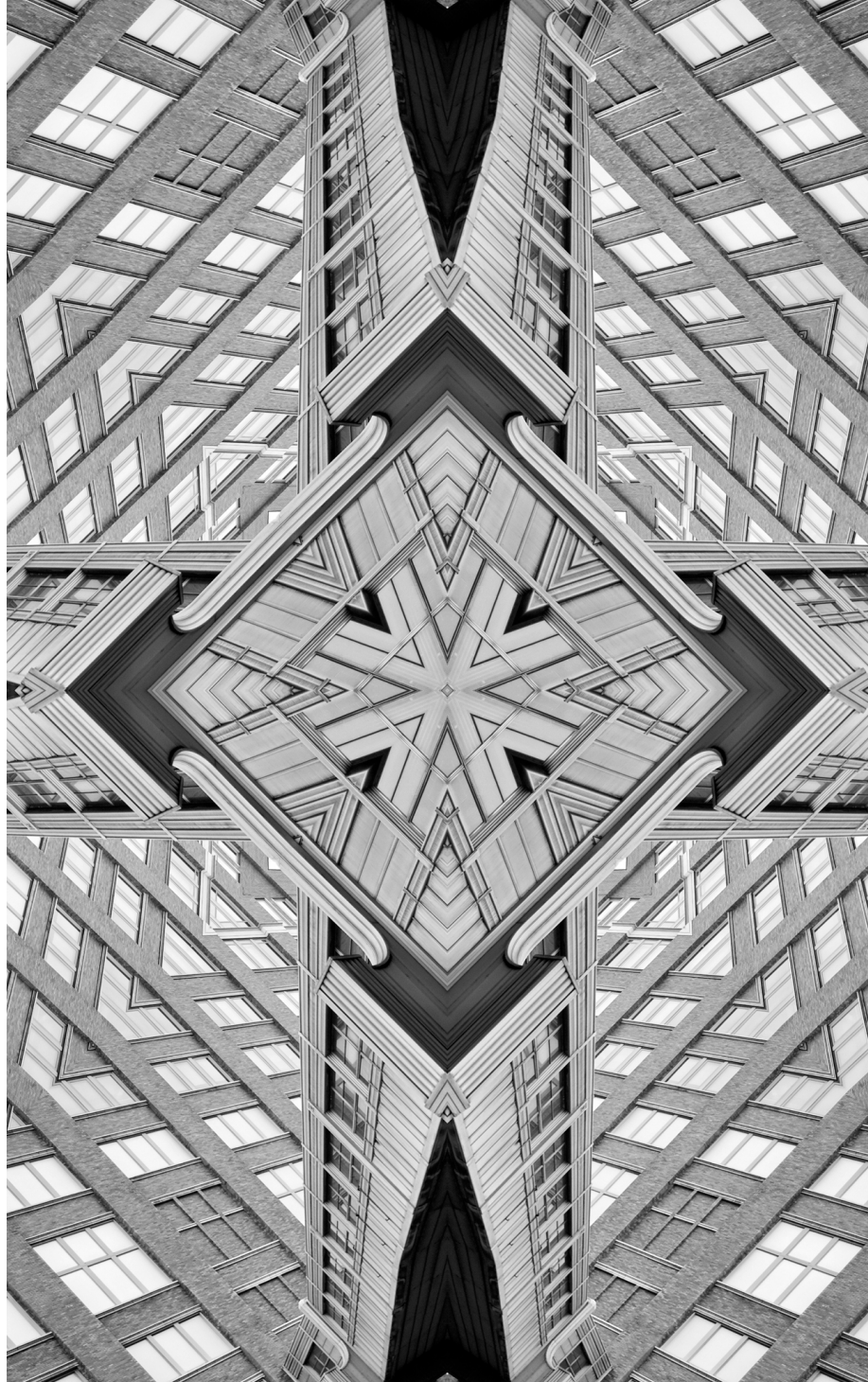


Issue

Brief

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Filling Policy and Implementation Gaps to Build India as a Biomanufacturing Hub

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Abstract

During the COVID-19 pandemic, India contributed to the global response by increasing its vaccine development and health diplomacy efforts, underscoring, among others, its potential as a biotechnology powerhouse. The Government of India continued its effort to make progress in biotechnology research and development in the years after, launching the BioE3 policy in 2024. The BioE3 framework aims to develop a US\$300-billion bioeconomy in India by 2030, through innovation in health, agriculture, clean energy, and sustainable manufacturing. This brief analyses India's biomanufacturing trajectory through the lens of the COVID-19 pandemic, focusing on the implementation of the BioE3 policy through biotech parks, public-private partnerships, and talent-development initiatives. It recommends reforms to address the challenges of weak intellectual property regimes, fragmented regulation, infrastructure asymmetries, and funding and talent shortfalls; the aim is to position India as a global hub for biotech innovation.

India's COVID-19 response was a seminal moment in its global health diplomacy and vaccine-production efforts. With its dissemination of newly innovated vaccines, the country emerged as a leading supplier of vaccines during the crisis, administering over 2.2 billion doses between 2020 and 2022.^{1,2} These accomplishments were the result of long-term investments in biotechnology research and innovation and an active public-private partnership model. Companies such as the Serum Institute of India, Bharat Biotech, and Biological E, played a central role in this effort.^{a,3}

The Government of India also introduced key regulatory and financial mechanisms to push vaccine development and distribution. Programmes such as 'Mission COVID Suraksha' helped finance clinical trials, enabling the listing of vaccines for emergency use through transparent, science-based processes.⁴ The government's CoWIN platform^b enabled real-time monitoring, slot booking, and digital certification of vaccinations, reaching some 950 million users.⁵ Production-linked incentive schemes also boosted manufacturing capacity to support scale-up activities along the vaccine supply chain.⁶

