International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Navigating India's Bioeconomy: Analyzing the BioE3 Policy, Innovation, and Emerging Challenges

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Abstract:
India's bioeconomy is a rapidly growing sector with significant potential for global leadership in biotechnology, biomanufacturing, bio-based solutions, and biopharma. The government's Bio-E3 (Biotechnology for Economy, Environment and Employment) initiative, a strategic framework aimed at enhancing the bioeconomy, emphasizes the need for stronger research infrastructure, improved regulatory systems, and increased funding for emerging technologies. However, challenges such as regulatory complexities, limited access to finance, and barriers to equitable distribution of bio-based innovations remain. Despite these obstacles, India's bioeconomy presents opportunities for sustainable economic growth, innovation in healthcare, and addressing global health challenges. This paper explores the current state of India's bioeconomy, focusing on the Bio-E3 framework, and identifies key challenges hindering its progress. It also proposes actionable strategies, including optimizing regulatory frameworks, expanding public-private partnerships, and fostering research collaborations, to unlock the sector's full potential.

Keywords: Bio E3 policy, Bioeconomy, Biopharm, Biotechnology, Biomanufacturing

Introduction:

As the world confronts mounting challenges, from the intensifying impacts of climate change to the growing need for sustainable healthcare systems; a paradigm shift is underway. At the intersection of biology, technology, and innovation lies the ***bioeconomy***, a concept that holds the promise of reimagining economic growth through sustainable practices. By harnessing biological resources in transformative ways, the bioeconomy is emerging as a vital strategy for addressing global imperatives such as environmental resilience, healthcare access, and inclusive development. Defined as the sustainable production and utilization of biological resources powered by science, technology, and innovation, the bioeconomy provides transformative solutions across economic sectors (IACGB, 2024) [1]. At its core, the bioeconomy advances transformative solutions, including precision medicines, innovative vaccines, and low-carbon manufacturing processes, driving sustainable progress across healthcare and beyond.. Countries like the U.S. have made significant strides with initiatives like BioMADE (Bioindustrial Manufacturing and Design Ecosystem), supporting over 4.9 million jobs and fostering advancements in biomanufacturing, while China's bio pharmaceutical market has more than doubled its sales in recent years, reflecting its strategic focus on this sector [2], [3]. Against this global backdrop, India, long

celebrated as the "pharmacy of the world," is poised to lead with its strong pharmaceutical foundation and vibrant biotechnology ecosystem.

India's bioeconomy, valued at $80.12 billion in 2021, is growing at an annual rate of 14%, contributing 2.6% to GDP. With over 3,500 biotech companies expected to grow to 10,000 by 2025. India's bioeconomy is anchored by its vibrant pharmaceutical and biotechnology sectors. Biopharma, accounting for 35.7% of the market, has been a cornerstone of this growth, driven by innovations in vaccines, diagnostics, and therapeutics, with a $39.4 billion economic output (IBER Report, 2024) [4]. It spans across diverse sectors, including bioenergy, bioindustrial manufacturing, and bio-agriculture, alongside biopharma. Together, these sectors form the backbone of a sustainable and inclusive economy, contributing to climate resilience, food security, and healthcare transformation. The 2024 launch of the BIO-E3 Mission by the Department of Biotechnology represents a strategic initiative to enhance biomanufacturing, streamline regulations and foster public-private collaboration, with a vision to achieve a $150 billion bioeconomy by 2025 backed by a low carbon, sustainable future while addressing global health demands.

