

India BioEconomy Report



This report has been prepared for "**Make In India Facilitation Cell for Biotechnology**" of Biotechnology Industry Research Assistance Council (BIRAC) by Association of Biotechnology Led Enterprises (ABLE). The report is written by **Narayanan Suresh**, Chief Operating Officer of ABLE and **Srinivas Rao Chandan**, Editorial Consultant for ABLE under the able guidance of **Mr G S Krishnan**, President, ABLE

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FOREWORD



Dr. Jitendra Singh

Union Minister of State (Independent Charge) for Science and Technology, Minister of State (Independent Charge) for Earth Sciences, Minister of State PMO, Department of Atomic Energy, Department of Space, Personnel, Public Grievances and Pensions

BioE3 Policy: Paving the Way for India's BioEconomy

India is on the verge of a biotech revolution that will shape the future, with our nation leading the charge. Over the past decade, India's BioEconomy has grown significantly, from \$10 billion in 2014 to \$151 billion by the end of 2023. We expect this to reach \$300 billion by 2030, marking a crucial step in our economic transformation and positioning India as a global biotech leader.

The recently launched BioE3 (Biotechnology for Economy. Environment and Employment) Policy is central to this transformation. Under Hon'ble Prime Minister Shri Narendra Modi's visionary leadership, this policy will enable India to lead the global biotech movement, much like how the IT revolution was driven by the West. The BioE3 Policy aims to create a greener, cleaner and prosperous India, contributing significantly to the global economy while protecting our environment.

This policy focuses on key areas: bio-based chemicals and enzymes, smart proteins, precision biotherapeutics, climateresilient agriculture, carbon capture and utilization, and advanced marine and space research. These areas represent the future of biotechnology and will drive growth and innovation across various industries.

The BioE3 Policy will support this transformation by establishing cutting-edge biomanufacturing facilities, bio foundry clusters, and Bio-AI hubs. The biotech hubs will bridge the gap between research and commercial manufacturing, fostering collaboration between startups, SMEs, and established companies. They will also integrate AI to analyze



Together, we can make India the epicenter of the global biotech revolution, driving innovation and ensuring a brighter, greener, and more prosperous future for all. large-scale biological data, paving the way for advancements in gene therapies, food processing, and more.

This policy is also expected to create significant employment opportunities, particularly in tier-II and tier-III cities. The biomanufacturing hubs will use local resources and contribute to regional economic development, promoting more inclusive growth.

TosuccessfullyimplementtheBioE3Policy, various ministries and departments are collaborating and sharing resources. For instance, the Ministry of Electronics and Information Technology will support AI-based biomanufacturing, while the Indian Council of Agricultural Research will focus on developing agribiologicals. Other ministries like New and Renewable Energy, Space, Health, Pharmaceuticals, and Earth Sciences will play critical roles in ensuring the policy's success.

This is our moment to lead the world in sustainable growth. I invite all stakeholders—scientists, entrepreneurs, industry leaders, and policymakers—to join us in this exciting journey. Together, we can make India the epicenter of the global biotech revolution, driving innovation and ensuring a brighter, greener, and more prosperous future for all.

I am happy to note the phenomenal progress made by biotech industry as captured in the **India BioEconomy Report 2024**, brought out by DBT-BIRAC. Powered by the visionary BioE3 policy, I strongly believe that Bharat would emerge as global biotechnology powerhouse with significant contribution of BioEconomy to our shared vision of **'Viksit Bharat'** by 2047. 6

From the DBT Secretary's Desk



Dr. Rajesh S. Gokhale

Secretary to the Government of India, Department of Biotechnology, DG BRIC and Chairman, BIRAC

As the world faces pressing challenges like climate change, resource depletion, and biodiversity loss, the BioE3 Policy positions biomanufacturing as a crucial solution for sustainable growth.