Global partnerships further reaffirmed India's position as a global vaccine partner. Strategic alliances with international pharmaceutical companies and grants from organisations such as the Coalition for Epidemic and Preparedness Innovations and Gavi, the Vaccine Alliance, enabled India to not only address its own needs but export vaccines to over 100 nations.⁷ India's Vaccine Maitri programme, started in January 2021, supplied 162.9 million doses of COVID-19 vaccines to 96 nations up to February 2022.⁸ This number included about 14.3 million doses donated by the government, with the rest comprising commercial exports (107.1 million doses)^c and donations via COVAX (41.5 million doses).^{9,10}

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- a The Serum Institute of India produces Covishield in collaboration with AstraZeneca and Oxford University; Bharat Biotech develops the indigenous Covaxin in collaboration with the Indian Council of Medical Research and National Institute of Virology; and Biological E produces Corbevax in partnership with companies in the US.
- b Covid Vaccine Intelligence Network is a web portal for Covid-19 vaccine registration owned and operated by the Ministry of Health and Family Welfare.
- c Export shipments were suspended temporarily during the second wave, roughly between April–June 2021, demonstrating the tightrope walk between local demands and global obligations. See: <https://www.thehindu.com/news/national/explained-why-has-india-agreed-to-resume-vaccine-export/article36674446.ece>.

As a leading vaccine manufacturing site throughout the pandemic, India showcased its ability to produce in mass and roll out huge domestic immunisation schemes. Efforts such as Vaccine Maitri and its participation in COVAX signalled its promise as a global partner for international health initiatives, even as they strain at the crosscurrents between international aspiration and domestic interest. These case studies reiterate India’s increasing contribution to pandemic preparedness, research and development (R&D) in vaccines, and global health diplomacy.

Table 1: India’s Global Advancements in Post-COVID-19 Vaccine Development

Project	Partners	Project Details	Key Outcomes
RTS,S/AS01 malaria vaccine scale-up	Bharat Biotech, GlaxoSmithKline (GSK), Program for Appropriate Technology in Health (PATH)	In Jan 2021, Bharat Biotech took over RTS,S antigen production from GSK under a tech-transfer deal, though GSK retains its AS01 adjuvant’s production in Belgium. ¹¹	Bharat Biotech will handle global distribution of the first malaria vaccine; it aims to reduce the price to < \$5/dose by 2028. ¹²
mRNA vaccine ecosystem development in India	Biological E, WHO, Medicines Patent Pool (MPP), Afrigen	In Mar 2022, Biological E was selected by WHO’s mRNA tech-transfer hub to build domestic capacity for mRNA vaccines, with support from MPP and Afrigen. ¹³	Enhances India’s pandemic preparedness by providing localised mRNA vaccines for COVID-19 variants and other diseases, reducing dependency on Western suppliers.
Shigella vaccine development	Bharat Biotech, GSK	In Jun 2025, Bharat Biotech in-licensed GSK’s shigella vaccine candidate, altSonflex1-2-3. It will lead Phase III trials of the vaccine, future regulatory steps, and manufacturing. ¹⁴	Bharat Biotech aims to reduce the cost of the shigella vaccine, to make it accessible to low- and middle-income countries.

Introduction

Project	Partners	Project Details	Key Outcomes
Oral cholera vaccine (Hillchol development)	Bharat Biotech	Phase III clinical trials complete; Indian license granted; WHO Prequalified Vaccine submission ongoing. ¹⁵ Technology transfer from International Vaccine Institute (IVI) to Biological E, commenced in 2024 and is to be completed in 2025.	Facilities in Hyderabad & Bhubaneswar can produce 200 million doses/year, twice the global demand, thus addressing global shortages. ¹⁶ Aimed at manufacturing OCV for Indian and international markets. ¹⁷

Source: Authors' own, using various sources, as cited.

Focus Areas and Flagship Programmes under BioE3

Building on its achievements during the COVID-19 era, India launched the Biotechnology for Economy, Environment and Employment (BioE3) policy in 2024, with the aim of establishing India as a hub for biomanufacturing and innovation by 2030.¹⁸ The policy envisions a US\$300-billion bioeconomy in India, doubling from US\$151 billion in 2023, by integrating biotechnology into nationwide missions in health, agriculture, clean energy, and climate resilience.¹⁹ It focuses on innovation in vaccine development, biologics, gene therapies, genetically modified crops, biodegradable materials, and synthetic biology. BioE3 aims to integrate India's biotechnology strength into one system that promotes climate resilience, food and water security, job creation, and sustainable growth. Financial and institutional support from organisations such as the Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) guarantees the strategy's feasibility,²⁰ while coordination with larger initiatives, including Atmanirbhar Bharat, Digital India, and the National Education Policy, ensures its multidisciplinary nature.

BioE3 has five pillars: growing innovation and R&D ecosystems through biofoundries^d and genomic initiatives; building talent through biotech entrepreneurship education and fellowship programmes; building infrastructure through biomanufacturing parks and collaborative lab spaces; overhauling policy and regulation to drive biotech patents and biosafety approvals; and fostering global partnerships through participation in international biotech alliances and bilateral ventures.²¹

The key is to develop ecosystems that link academia, industry, and government research institutes. BioE3 imagines this through the establishment of biotech parks. These centres provide startups and mature companies alike with access to state-of-the-art infrastructure, equipped laboratories, and shared facilities, including biofoundries and Good Manufacturing Practices (GMP)-certified facilities.^e Through the provision of collaborative spaces, these clusters drive cross-disciplinary research and facilitate the rapid commercialisation of new biotech products.²² Moreover, the clusters are strategically located not only in metropolitan areas but also increasingly in Tier-2 and Tier-3 cities,^f democratising access to biotech resources and encouraging regional innovation.²³

d A facility meant to test and develop biological systems.

e Good Manufacturing Practices Standards. See: <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp>.

f Cities generally referring to those with populations lower than 4 million.