The mission has set ambitious goals to position India as a leader in biopharma and the broader bioeconomy. The stepping stones of bio based industries in India have been the development of the biotech sector, it has built upon decades of consistent efforts and infrastructure development since the 1990s. The accompanying flowchart *(figure1)* illustrates this evolution, emphasizing the alignment of infrastructure, policy, and industry efforts over the years. The trajectory began with the establishment of the Department of Biotechnology (DBT) in 1986, marking a foundational commitment to biotechnology research and development. The 1990s saw the emergence of biotech startups, such as Biocon, and early innovations in recombinant DNA technology, setting the stage for biopharma growth and further paving the way for the bioeconomy to bloom in the future. The Indian Biotechnology Policy of 2000 and the introduction of product patents in 2005 further strengthened the ecosystem, encouraging innovation in biosimilars and biologics. The 2000s witnessed significant momentum with companies like Dr. Reddy's Laboratories, Lupin, and Serum Institute of India diversifying into biologics and vaccines. Milestones such as Biocon's approval of India's first cancer biosimilar in 2017 and India's COVID-19 vaccine success in 2020 underscored the nation's capacity to deliver affordable and innovative biopharma solutions. Building on this, the Production Linked Incentive (PLI) scheme of 2021 was introduced to strengthen the manufacturing potential of the pharmaceutical industry and foreign investment [5], [6].