India's BioEconomy: Pioneering Growth Through Innovation and Sustainability

Leap Towards the Next Phase of Biomanufacturing Potential

India's BioEconomy represents a remarkable journey of innovation, growth, and increasing global influence. Over the past decade, it has emerged as a significant force, driven by key sectors such as vaccines, biotherapeutics, diagnostics, bioethanol, enzymatic applications, and bioservices. With more than five sectors generating over \$1 billion each month, India's BioEconomy reached a value of \$151 billion in 2023. This growth is matched by a thriving entrepreneurial landscape, with 1.776 new biotech startups joining the ecosystem, showcasing India's robust innovation capabilities.

Although the concept of the BioEconomy is relatively recent, it has gained global traction, especially as bio-based products impact sectors like food, fuel, healthcare, agriculture, and environmental sustainability. India has been at the forefront of this movement, with the Department of Biotechnology (DBT) playing a pivotal role in fostering an enabling ecosystem for biotechnology research and innovation. DBT/BIRAC's catalytic and enabling initiatives are fostering the Made in India development of vaccines, biosimilars, and medical devices that address critical healthcare challenges.

The annual India BioEconomy Report (IBER) has been instrumental in capturing the sector's rapid transformation. The 2024 edition, prepared by the Make in India Facilitation Cell of BIRAC with research support from the Association of Biotechnology Led Enterprises (ABLE). highlights that India's BioEconomy achieved a landmark value of \$151 billion in 2023, reflecting impressive double-digit growth. The report also gives hope that India is in the right direction to cross the \$300 billion mark by 2030.

Amidst this growth, the Indian government introduced the BioE3 (Biotechnology for Economy, Environment, and Employment) Policy—a strategic framework designed to propel India into the next era of industrialization through highperformance biomanufacturing. As the world faces pressing challenges like climate change, resource depletion, and biodiversity loss, the BioE3 Policy positions biomanufacturing as a crucial solution for sustainable growth.



The BioE3 Policy: Catalyzing India's Biomanufacturing Revolution

The BioE3 Policy is a forward-looking initiative that harnesses the potential of biomanufacturing to drive green growth. This framework is designed to empower Indian institutions, startups, and industries to engage in transformative innovations that address the intertwined challenges of climate change, resource efficiency, and economic development.

Biomanufacturing, which uses engineered biological systems to produce commercially important products, offers a sustainable alternative to traditional manufacturing processes. By utilizing resources more efficiently and reducing environmental impact, biomanufacturing can play a key role in building a greener and more resilient economy.

The BioE3 Policy outlines several enabling mechanisms, known as "मूलांकुर Bio-Enablers', to support biomanufacturing across prioritized sectors. These include Bio-Artificial Intelligence (AI) Hubs, which integrate biological and computational expertise to advance the understanding of living systems and drive innovation in areas such as disease diagnosis, drug discovery, and sustainable agriculture. These hubs will be instrumental in pushing the boundaries of biological research and application.

Additionally. Biomanufacturing Hubs will address gaps in scaling up research and production. These hubs will provide essential infrastructure for pilot and precommercial manufacturing, ensuring that novel bio-based products reach the market efficiently. They will also serve as training centers to develop a skilled workforce adept in biomanufacturing technologies, thus supporting sectoral growth.

Regulatory reforms are also a key component of the BioE3 Policy, focusing on harmonizing standards with global benchmarks to create an enabling environment for research, innovation, and commercialization. The policy emphasizes the need for a data governance framework that balances intellectual property protection with equitable distribution of benefits derived from biomanufacturing.

Partnerships and collaborations, both national and international, will be crucial to the success of India's biomanufacturing initiative. A public-private co-creation model will be central to the initiative, combining expertise from academia, startups, and industry. International collaborations will further enhance India's position as a global hub for biomanufacturing innovation, leveraging the country's strengths in biologics manufacturing to address global challenges.

India's BioEconomy stands at a critical juncture, with the BioE3 Policy serving as a catalyst for the next wave of growth. By fostering high-performance biomanufacturing, the policy aims to drive economic development and contribute to global sustainability efforts. Through strategic interventions, enabling mechanisms, and robust partnerships, India is poised to realize the full potential of its BioEconomy, paving the way for a green and prosperous future.