Focus Areas and Flagship Programmes under BioE3

Table 2: Biotech Parks in India

Biotech Park	Key Stakeholders	Focus Areas	Support to Industry	Facilities	Training and Outreach
Biotech Park, Lucknow	DBT, Department of Science and Technology (UP)	Analytical and quality assurance; extraction facilities	Partnership with 14 incubatees (of which 5 are new entrepreneurs: Vatican Shona, Capre Diem, Adayma Herbals, Ceyon Healthcare, Rad Care Research)	Analytical lab; extraction unit	Trained 234 students for periods ranging from 1 to 6 months
Chhattisgarh Biotech Park	DBT, Department of Agriculture, Farmer Welfare & Biotechnology (Chhattisgarh)	Agriculture, healthcare, and industrial biotech	Support to over 15 start-ups	Subhash Chandra Bose Biotechnology Incubation Centre (SCBinc); lab space for 23 companies	Provided skill training to 30 students from five institutes; generated engagement with over 500 youth; produced over 15,000 litres of biofertilisers
Guwahati Biotech Park (Technology Incubation Centre)	DBT, Government of Assam	Human resource development in biotechnology and allied sectors; entrepreneurship in the Northeast	Support to several technology-oriented start-ups	Business Enterprise Zone; strong academic linkages	Provided students from institutes in the region access to its lab facilities

Focus Areas and Flagship Programmes under BioE3

Biotech Park	Key Stakeholders	Focus Areas	Support to Industry	Facilities	Training and Outreach
Biopharma Growth Phase Park, Genome Valley, Hyderabad	Govt. of Telangana, DBT	Biopharma; R&D; scale-up manufacturing	Facilitation of the growth of early-stage companies	Modular R&D lab suites; scale-up facilities	Provides a biopharma training facility; expected to generate over 300 jobs
Industrial Biotech Parks, Jammu and Kashmir	DBT, J&K Science, Technology and Innovation Council, CSIR-Indian Institute of Integrative Medicine (Knowledge partner)	Agri-biotech; technology incubation; training and skill development	Support to new start-ups, agri-entrepreneurs, and farmers	Herbal extraction; fermentation; distillation; plant tissue culture; tech incubation	Provides training and skill development to youth across J&K and neighbouring states
Kolkata Biotech Park	Government of West Bengal, DBT	Commercialisation of biotech products	Incubation support for seven operational biotech companies, with six more selected for incubation	Business support services, including IP management, tech transfer, project management, and regulatory support	Created 24 direct jobs, with INR 90 lakhs invested by its incubatees

Source: Department of Biotechnology²⁴

Another flagship measure under the policy is the promotion of public-private partnerships to leverage strengths from multiple sectors. These partnerships enable risk-sharing in high-cost biotech research, and facilitate knowledge transfer between government labs and private enterprises. The state role tends to involve subsidising research in the initial stages and

Focus Areas and Flagship Programmes under BioE3

granting incentives, such as through tax relief, grants, and subsidies, to spur private investment.²⁵ Schemes like BIRAC's Biotechnology Ignition Grant (BIG), for instance, play a crucial role in developing startups by providing funding, mentorship, and market linkage. BIG has committed INR 5 lakh to help startups establish themselves beyond the primary years, thus helping bridge the so-called 'valley of death' for biotech startups where research gets stalled in the absence of commercialisation assistance.²⁶

In addition, BioE3 focuses on human resource development and capacity building through sectoral training programmes, scholarships, and fellowships. These programmes aim to equip scientists, engineers, and business professionals with the most up-to-date technical expertise and entrepreneurial skills required in the rapidly evolving biotech industry. The policy also seeks to design industry internships and programmes that promote interdisciplinary learning, specifically at the intersection of biotechnology and chemical engineering, to ensure that graduates are equipped to meet the industry's workforce demands.²⁷ Other initiatives to draw in and retain top talent include new provisions for research grants, centres of excellence, and cooperative projects involving the Indian diaspora.²⁸

Central to BioE3's goals is building regulatory clarity and international competitiveness in biotech. The policy advocates for the modernisation of regulations to make them more transparent, efficient, and in sync with global standards. Key regulatory changes currently in progress include the adoption of digital approvals, single-window clearance systems, and fast-track review mechanism for pioneering therapies and technologies.²⁹

BioE3 also focuses on environmental sustainability and responsible green innovation, supporting the development and deployment of green biotech in the form of bio-based materials, bioenergy, and bioremediation technologies. By promoting sustainable practices and supporting sectors of the bioeconomy that have lower carbon footprints, the policy aligns India's biotech development with international climate objectives. Specific programmes focus on leveraging indigenous biodiversity and traditional knowledge, and utilising ethical and inclusive models of innovation.³⁰

Lastly, BioE3 emphasises global cooperation and market outreach. India aims to be a reliable supplier of affordable, high-quality biotech products to both developing and advanced markets. By leveraging its strengths in

Focus Areas and Flagship Programmes under BioE3

research, production, and regulatory compliance, the country is growing from a biosupplier to a co-developer on the international biotech stage. The country's increasing involvement in international cell and gene therapy consortia—where startups supported by BIRAC are collaborating with the United States (US) and European Union (EU) biotech accelerators for cross-border technology transfer and clinical trials—illustrates this vision in action. Through such partnerships, Indian businesses can offer high-quality, reasonably priced manufacturing solutions at scale while gaining access to cutting-edge technologies, such as AI-powered biologics design and synthetic biology platforms.

These focus areas are guided by a larger national vision. BioE3 is not just an economic strategy but a reaction to global challenges such as climate change, energy transformation, food and water security, and the imperative of green growth. India envisions biotechnology as a cross-cutting facilitator in achieving its goals of decarbonisation, circular economy principles, and import substitution in strategic sectors such as healthcare, energy, and agriculture.