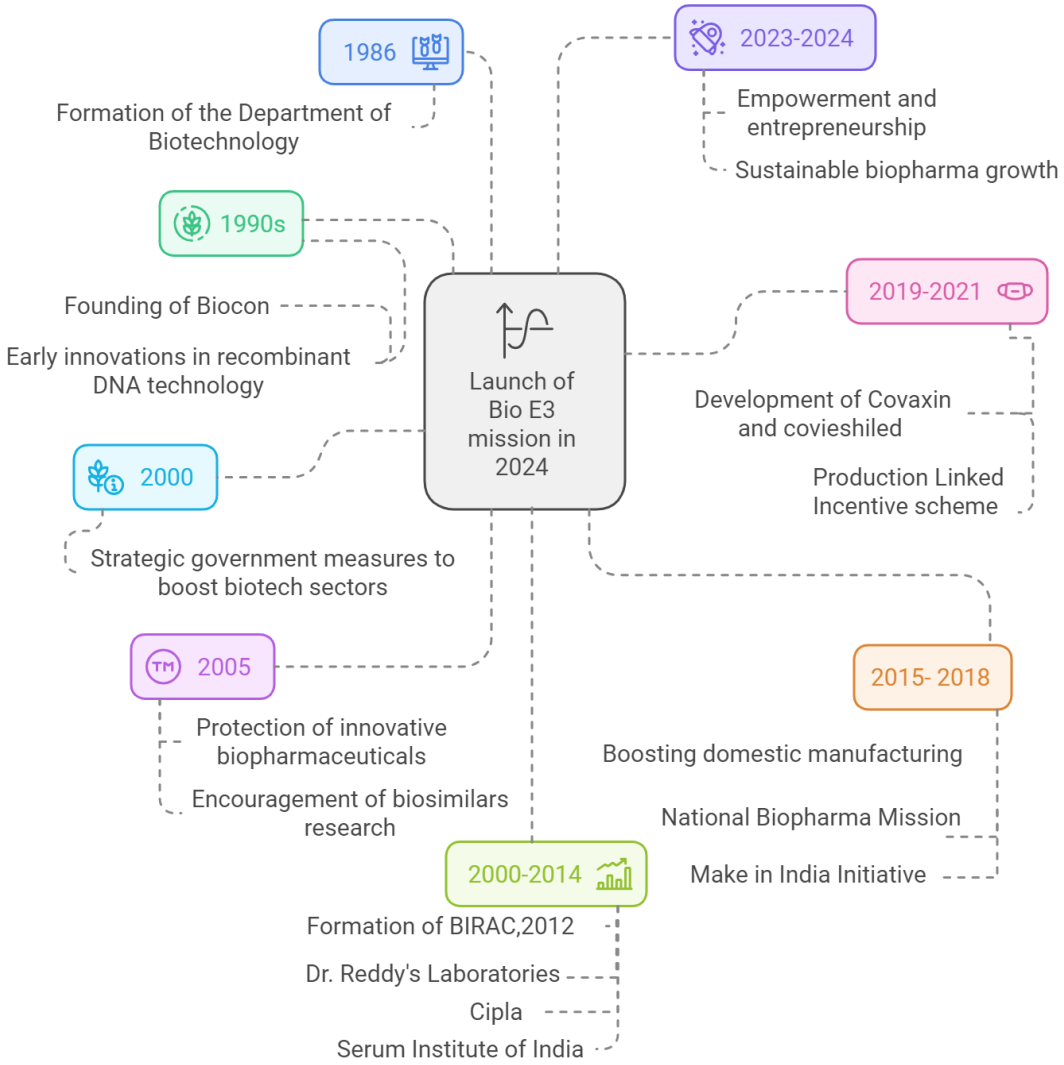

Figure 1: Timeline of bio based industry development in India

Source: Department of Biotechnology, Ministry of Science and Technology, India Despite India's progress, challenges such as regulatory hurdles, funding gaps, and equitable access to bio-based solutions remain significant. Addressing these bottlenecks is crucial to realizing the full potential of the bioeconomy, both domestically and globally. India's emerging bioeconomy has the potential to tackle global concerns like antimicrobial resistance, climate adaptation, and pandemic preparedness. This paper evaluates India's bioeconomy through a comprehensive nine-part framework (source: Mckinsey & Company Report), examining its strengths, global relevance, and challenges, while proposing actionable strategies to address future demands [7].

Discussion:

To analyze India's bioeconomy, a comprehensive nine-part framework *(figure 2)* can be employed. This framework examines three key pillars: **enablers, value chain capabilities, and innovation**, each encompassing critical subcomponents. Under enablers, the focus lies on the integration within global regulatory frameworks, access to diverse funding sources, and the vibrancy of cross-border collaborations, both at the asset and company levels. Value chain capabilities assess India's contributions to global

research and discovery, clinical development pipelines across therapeutic areas, and lays emphasis on manufacturing excellence in meeting global quality and cost standards. Lastly, the innovation pillar evaluates the development of affordable, high-quality therapeutics to improve access, contributions to first-in-class or best-in-class breakthrough innovations, and the impact of enabling technologies, such as advanced modalities and AI. This structured framework provides a robust lens to evaluate India's current progress and potential in driving sustainable growth and global competitiveness in the bioeconomy.