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From the ABLE President's Desk



G S Krishnan

Honorary President, Association of Biotechnology Led Enterprises (ABLE)

\$151 billion India BioEconomy gets booster shot with BioE3 policy

A decade ago, when the biotech industry set itself reaching \$100 billion BioEconomy by 2020 it was an aspirational move. The industry registered quick growth and the target was revised to \$150 billion by 2025.

But as the India BioEconomy Report (IBER) 2024 indicates, even this lofty goal has been achieved two years before the target date, thanks to impressive adoption of sustainable biotechnologies by many industrials segments and the industry developing a wide range of complex medical products that enhance healthcare significantly.

It is clear now that India's BioEconomy has been making steady progress in the past 10 years. The national BioEconomy's growth with get further momentum with the newly unveiled BioE3 policy of the Department of Biotechnology. It is just the right catalyst to push our BioEconomy to the higher orbit by harnessing the power of biomanufacturing. The Covid-19 response demonstrated India's vaccine manufacturing prowess and BioE3 has the potential to replicate this success in many other sectors of our industry, particularly in the emerging areas of alternate proteins, biofuels, cell and gene therapy and so.

On behalf of the biotechnology industry, ABLE looks forward to working with DBT to take forward this path-breaking initiative and nudge the sector towards a new transformative path, to take global leadership in biotechnology in the next few decades.

I am happy to note that the national BioEconomy is now employing more than 40 lakh people and touching the lives of 2 crore people directly. The wide array of products and services provided by biotechnology touches the lives of almost every Indian and many more around the world daily. As our global biotech profile increases, these numbers are only going to multiply further.

The India BioEconomy Report (IBER 2024) is an attempt to chronicle the growth of our BioEconomy in a scientific manner and also place it in the global context.

Section 2 EXECUTIVE SUMMARY

By Narayanan Suresh & Srinivas Rao Chandan, ABLE

Note on Data Presentation

In this report, numerical figures have been rounded to improve clarity and ease of presentation. For example, \$150.97 billion may be rounded to \$151 billion in charts, tables, or the narrative text. These adjustments are made to enhance readability and should not be interpreted as errors or discrepancies. All data has been carefully sourced and rounded in a consistent manner to maintain accuracy across the report.

In cases where figures are presented without rounding, they reflect the precise values as reported and are accurate as provided. Please note that due to rounding, totals, averages, or shares may differ slightly from calculations using two decimal places. The rounding is intended to make the information more accessible and should not affect the overall analysis or conclusions drawn from the data.

India's BioEconomy Surges to \$151 Billion

India's BioEconomy had another stellar year, reaching \$150.97 billion (\$151 billion) in 2023. This growth highlights the sector's increasing significance as it now accounts for 4.25% of India's Gross Domestic Product (GDP) of \$3.55 trillion in 2023 calendar year. This is slightly more than its share of **4.10%** of national GDP of \$3.35 trillion in 2022 when the BioEconomy contributed \$137.2 billion to the nation. The steady progression reflects a sustained push toward integrating biotechnology across industries, driving innovation, and supporting economic growth.

In 2023, India's BioEconomy registered a **10%** growth rate. However, as the BioEconomy matures, maintaining such high growth will

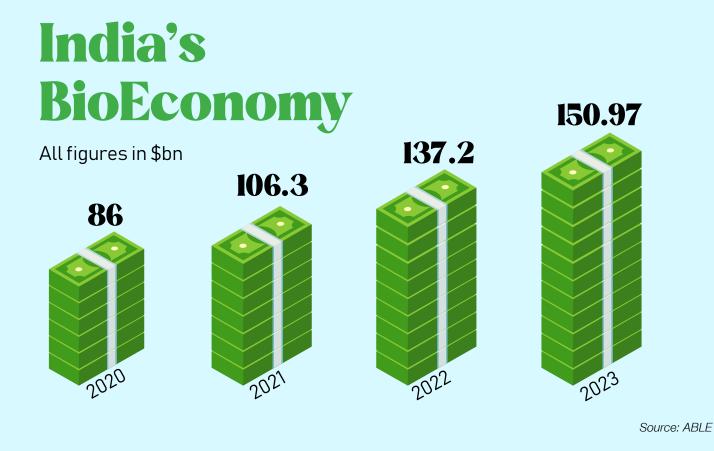
> The national BioEconomy has expanded rapidly, nearly doubling in four years, growing from **\$86 billion** in **2020** to its current valuation, driven by advancements in biotechnology, agricultural innovation, biomanufacturing, and healthcare.