Challenges to India's Biotech Development

The BioE3 framework outlines a roadmap for growth and innovation in biotech, covering infrastructure development, financing models, capacity development, regulatory easing, sustainability, and international integration. There are multiple challenges, however, including intellectual property rights issues, regulatory inefficiencies, infrastructure constraints, funding deficits, and worldwide integration gaps. These problems must be resolved to ensure the policy's long-term sustainability and competitiveness.

Overcoming the structural hurdles is a matter of critical importance both for India's domestic innovation and global position in the biotechnology field. While BioE3 has set the stage for expansion, other leading economies are rushing to follow. The US has invested billions in its National Biotechnology and Biomanufacturing Initiative, the EU has launched its Biotech and Biomanufacturing Initiative to enhance resilience and sustainability in the sector, and China has made strategic investments in synthetic biology and industrial biotech under its 14th five-year plan.^{31,32,33} Emerging economies in South America, too, are increasing spending in bio-based industries.

Without proactive measures, India will fall behind in the international bioeconomy competition and miss out on its biotech potential, especially in high-risk areas such as gene therapy, synthetic biology, and personalised medicine. For BioE3 to be a force for change, India must address the gaps in the following domains:

Intellectual Property Rights and Technology Transfer

India has historically faced delays in processing biotech patents because of structural limitations, with the Bureau of Indian Standards examiners carrying heavy workloads. The Patent (Amendment) Rules, 2024, that came into force on 15 March 2024 have brought improvements to this process.³⁴ The time limit for a patent applicant to submit a Request for Examination (RFE), which initiates the examination of the application, has been cut down from 48 months to 31 months from the date of filing or priority date. Further, an applicant's response to the First Examination Report (FER) can now be requested within a maximum of nine months (previously, six months), thus providing relief during legal proceedings.³⁵ These reforms are preliminary steps toward efficiency, but the backlog, and until recently the absence of examiner capacity and technical competence in advanced biotech fields (such

Challenges to India's Biotech Development

as CRISPR, recombinant DNA, and molecular diagnostics), still deters timely and effective processing of biotech patent applications.

Such intellectual property rights climate directly impacts technology transfer, which is vital for fostering global partnerships and scaling innovation. Multinational firms are often hesitant to license their proprietary technologies to Indian counterparts due to concerns about intellectual property leakage, inadequate legal safeguards, and weak enforcement.³⁶ Consolidating the intellectual property rights regime by supplying biotech-specific rules, implementing better enforcement systems, and incentivising patent applications can help make India a hub of biotech innovation and international cooperation.

Regulatory Fragmentation and Inefficiency

India's biotech regulatory environment is overseen by a network of agencies that supervise the different aspects of product development, clinical trials, environmental safety, and commercialisation. These institutions include the DBT, the Central Drugs Standard Control Organisation (CDSCO), the Indian Council of Medical Research (ICMR), the Ministry of Environment, Forest and Climate Change, and several state government regulatory agencies. A company working on a new gene therapy product, for example, would require concurrent approvals from the DBT for genetic engineering, the CDSCO for clinical trials, and the ICMR for ethics compliance—each of them with varying timelines and minimal inter-agency coordination. This overlap in jurisdictions results in redundant approvals, procedural delays, and bureaucratic ambiguity for sophisticated biologics and genetically modified organisms.³⁷

Recent efforts have been made to implement single-window clearance and online submission systems. The CDSCO operates the SUGAM portal to digitise and ease application procedures for drug approvals and clinical trials. Likewise, the National Single Window System (NSWS) is meant to be a single platform for businesses and investors to get regulatory approvals across ministries, including for biotech ventures. Further, the New Drugs and Clinical Trials (NDCT) Rules, 2019, have brought regulatory change by incorporating timelines for approvals, ethical review mechanisms, and differentiation among the various categories of biomedical products. However, there is a need for overarching reforms that will enhance operational effectiveness, assign clear

Challenges to India's Biotech Development

institutional roles, simplify digital frameworks, and harmonise timelines.³⁸ Without this coordination, platforms like SUGAM and NSWS are at risk of being underutilised, with the desired benefits reduced, especially for high-risk, high-reward biotech advances.

A more streamlined, transparent, and harmonised regulatory framework based on international best practices is necessary to foster biotech innovation in India. An important step could come via implementation of the draft on revamping clinical trials that was under circulation at the time of writing.³⁹ The draft is aimed at strengthening clinical trial protocols by industry players and is in accordance with NDCT, 2019, Drugs and Cosmetics Act, 1940, and Good Clinical Practice Guidelines.

Notably, the Biotechnology Regulatory Authority of India (BRAI) Bill, introduced in Parliament in 2013 to create a single, independent biotechnology regulator, was not passed because it raised questions over transparency, federalism, and environmental protection. No general replacement has been passed since then. Bringing back or reimagining such an infrastructure could be pivotal to encouraging innovation and investment in emerging areas of biotech.⁴⁰

Infrastructure Shortfalls and Asymmetric Innovation Spread

While large cities such as Hyderabad, Bengaluru, and Pune have well-established biotech clusters with cutting-edge laboratories, incubators, and manufacturing facilities, much of the country is short of such infrastructure.⁴¹ Biotech startups and researchers in Tier-2 and Tier-3 cities have to work with meagre lab space, limited access to sophisticated equipment, and poor quality control and compliance facilities, particularly in comparison to global standards in Germany, South Korea, China, and Australia.⁴² Though BioE3 has addressed some of these limitations with its biotech parks, the lack of centralised testing facilities, bioreactor facilities, and biosafety-approved environments still makes it challenging for smaller players to manufacture and qualify products in volumes.