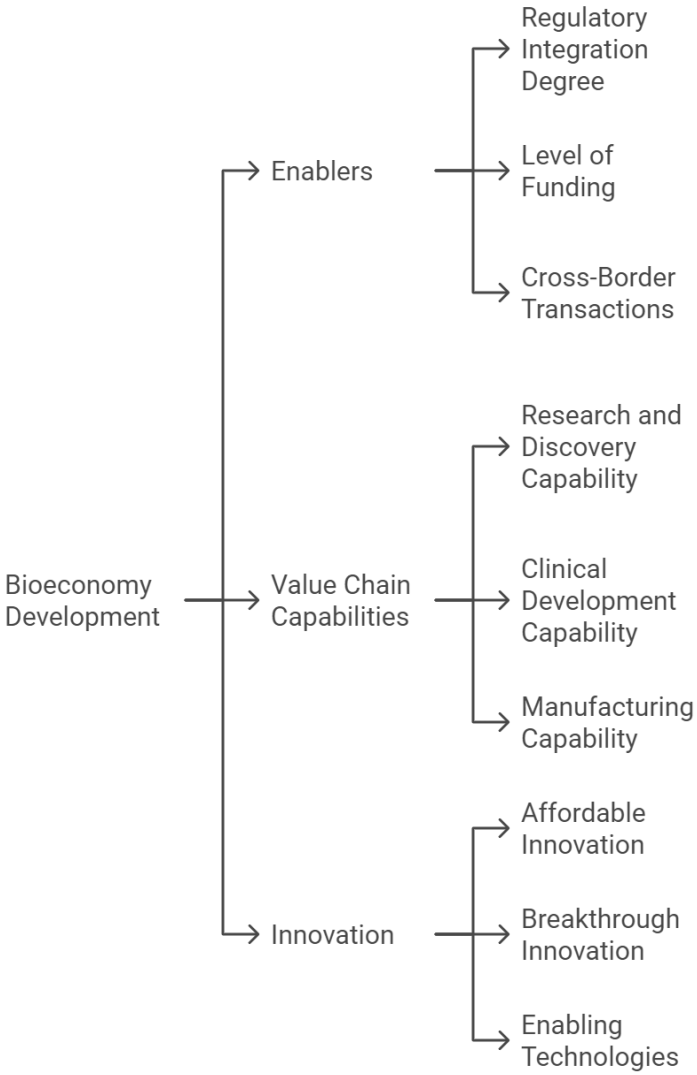

Figure 2: Nine part framework analysis model

Source: Vision 2028, Mckinsey & Company, Life Sciences Practice (7)

Enablers:

Regulatory integration: India is steadily positioning itself as a global leader in biotechnology through a series of strategic initiatives aimed at strengthening its bioeconomy. One of the key components of this effort has been the Biomanufacturing Initiative, which includes setting up Bio-Foundries and Biomanufacturing Hubs to scale operations and develop sustainable, eco-friendly bio-based products. This initiative is in line with India’s goal to reduce carbon emissions while driving forward the production of cutting-edge biotech solutions. At the same time, the BioRRAP (Biological Research Regulatory Approval Portal) simplifies the often cumbersome approval process for biological research, ensuring that innovators

can move from concept to commercialization more quickly and efficiently, with fewer regulatory hurdles. This initiative has sped up the manufacturing process. Figure 3 highlights the streamlined efforts in place to better regulate the upcoming bioeconomy sector. [8]

To further enhance the biotech capabilities, the government of India has overhauled its intellectual property (IP) guidelines, ensuring that public-funded research can be more easily commercialized. This includes provisions like March-in Rights, which guarantee that the fruits of research can be shared widely, maximizing their socio-economic impact. In parallel, the Department of Biotechnology (DBT) has restructured 14 institutes into the Biotechnology Research and Innovation Council (BRIC), consolidating efforts to streamline governance and accelerate the translation of research into real-world solutions. India's commitment to innovation is also reflected in the National Medical Device Policy and the National Green Hydrogen Mission [9]. The medical device policy, announced in 2023, aimed to enhance the quality and affordability of medical products, while encouraging greater collaboration between industry and academia [10]. Similarly, the National Green Hydrogen Mission backed by a $2.4 billion investment, places India at the forefront of the green energy revolution, supporting sustainable biofuel production and driving international partnerships in renewable energy. Additionally, updated guidelines for genetically engineered insects ensure safe, regulated advancements in biotechnology, paving the way for breakthroughs in agriculture and public health [11].

