biotechnological branches[6]. However, fresh graduates from science colleges need about a year or two of training before they are productive to the organization and the current industry needs people who can be productive from first day of employment. Hence, academic and industry sectors need to collaborate closely to upgrade educational programs and provide internship opportunities or other periodic opportunities for hands-on learning. This will enable fresh graduates to be employed in the biologics industry with minimal training. There is also a need to change the education system and improve hands-on experience for science graduates. For instance, it is important to introduce industry relevant concepts and practical training related to cell and gene therapies and others advanced biologics so that student is ready to be productive from the first day of their employment. Premier Indian institutes such as IITs, AIIMS and others should proactively offer paid internships to students to help close the deep skill gaps in the life science sectors. This will also help create academic spin-offs across the Indian biologics' innovation landscape.
- The Indian Pharmaceutical Alliance (IPA) has founded the Foundation for Pharma Academy for Global Excellence (PAGE), that intends to create a "world-class institute to build talent for the pharmaceutical industry" and promote a culture of manufacturing excellence. The vision of the initiative is to set-up advanced infrastructure, create targeted manufacturing programs, improve funding and collaboration and provide improved access to leadership and guidance for advancing bio-innovation hubs. There is a rising need to promote awareness for such Government initiatives and ensure they are utilized optimally.
- The public regulatory and patenting agencies also need skilled biologics personnel to provide timely guidance to innovators and expedite the approval and grant processes. They need to be trained and upskilled to handle queries related to the biotech and biopharma industries.
- Most importantly, there is also a mindset change that is needed. There needs to be improved awareness across all sectors about emerging job opportunities in the Indian biotech and biopharma sectors, as the current perception tends to be skewed towards lucrative opportunities across the IT and finance sectors. It important for industries, public sectors and private organizations to work closely to ensure improved awareness regarding the emerging job opportunities within the Indian biotech industry.

[6] Statista Research Department, Sep 4, 2024

- The academic, public and industrial biotech sectors should work closely to

	Improve educational curriculum to ensure industry relevance
	Provide periodic opportunities for industry-relevant hands-on learning & development
	Improve awareness of emerging employment opportunities in the life sciences, biopharma and biotech industries
	Provide paid internship opportunities so that fresh graduates can on-board quickly and help accelerate the progress of the Indian biotech sector

- Cross-disciplinary studies that combine chemical and engineering sciences with biological, biopharma and biotech studies should be incorporated in academic curriculums.
- All biotech academicians, regulators, approvers and industry experts need periodic courses and trainers to help them upskill on new developments across the Indian biologics landscape to ensure seamless growth of this sector.
- Educational institutes need to be incentivized to be industry-relevant will improve employability of fresh graduates in the biotech and biopharma industries.

Increasing Funding, Especially for High-Risk Biotech Start-Ups in India

- Biologics innovators and start-ups often struggle to secure funding during early stages of product development. Central government funding bodies such as Biotechnology Ignition Grant Scheme (BIG) and BIRAC SEED Fund offer grant up to 30 to 50 lakhs INR which is not sufficient for the discovery and development of biologics such as CAR-T cell therapies whose manufacturing costs are about 3 to 4 crores INR per person. Manufacturing of biologics is a highly complex process and is very cost intensive and a high-risk process. Private investors often tend to be risk averse. Additionally, the return on investment for biologics is not always lucrative and often delayed when compared to other start-ups. Thus, there is a rising need for Central Government agencies to encourage biologics research by substantially increasing the quantum of funding.
- Central Government should create initiatives that increase funding of early stage, high-risk start-ups to help transform the Indian biologics segment from a biosimilar hub to a biologics innovation hub which is at par with international quality standards.
- Leap Fund (Launching Entrepreneurial Driven Affordable Products Fund), implemented through BioNEST Incubators that receive grant-in-aid support of INR 500 lakhs/cycle should be promoted further and there should rising public awareness campaigns for such initiatives.
- The BioAngels Program launched by BIRAC and IAN (Indian Angel Network) should invest further in biotech sectors, especially to accelerate high-risk biologics development.
- Accelerating Entrepreneurs (AcE) Fund has already supported 65 biotech start-ups through INR 733 crore investments and should continue to invest further to encourage growth of the Indian biotech landscape.

OUTLOOK

Indian bioeconomy is projected to reach US$300 billion by 2030. The current Indian biotech sector has over 5000 biotech companies and over 750 biotech start-ups[7] .New biologics and biosimilars are likely to contribute to the continued growth of this sector in the future. Government initiatives such as the NBM and Make in India will enhance the volume and quality of Indian biologics innovations. Additionally, as India's clinical trial costs are about 50% lower than that of developed economies such as the US, it is likely to provide a lucrative and competitive innovation hub for new biologics development. The increasing adoption of AI, in-silico models, and digital twins in biologics discovery, development, and manufacturing will help reduce time and costs, enhance efficiency, and mitigate risks in clinical trials. Rapid technological advances, rising biologics pipeline and growing investments will help India to emerge as a global innovation hub for novel biologics discovery and development in the next ten years.

[7] Department of Biotechnology, Ministry of Science & Technology, Government of India

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