Cold chain logistics and waste-management systems for biohazardous material also remain underdeveloped. Lacking access to well-equipped biofoundries or GMP-approved facilities, many startups must depend on foreign collaborators for product verification at steep costs. These infrastructure constraints

Challenges to India's Biotech Development

restrict regional involvement in biotech development. Increasing shared infrastructure, particularly in less-represented areas, will be instrumental in democratising biotech innovation and making resources more equally accessible.

Funding Restrictions and Risk Capital Constraints

Biotechnology is a capital- and risk-intensive business that needs continuous investment over long product-development periods. BIRAC's equity schemes form a pillar of support for startups and biotech enterprises.⁴³ Initiatives such as the Sustainable Entrepreneurship and Enterprise Development (SEED) Fund, the Launching Entrepreneurial Driven Affordable Products (LEAP) Fund, and the Biotechnology Innovation Accelerating Entrepreneurs (AcE) Fund have enabled early-stage startups to scale and attract private investment from angel investors and venture capitalists. By FY 2023–24, nearly 210 startups had received equity support under SEED and LEAP, with more than 60 percent of them securing follow-on funding worth INR 856 crore.⁴⁴ Notably, there has been a marked rise in biotech startups drawing investments from angels, high-net-worth individuals, and early-stage venture capitalists of US\$~2 billion across 495 investment opportunities, underscoring the sector's growth trajectory.⁴⁵

The AcE Fund-of-Funds has further amplified this momentum, with BIRAC committing INR 149.50 crore across 14 daughter funds, which, in turn, have mobilised INR 1,172 crore of investment into 88 biotech companies.⁴⁶ The AcE portfolio continues to expand with the onboarding of new daughter fund partners, creating a deeper pipeline of funding opportunities for India's biotech innovators.

Yet, despite these strides in initial-stage funding, entry into growth-stage and late-stage capital continues to face bottlenecks, for instance, in the transition from pre-clinical studies to clinical ones.⁴⁷ Venture capitalists and private equity investors have historically perceived biotech as too risky—often due to a lack of robustness in preclinical models—due to its long lead times, regulatory complexities, and technical risks, and this trend continues.⁴⁸

The funding shortfall is particularly sharp for startup companies developing new therapeutics, gene therapies, and synthetic biology, where product development can take a decade before commercialisation. Most Indian biotech

Challenges to India's Biotech Development

startups have to dilute equity at early stages or be dependent on foreign funds, limiting the scope for innovation and long-term goals of smaller firms. Further, startups often fail to transition to larger-scale manufacturing firms owing to a 'startup mindset' limiting their scope.⁴⁹

Talent Shortages and Brain Drain

Although India churns out high numbers of science and engineering graduates annually, the industry-ready biotech talent gap is significant. Most universities still stress on theoretical courses, with little priority given to the practical training, cross-disciplinary learning, and entrepreneurship that are all important in biotech. Cross-disciplinary training in chemical engineering, for instance, is an essential aspect of specialised courses such as immunology, key to harnessing biotech products that are both innovative and marketable.⁵⁰ Apprenticeships or post-study training programmes that are guided through academia and industry-led linkages are also crucial to create sustainable and attractive pathways for graduates to partake in the application of theoretical concepts to real-world biological challenges.⁵¹

The problem is compounded by the propensity among many of India's best biotech scientists to pursue opportunities outside the country because of the availability of superior research infrastructure, better remuneration, and more attractive career opportunities. This brain drain depletes the local pool of talent, especially in specialised areas like genomics, stem cell biology, and bioinformatics. While the government has initiated skill-based training programmes, including the Biotech Industrial Training Program, and fellowships for returning scientists, a stronger strategy must be framed to retain talent.⁵²

Strategic Recommendations for Global Alignment

As India aims to become a global biotech hub, it must adhere more closely to global quality, ethics, safety and innovation standards. Today, most Indian biotech products and processes encounter difficulties entering international markets in developed economies owing to the absence of harmonisation with international regulatory guidelines such as those provided by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the World Health Organization (WHO), or the Best Practices guidelines on vaccine access from the Organisation for Economic Co-operation and Development (OECD).^{53,54}

These obstacles are not insurmountable. India's vaccine regulatory system, for instance, has been categorised at Maturity Level 3 under the WHO Global Benchmarking Tool, marking it as 'functional'.⁵⁵ This milestone has enhanced confidence and trust, cementing global reliance on India's regulatory framework. It also highlights WHO's continued role in helping India strengthen regulatory capacities while advancing equitable access to safe, effective, quality, and affordable vaccines.

Similarly, points of friction in other areas of India's biotech ecosystem can be addressed if BIOE3 is augmented with reforms in intellectual property regimes, regulatory mechanisms, infrastructure, talent, and global collaboration. To this end, the DBT and ICMR must work on the following:

1. Building Intellectual Property and Technology Transfer Frameworks

India needs to revamp its intellectual property regime to provide quick, transparent, and biotech-specialised patent processing. This involves developing technical capabilities in patent offices, streamlining guidelines for patentable subject matter, and implementing quick-track review channels for biotech inventions. Further, the DBT could partner with industry experts to offer free or subsidised legal, business, and market assistance to researchers, thus enabling the translation of discoveries in labs into products for commerce. Milestone-based grants for patent applications and license agreements are other incentives that could induce innovation and drive industry-academia collaborations.

Strategic Recommendations for Global Alignment

2. Simplifying and Harmonising Regulatory Frameworks

A single, biotech-oriented regulatory regime that brings together approvals is essential. In this context, the Biotechnology Regulatory Authority of India (BRAI), which has already been recommended in Parliament and promises inter-agency coordination, can reduce redundancies and approval times. Further, regulations must evolve continuously to keep pace with developments in frontier areas like gene editing, microbiome therapeutics, and digital health technologies.