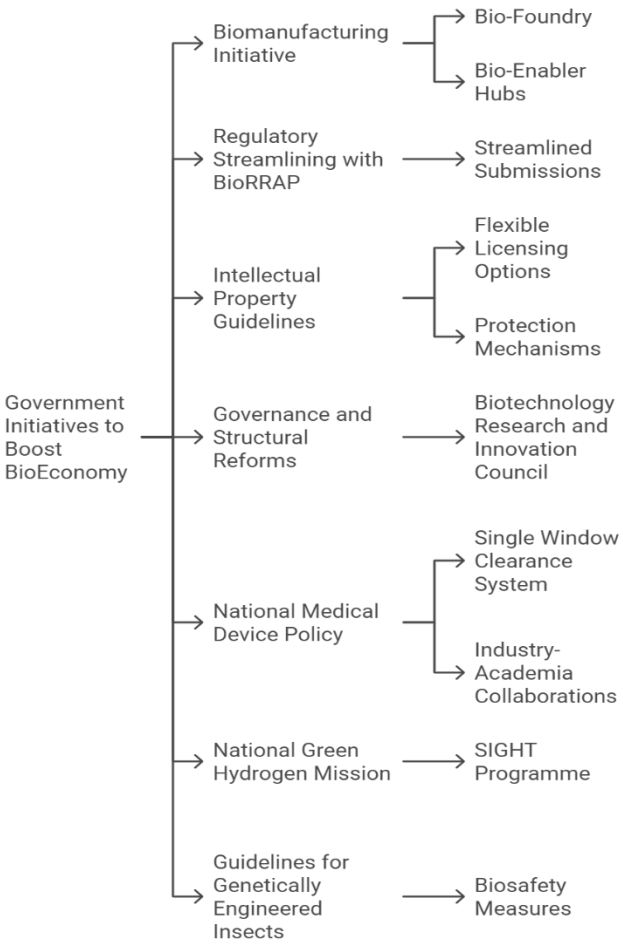

Figure 3: Recent government initiatives to boost Bioeconomy

Source: National biotechnology research strategy 2024 [12]

Level of funding: India is making significant strides in funding its bio-based industry, with a range of programs designed to support innovation and entrepreneurship in biotechnology. The Biotechnology Ignition Grant (BIG), a flagship initiative by BIRAC, is the largest early-stage biotech funding program in India, offering grants of up to INR 5 million (approximately USD 70,000) to young startups and entrepreneurs. This funding helps refine innovative ideas and build them into proof-of-concept projects [13]. In addition, the government has approved an impressive ₹9,197 crore outlay for the Biotechnology Research Innovation and Entrepreneurship Development (Bio-RIDE) scheme, which will run through the 15th Finance Commission period (2021-2026). This initiative aims to accelerate research, bio-entrepreneurship, and biomanufacturing, positioning India as a global leader in biotechnology [14]. Recent trends in healthcare funding further reflect this commitment, with India's health expenditure reaching 2.1% of GDP in 2022-23- a notable increase that aligns with the Fifteenth Finance Commission's recommendation to raise public health expenditure to 2.5% of GDP by 2025. Additionally, the DBT-BIRAC Amrit Team Grants initiative aims to foster innovative collaborative research programs that address national needs and enhance India's competitiveness in biotechnology on the global stage [15]. These efforts collectively demonstrate India's robust financial commitment to building a sustainable and globally competitive bioeconomy.

Cross border transactions: According to the Start Up Compendium 2023 report by BIRAC, more than 135 novel bio based products have been developed by Indian start-ups and half of them are targetted to be marketed globally in the coming years. For instance, Bioscan Research Pvt. Ltd has introduced *Cerebo*, an innovative handheld device that can detect asymptomatic intracranial bleeds non-invasively in just one minute. Designed for rapid and easy use, *Cerebo* is portable and ideal for trauma centers, emergency rooms, ambulances, and even sports fields, making it a game-changer for managing mild traumatic brain injuries. In India alone, where TBI causes significant deaths and disabilities every hour, this device has the potential to save countless lives. A true Make-in-India innovation, *Cerebo* not only addresses a critical national need but is also making its mark globally, with patents granted in India and the U.S., and others pending worldwide. By replacing imports and entering international markets, this startup showcases how Indian innovations are now driving global healthcare solutions [16].

Value Chain Capabilities:

Research and development: Research and development (R&D) activities play a pivotal role in driving India's bioeconomy forward, supported by several key initiatives and successful case studies. The Star College Programme, launched by DBT in 2008, has significantly improved science education at the undergraduate level across India [17]. Starting with just 30 colleges, the program now supports over 300 institutions, producing a skilled biotech workforce of over 1 million through mentorship, fostering critical thinking, and encouraging hands-on experimental science. Furthermore, the Bio-RIDE scheme, with an investment of Rs. 9,197 crore for 2021-2026, accelerates biotechnology research, bio-entrepreneurship, and biomanufacturing. The scheme nurtures innovative biotech startups, promotes cutting-edge research in areas such as biopharmaceuticals and bioenergy, and facilitates academia-industry collaboration, all while prioritizing sustainable biomanufacturing practices aligned with India's green goals [18]. Additionally, the Vigyan Dhara scheme, approved with a budget of Rs. 10,579.84 crore, aims to expand India's R&D capacity by building a critical human resource pool and increasing the number of full-time researchers [19]. Industry examples, such as Biocon Biologics, ranked among the top 15 global biomanufacturers, and Syngene International, a leading contract research and manufacturing organization,

showcase the immense potential of India's biomanufacturing sector, which is driving innovation in global healthcare, particularly in affordable biologics and cutting-edge therapeutic solutions. These efforts together are vital in positioning India as a future global leader in biotechnology, contributing to the goal of a US$300 billion bioeconomy by 2030.