require further innovation, scaling of bio-based solutions, and overcoming infrastructure and policy bottlenecks. The national BioEconomy has expanded rapidly, nearly doubling in four years, growing from \$86 billion in 2020 to its current valuation, driven by advancements in biotechnology, agricultural innovation, biomanufacturing, and healthcare.

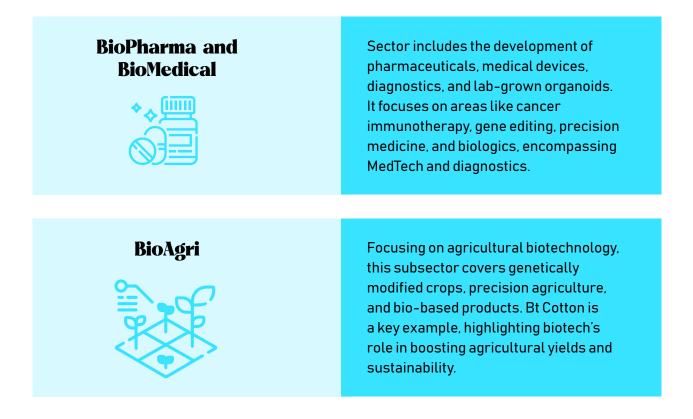
India's BioEconomy reached a significant milestone, surpassing \$150 billion by December 2023. The country was hoping to achieve this target only in 2025 but the \$150 billion milestone has been achieved two years ahead of estimates. This number is significant

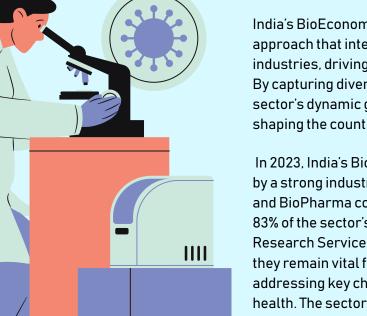
because it positions the country among the Top 5 BioEconomies in the world. And as the country embarks on an ambitious new Biomanufacturing initiative with the new BioE3 program, the leap forward will send India further up on this ladder during the current decade.

The sector's progress underscores its vital role in promoting sustainable development and enhancing resilience in key areas like healthcare and agriculture. Moving forward, strategic investments, technological advancements, and supportive regulatory frameworks will be crucial for harnessing the full potential of this dynamic sector.



India's BioEconomy spans several key subsectors, each contributing significantly to national growth through biotechnology:





India's BioEconomy showcases a comprehensive approach that integrates biotechnology across industries, driving innovation and sustainability. By capturing diverse value chains, it reflects the sector's dynamic growth and evolving role in shaping the country's economic landscape.

In 2023, India's BioEconomy was characterized by a strong industrial focus, with BioIndustrial and BioPharma collectively accounting for over 83% of the sector's value. While BioAgri and BioIT/ Research Services represent smaller shares, they remain vital for driving innovation and addressing key challenges in agriculture and health. The sector's overall growth emphasizes the increasing integration of biotechnology across various industries, positioning India as a key player in the global BioEconomy.

BioIndustrial



This emerging sector deals with biobased chemicals and products created using enzymes, biosynthetic processes, and recombinant DNA technology. It includes biofuels, bioplastics, biogas, and enzymatic applications across industries ranging from beverages to detergents.