3. Democratising and Diversifying Infrastructure

Government and private partners need to invest proactively in developing biotech infrastructure outside conventional hubs. This involves creating more regional biotech innovation parks, shared research labs, pilot plants compliant with GMP, and biofoundries that are available to startups and academia. In addition, promoting public–private partnerships and incentivising private-sector infrastructure development can help bring about a pan-India biotech ecosystem to drive inclusive growth.

Apart from democratising infrastructure, attention must be paid to strengthening the resilience of supply chains, especially in light of tariff barriers. This requires investing in diversifying sources of materials and reagents and in developing indigenous products.⁵⁶ Further, safe and effective product development in the biotech sector necessitates securing cold-chain logistics and waste management systems.

Existing limitations in this area are exemplified in India's Universal Immunisation Programme and other immunisation-related efforts. Although the National Cold Chain and Vaccine Management Resource Centre provides key insights into India's immunisation supply chain, weaknesses persist. Infrastructural limitations, particularly in uninterrupted power supply in rural areas, are common, as are coverage gaps and accessibility limitations. These are compounded by infrequent cold-chain assessments, and inconsistencies in implementation due to lack of awareness and training.⁵⁷

Strategic Recommendations for Global Alignment

Biomanufacturing also requires consideration of biomedical waste management. The Bio-Medical Waste Management Rules, 2016, have strengthened India's regulatory framework, but weaknesses persist.⁵⁸ Compliance remains uneven, especially in smaller healthcare facilities, due to inadequate monitoring by state Pollution Control Boards and limited availability of treatment facilities outside urban centres. Waste segregation at source is poorly practised, barcoding and real-time tracking are inconsistently implemented, and overlaps in e-waste, hazardous, and household biomedical waste remain unaddressed. The COVID-19 pandemic exposed the system's lack of surge capacity, with treatment facilities overwhelmed by PPE and testing waste. Heavy reliance on incineration, weak enforcement of penalties, and insufficient training for frontline waste handlers continue to undermine safe and sustainable biomedical waste management.⁵⁹

4. Catalysing Risk Capital and Investment

India must nurture a stronger investment ecosystem for biotech through policy-based incentives for risk capital inflows, including the timely release of funds, tax relief for biotech-dedicated funds and concessional financing programmes. One measure to achieve this goal can be the creation of a sovereign biotech venture capital fund under DBT that would assist in de-risking early-stage investment and bring in additional private-sector players. Enhanced financial literacy among entrepreneurs and access to international investor networks can also unleash the much-needed capital for growth.

Initiatives like Global Bio-India, which brings together biotech stakeholders, can be conducted biannually,⁶⁰ with more engagement at the state level, to create more awareness about early-stage investment opportunities and act as a pivotal platform for stakeholder engagement. Increased cooperation between biotech specialists and financial institutions can enable creative financing tools, such as revenue-based or milestone-driven loans, thus enabling better financial schemes. Finally, the utilisation of the INR 1-lakh crore corpus of funds established under the government's Research Development and Innovation Scheme should be given the utmost priority.⁶¹ This venture supports innovation in strategic sectors like biotech and the scaling-up of pilot projects.

Strategic Recommendations for Global Alignment

5. Closing Gaps in Talent through Education and Retention

A multifaceted strategy is needed to nurture and retain biotech talent. Universities must change their curricula to incorporate hands-on training and cross-disciplinary learning, and encourage entrepreneurship. Expanding fellowship programmes, apprenticeships, and internships can help create a workforce ready to meet the evolving demands of the sector. Additionally, more funding must be extended to universities, allowing them to offer employees competitive pay, research grants, and clear career advancement options to help reduce brain drain.


6. Strengthening Global Integration and Leadership

India needs to play a proactive role in evolving global standards and regulatory directions and establish itself as a global leader in biotech. Bilateral and multilateral alliances, such as the Quad, Association of Southeast Asian Nations (ASEAN), and US–India TRUST (Transforming the Relationship Utilizing Strategic Technology),^g must be mobilised to strengthen technology sharing, collaborative research and development, and capacity building. Harmonising regulations with international standards and showcasing Indian biotech products globally through foreign trade missions and quality certifications can provide new export market opportunities. Further, India's promise to ensure equitable access and capacity development in low-income countries can increase its soft power and global role in health diplomacy.

^g An initiative aimed to strengthen supply chains on critical and emerging technologies, including biotechnology and pharmaceuticals. See: <https://www.whitehouse.gov/briefings-statements/2025/02/united-states-india-joint-leaders-statement/>.

India's BioE3 blueprint puts in place a solid foundation for development in biomanufacturing and innovation. In addition to this sectoral focus, BioE3 is also part of India's larger strategic vision to reduce import dependence, promote energy and economic security, and address climate and employment issues through innovation. As global challenges increasingly intertwine with each other, from climate resilience to sustainable agriculture, pandemic preparedness, and food security, India is positioning its bioeconomy at the centre of inclusive, green, and self-reliant growth. BioE3 is thus neither a reaction to pandemic-era momentum nor a responsive tool but a vision-driven agenda to fulfil India's Paris Agreement obligations, generate high-value employment, and drive global competitiveness in affordable and sustainable bio-innovation.

The policy's success, however, will hinge on fulfilling systemic gaps. Enhancing intellectual property rights and establishing a streamlined regulation regime are vital to fast-tracking commercialisation and imparting global trust in Indian biotechnology products. Indian biotech standards must be brought on par with international regulatory frameworks to strengthen collaborations that will enable India to move beyond being a low-cost producer to becoming a reliable co-developer and supplier of emerging technologies. In tandem, investment in infrastructure must be extended beyond key centres to ensure that regional biotech parks, GMP-certified pilot facilities, and shared biofoundries facilitate inclusive innovation.