Clinical development capability: India's clinical development capacity has significantly advanced due to consistent government support and strategic investments. In FY24, the healthcare budget was increased by 13% to Rs. 89,155 crore, with Rs. 2,980 crore specifically allocated for healthcare research. Under the "Strengthening of Pharmaceutical Industry" (SPI) initiative, the Department of Pharmaceuticals has committed Rs. 500 crore (USD 60.9 million) for the period from FY 2021 to FY 2026 [20]. As India's clinical trial ecosystem has matured, it has seen substantial improvements in infrastructure, expertise, and human capital, allowing the country to conduct trials that meet international standards. Collaborations between academia, industry, and government agencies have fostered innovation, enabling India to emerge as a global hub for medical research. Key regulatory changes, such as the introduction of the New Drugs and Clinical Trials Rules in 2019 and the Digital Personal Data Protection Act in 2023, have streamlined approval processes and enhanced patient data security, boosting India's appeal as a clinical research destination [21], [22]. The rise of decentralized clinical trials (DCTs), supported by digital data tracking, has further accelerated the clinical development process by enabling remote participation and improving data collection efficiency. A notable example of India's growing clinical capacity is the partnership between Dr. Reddy's Laboratories and Merck Serono to co-develop biosimilars, highlighting the country's ability to forge successful global collaborations. These partnerships not only ensure high manufacturing standards but also help Indian companies navigate international regulatory and intellectual property landscapes, positioning India as a competitive player in the global biopharma sector [23].

Manufacturing capability: India's manufacturing capabilities are being significantly bolstered under the BioE3 Policy, which fosters cross-sector collaboration between various ministries and departments. The Ministry of Electronics and Information Technology will play a pivotal role in supporting AI-driven biomanufacturing, while the Indian Council of Agricultural Research focuses on advancing agribiologicals. Other ministries, such as New and Renewable Energy, Space, Health, Pharmaceuticals, and Earth Sciences, are also contributing to the policy's success, ensuring a coordinated approach to scaling up India's bioeconomy. A core element of the BioE3 Policy is the development of Bio-Enablers like Bio-Artificial Intelligence (AI) Hubs and Biomanufacturing Hubs. These hubs will integrate cutting-edge biological research with AI and computational technologies, enabling breakthroughs in areas such as disease diagnosis, drug discovery, and sustainable agriculture. Moreover, Biomanufacturing Hubs will address key gaps in scaling up production, providing critical infrastructure for pilot and pre-commercial manufacturing, and facilitating the training of a skilled workforce in advanced biomanufacturing techniques [24]. India's bioindustrial sector is already making significant strides, as evidenced by the rapid growth in several key areas. The alcoholic beverages sector, for example, accounted for $16.2 billion of the bioeconomy value in 2023, reflecting an 11.57% increase from the previous year. India also remains a global leader in vaccine production, being the largest supplier of DPT, Measles, and BCG vaccines. In the biofuels sector, India's ethanol production reached 1,380 crore liters by the end of 2023, positioning the country as the third-largest producer of blended ethanol globally. Biofuels contributed $7.9 billion to the bioeconomy in 2023, marking a growth of 17.91%. Figure 4 visualizes the four major contributors to the current bioeconomic system in India [4].

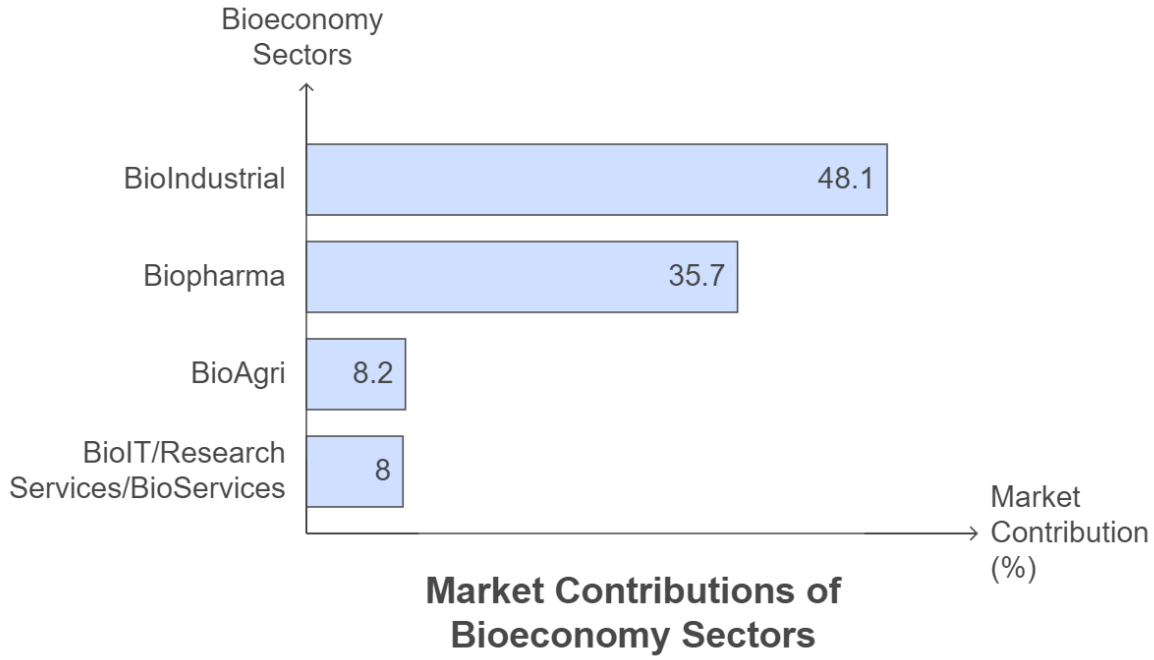

Figure 4: Market contributions of Bioeconomy sectors in India
Source: IBER 2024

Innovation:

India is rapidly advancing in biotechnology innovation, with a strong focus on precision medicine, AI-driven drug development, and collaborative platforms that foster the exchange of ideas. Precision medicine, which tailors healthcare based on genetic, environmental, and lifestyle factors, is gaining momentum in India. In drug development, AI is proving to be a game-changer by expediting the identification of novel disease targets and analyzing clinical trial data to identify potential drug efficacy in different patient populations. These advancements not only shorten R&D timelines but also improve the probability of successful drug approvals, making the drug development process more efficient. For example, Biocon's AI-driven platform is being used to analyze clinical trial data more effectively, identifying patterns and predicting potential responses in different patient populations. This approach has helped streamline the development of biosimilars and monoclonal antibodies, reducing the time required for preclinical and clinical testing [25].

In addition to technological innovations, collaborative initiatives like the Global Bio-India 2023 event serve as platforms for the exchange of groundbreaking ideas. With over 370 exhibitors, the event showcased the latest advancements in biotechnology, biomanufacturing, and AI applications, providing a space for experts from academia, industry, and government to discuss the future of the bioeconomy. Notably, discussions around biomanufacturing and the role of AI and big data in driving future biotech innovations highlighted India's growing leadership in the field. Additionally, initiatives like the JanCare Talent Program exemplify the power of public-private partnerships in fostering health-tech solutions. This program, focused on affordable innovations for underserved populations, supports startups addressing critical healthcare needs in low-resource settings. Products launched through JanCare, such as portable ECG devices and AI-powered maternal care platforms, are paving the way for more accessible healthcare across India's vast public health infrastructure. These efforts reflect India's commitment to advancing its

bioeconomy through innovative solutions that enhance healthcare delivery and contribute to global bio-based industry growth [26].