Also essential is fostering a more robust stream of risk capital to finance high-risk, long-cycle enterprises, and bringing in reforms in education and career paths critical to developing and retaining talent in the field. If pursued efficiently, these reforms can promote equitable access to life-saving technologies, build strong global health efforts, and add to sustainable economic growth in the country. 

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The authors interviewed Vivek Mishra, founder and CEO of Fibroheal Woundcare Pvt. Ltd, and Amulya K. Panda, Associate Director, Panacea Biotech Ltd and former Director, National Institute of Immunology, for industry insights on the progress and future of BioE3.

All views expressed in this publication are solely those of the authors, and do not represent the Observer Research Foundation, either in its entirety or its officials and personnel.

- 1 Ministry of Finance, Government of India, <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1894907>.
- 2 Ministry of Health and Family Welfare, Government of India, <https://mohfw.gov.in/?q=%2Fpress-release-tb%2F8380&>.
- 3 Press Trust of India, “Bharat Biotech Urges Centre to Include Its Intranasal COVID Vaccine in CoWIN Portal,” *The Hindu*, December 11, 2022, <https://www.thehindu.com/sci-tech/health/bharat-biotech-urges-centre-to-include-its-intranasal-covid-vaccine-in-cowin-portal/article66250858.ece>.
- 4 Ministry of Science and Technology, Government of India, <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1894167>.
- 5 “Winning Over COVID (CoWIN),” United Nations Development Programme, <https://www.undp.org/india/projects/winning-over-covid-cowin>.
- 6 Ministry of Commerce and Industry, Government of India, <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=1710134>.
- 7 “Gavi and Government of India Establish New Partnership to Protect Millions of Children by 2026,” Gavi, The Vaccine Alliance, January 3, 2025, <https://www.gavi.org/news/media-room/gavi-and-government-india-establish-new-partnership-protect-millions-children-2026>.
- 8 “Vaccine Maitri,” Ministry of External Affairs, Government of India, <https://www.mea.gov.in/vaccine-maitri.htm>.
- 9 “Vaccine Maitri,” Ministry of External Affairs, Government of India
- 10 “COVAX Explained,” GAVI, November 8, 2022, <https://www.gavi.org/vaccineswork/covax-explained>.
- 11 “GSK, PATH, and Bharat Biotech Sign Product Transfer Agreement to Help Ensure Long-term Supply of RTS,S/AS01E Malaria Vaccine,” GSK, January 27, 2021, <https://www.gsk.com/en-gb/media/press-releases/gsk-path-and-bharat-biotech-sign-product-transfer-agreement-to-help-ensure-long-term-supply-of-rtss-as01e-malaria-vaccine/>.
- 12 Reuters, “Bharat Biotech, GSK to Halve Price of Malaria Vaccine by 2028,” *The Economic Times*, June 25, 2025, <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/bharat-biotech-gsk-to-halve-price-of-malaria-vaccine-by-2028/articleshow/122064325.cms?from=mdr>.
- 13 “Indian Manufacturer New Recipient of mRNA Technology Through the mRNA Technology Transfer Hub,” World Health Organization, March 31, 2022, <https://www.who.int/news/item/31-03-2022-indian-manufacturer-new-recipient-of-mrna-technology-through-the-mrna-technology-transfer-hub>.

- 14 “GSK Licenses Shigella Vaccine Candidate to Bharat Biotech for Continued Development,” GSK, June 12, 2025, <https://www.gsk.com/en-gb/media/press-releases/gsk-licenses-shigella-vaccine-candidate-to-bharat-biotech-for-continued-development/>.
- 15 The Hindu Bureau, “Phase III Clinical Trials of Bharat Biotech’s Oral Cholera Vaccine Over,” *The Hindu*, May 21, 2025, <https://www.thehindu.com/news/cities/Hyderabad/phase-iii-clinical-trials-of-bharat-biotechs-oral-cholera-vaccine-over/article69602317.ece>.
- 16 “Hillchol: Bharat Biotech’s Oral Cholera Vaccine Demonstrates Success in Phase III Clinical Studies,” Express Pharma, May 21, 2025, <https://www.expresspharma.in/hillchol-bharat-biotechs-oral-cholera-vaccine-demonstrates-success-in-phase-iii-clinical-studies/>.
- 17 “IVI starts technology transfer to Biological E. Limited to manufacture oral cholera vaccine for India and global markets,” International Vaccine Institute, <https://www.ivi.int/ivi-starts-technology-transfer-to-biological-e-limited-to-manufacture-oral-cholera-vaccine-for-india-and-global-markets/>.
- 18 Ministry of Science and Technology, Government of India, <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2048569>.
- 19 Ministry of Science and Technology, Government of India, <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2048569>.
- 20 Insights from interview with Dr Vivek Mishra.
- 21 Ministry of Science and Technology, Government of India, <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2048569>.
- 22 Department of Biotechnology, “Biotech Parks,” Ministry of Science and Technology, Government of India, <https://dbtindia.gov.in/scientific-directorates/bio-wealth-biosafety/biotech-park>.
- 23 Department of Biotechnology, “Biotech Parks”
- 24 Department of Biotechnology, “Biotech Parks”
- 25 “Biotechnology Start up Ecosystem in India,” 2019, <https://www.biotech.co.in/sites/default/files/2020-01/Biotechnology-Startup-Ecosystem-in-India.pdf>
- 26 “Biotechnology Ignition Grant Scheme (BIG),” BIRAC, <https://birac.nic.in/big.php>.
- 27 Insights shared by Dr Amulya Panda during an interview with the authors.
- 28 Department of Biotechnology, “BioE3 Policy,” Ministry of Science and Technology, Government of India, <https://bmi.dbtindia.gov.in/pdf/folder.pdf>.
- 29 Department of Biotechnology, “BioE3 Policy”
- 30 Department of Biotechnology, “Brochure On Green Growth Through BIOE3,” Ministry of Science and Technology, Government of India, <https://dbtindia.gov.in/sites/default/files/BioE3%20Policy%20Brochure.pdf>.

- 31 “White House Releases Report on Growing U.S. Biomanufacturing Capacity for the American Bioeconomy,” Federal Government of the United States of America, November 15, 2024, <https://bidenwhitehouse.archives.gov/ostp/news-updates/2024/11/15/white-house-releases-report-on-growing-u-s-biomanufacturing-capacity-for-the-american-bioeconomy/>.
- 32 “Introducing the New Biotech and Biomanufacturing Hub,” European Commission, April 4, 2025, <https://ec.europa.eu/newsroom/growth/items/872111/>.
- 33 Xu Zhang, “The roadmap of Bioeconomy in China,” *Eng Biol* 6, no. 4 (2022), <https://pmc.ncbi.nlm.nih.gov/articles/PMC9995158/#enb212026-sec-0010>.
- 34 Obhan & Associates, “Patent (Amendment) Rules, 2024: Key Changes,” Mondaq, March 26, 2024, <https://www.mondaq.com/india/patent/1442682/>.
- 35 Obhan & Associates, “Patent (Amendment) Rules, 2024: Key Changes”
- 36 Pratyush Prakarsh et al., “The Role of Intellectual Property in Fostering Innovation and Economic Growth,” *International Journal for Multidisciplinary Research* (2024), <https://doi.org/10.36948/ijfmr.2024.v06i05.28732>.
- 37 Shravishtha Ajaykumar, “Laboratory Biosafety in India: In Search of a Sound Regulatory Framework,” Observer Research Foundation, April 9, 2024, <https://www.orfonline.org/research/laboratory-biosafety-in-india-in-search-of-a-sound-regulatory-framework>.
- 38 Ashwin Sapra, “New Drugs and Clinical Trials Rules, 2019 – a Regulatory Overview,” Mondaq, August 5, 2019, <https://www.mondaq.com/india/healthcare/832924/>.
- 39 “Inside India’s Plans for Revamping Clinical Trials,” *Live Mint*, April 17, 2024, <https://www.livemint.com/industry/inside-india-s-plans-for-revamping-clinical-trials-11713359607897.html>.
- 40 Shravishtha Ajaykumar, “Laboratory Biosafety in India: In Search of a Sound Regulatory Framework”
- 41 Ministry of Science and Technology, Government of India, <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=1689929>.
- 42 Insights shared by Dr Amulya Panda during an interview with the authors.
- 43 Biotechnology Industry Research Assistance Council, *12th Annual Report 2023-2024*, https://birac.nic.in/webcontent/birac_annual_report_2024_e.pdf
- 44 Jitendra Kumar, “The Startup Revolution,” *Science India Mag*, October 14, 2024, <https://scienceindiamag.in/the-startup-revolution/>.
- 45 Minakshi Sangwan, “India’s Life Sciences Startups Secure USD 1.9 Bn in Five Years,” *Entrepreneur*, April 10, 2025, <https://www.entrepreneur.com/en-in/news-and-trends/indias-life-sciences-startups-secure-usd-19-bn-in-five/489838>.

- 46 Parul Chugh, “Funding Opportunities in the Biotech Ecosystem,” Invest India, June 5, 2023, <https://www.investindia.gov.in/team-india-blogs/funding-opportunities-biotech-ecosystem-equity-support-startups-dbt-birac>.
- 47 Biotechnology Industry Research Assistance Council, *12th Annual Report 2023-2024*
- 48 Seema Singh, “Private Investment Eludes Indian Biotech,” Science Business, June 20, 2007, <https://sciencebusiness.net/news/72054/Private-investment-eludes-Indian-biotech>.
- 49 Insights shared by Dr Vivek Mishra during an interview with the authors.
- 50 Insights shared by Dr Amulya Panda during an interview with the authors.
- 51 Insights shared by Dr Amulya Panda during an interview with the authors.
- 52 Department of Biotechnology, “Biotechnology Industrial Training Programme (BITP) Apprenticeship,” Ministry of Science and Technology, Government of India, <https://dbtindia.gov.in/dbt-biotechnology-industrial-training-programme-bitp-apprenticeship>.
- 53 “Guidelines,” ICH, <https://www.ich.org/page/ich-guidelines>.
- 54 “Access to COVID-19 Vaccines: Global Approaches in a Global Crisis,” OECD, March 18, 2021, https://www.oecd.org/en/publications/2021/03/access-to-covid-19-vaccines-global-approaches-in-a-global-crisis_c34ca5e0.html.
- 55 “India meets WHO global standards for vaccine regulation,” World Health Organisation, <https://www.who.int/india/news-room/detail/15-10-2024-india-meets-who-global-standards-for-vaccine-regulation>.
- 56 Insights shared by Dr Vivek Mishra during an interview with the authors.
- 57 Sandeep Kumar et al., “Using new cold chain technologies to extend the vaccine cold chain in India: Equipment performance, acceptability, systems fit, and costs,” *Vaccine X* 9, no. 15 (2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10509701/>.
- 58 Central Pollution Control Board, *Annual Report on Biomedical Waste Management for the year 2022 as per Biomedical Waste Management Rules, 2016*, https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/AR_BMWM_2022.pdf.
- 59 K.S. Uplabdh Gopal, “The Missing Circular Economy of Biomedical Plastic Waste in India,” Observer Research Foundation, <https://www.orfonline.org/expert-speak/the-missing-circular-economy-of-biomedical-plastic-waste-in-india>.
- 60 Insights shared by Dr Vivek Mishra during an interview with the authors.
- 61 Cabinet, Government of India, <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2141130>.



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