Challenges:

While India has laid a solid foundation for its bioeconomy through initiatives like the BioE3 Policy and significant government support, several challenges remain that could hinder its growth and long-term sustainability. One of the primary challenges lies in regulatory gaps, particularly in the area of biobanking. Unlike countries such as the U.S., U.K., and Japan, which have well-established regulations governing biobanks, India's current framework is inconsistent and lacks robust protection for individual rights, privacy, and data security. This can undermine public trust and slow down the adoption of precision medicine, a key area of growth for India's bioeconomy. Furthermore, while India is positioning itself as a leader in biopharmaceuticals and next-generation therapeutics, aligning its biobanking laws with global standards will be essential to attract international collaboration and encourage broader public participation in the sector [27]. The ethical and environmental risks associated with biotechnology also pose significant challenges. Innovations in biotechnology—while transformative—often come with profound risks due to the self-sustaining and interconnected nature of biological systems. Accidental misuse or unethical manipulation of biological materials could lead to unintended consequences, such as health risks or environmental damage. The accessibility of cheap, powerful tools and materials only increases these risks, making it crucial for India to approach biotech innovations with caution. This challenge is compounded by the potential for "sustainability tunnel vision," where an overemphasis on economic growth through biomanufacturing, such as bioenergy and biofuels, could lead to unsustainable practices, like deforestation or biodiversity loss. To mitigate these risks, India must adopt a more holistic view of sustainability, balancing both economic and environmental goals as part of its bioeconomy strategy. Drawing lessons from other countries, which have been more effective in integrating these concerns into policy, India could avoid the mistakes of over-exploiting natural resources in pursuit of short-term growth [28].

Another challenge is the monitoring and evaluation of biotechnology's growth. While India has taken significant steps to promote biotech innovation, monitoring mechanisms are often insufficient to track the progress of early-stage companies, startups, and spin-outs, which are crucial for driving long-term sectoral development. In contrast, countries like those in the European Union, Canada, and the U.S. have established comprehensive monitoring frameworks that track the evolution of the bioeconomy. These frameworks include regular data assessments and involve diverse stakeholders, ensuring that programs are adaptable to new developments and public concerns. Without a robust monitoring and evaluation system, India risks missing early signals of exploitation or inefficiencies in its bioeconomy programs, which could slow down progress or lead to wasteful practices. The future of India's bioeconomy will largely depend on its ability to leverage technology, especially artificial intelligence (AI), machine learning (ML), and automation to accelerate research, improve manufacturing processes, and drive sustainable growth. However, the shift to a tech-driven bioeconomy also presents its own set of challenges. For one, the integration of these technologies requires significant investments in infrastructure, skilled labor, and research capabilities, which may not be uniformly available across India. Additionally, there is the risk that an over-reliance on technology could alienate smaller, rural players who are crucial for inclusive growth in sectors like agriculture and healthcare. Moreover, the rapid pace of technological advancement could outstrip the regulatory frameworks in place, leaving gaps in oversight that might allow for malpractices or ethical concerns related to gene editing, data privacy, and digital health [29]. In

summary, while India's bioeconomy is set for remarkable growth, it will require focused attention towards regulatory alignment, ethical considerations, environmental sustainability, and robust monitoring systems.

Conclusion:

In conclusion, India's bioeconomy holds immense potential to drive transformative change across healthcare, agriculture, energy, and environmental sustainability. With a strong foundation laid through initiatives like the BioE3 Policy, Bio-RIDE, and various government-supported programs, India is well-positioned to become a global leader in biotechnology innovation, manufacturing, and entrepreneurship. However, realizing this vision requires addressing critical challenges, including strengthening regulatory frameworks, ensuring ethical practices, balancing economic growth with environmental sustainability, and implementing robust monitoring systems. By learning from the experiences of other countries and embracing a tech-driven, inclusive approach, India can harness the full potential of its bioeconomy while mitigating risks. With careful planning, international collaboration, and a commitment to sustainable development, India's bioeconomy can not only meet the nation's needs but also emerge as a key player in solving global challenges, contributing to both national prosperity and global well-being.

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