BioResearch and BioIT (BioServices)



This segment involves contract research, clinical trials, biotech software and databases, specialized equipment, and bioscience education services.

Key Subsector Contributions to India's BioEconomy

BioIndustrial (48.09% Share, \$72.6 Billion)

The BioIndustrial segment, representing nearly half of the total BioEconomy, is valued at \$72.6 billion. Its dominance reflects the growing adoption of biobased solutions across sectors such as biofuels, chemicals, bioplastics, and enzymatic applications in various industries. The push toward sustainability and green technology has positioned this segment as a cornerstone of India's BioEconomy.

BioPharma (35.65% Share, \$53.8 Billion)

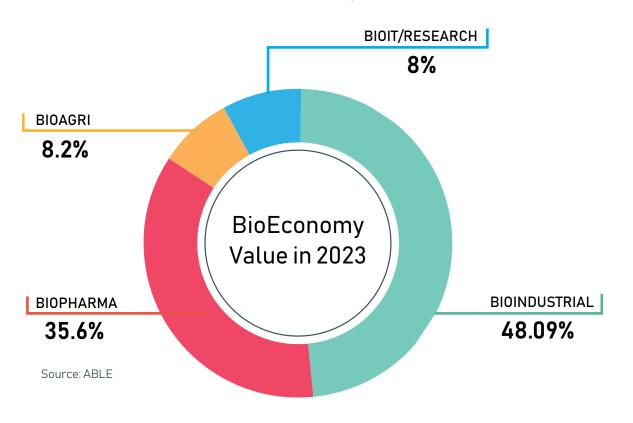
With a significant 35.65% share, valued at \$53.8 billion, this segment is crucial to healthcare and medical innovation. BioPharma's focus on pharmaceuticals, medical devices, diagnostics, and biologics emphasizes India's growing role as a global leader in affordable biopharmaceuticals.

BioAgri (8.24% Share, \$12.4 Billion)

Contributing 8.24% to the total BioEconomy, BioAgri centers on agricultural biotechnology. Valued at \$12.44 billion, this segment enhances agricultural productivity and resilience through genetically modified crops like Bt Cotton and precision agriculture technologies.

BioIT/Research Services (8.02% Share, \$12.1 Billion)

This segment, valued at \$12.1 billion, includes contract research, clinical trials, bioinformatics, biotech software, and bioeducation. It reflects India's growing stature as a global hub for research and development services, offering costeffective solutions in drug discovery and data management.





BIOAGR

Key Pillars Driving India's BioEconomy Success

Capacity Building

Investments in human capital and infrastructure are critical for meeting the demands of emerging biotech technologies, ensuring a skilled workforce and advanced facilities.

Innovation Ecosystem

Developing a robust research environment that integrates institutions, startups, large industries, and regional centers is key to fostering biotech advancements.

Product Commercialization

Promoting public-private partnerships and collaborative models is vital for translating research into commercial products, from lab discoveries to market-ready technologies.

Balanced Research

A strategic balance between basic and translational research is necessary to create a continuous pipeline of innovation and commercialization.

By prioritizing these pillars, India has not only exceeded its BioEconomy goals but has also solidified its position as a global leader in the biotech industry.

Major Biotech Achievements in 2023

A Leading Role in Global Vaccine Manufacturing

India has consolidated its position as a top global vaccine manufacturer. According to the WHO Global Vaccine Market Report, the Serum Institute of India's share of the global vaccine market, excluding COVID-19 vaccines, increased from **19% in 2021** to **24% in 2023**. This growth was largely driven by a rise in the production of pneumococcal conjugate vaccine (PCV), measles-rubella (MR) vaccine, and tetanusdiphtheria (Td) vaccine. The adoption of new technology platforms also played a crucial role in scaling up COVID-19 vaccine production.

The global vaccine market remains highly concentrated, with just nine manufacturers

accounting for **over 70%** of the global supply, excluding COVID-19 vaccines. Notably, three of these manufacturers—**Serum Institute of India**, **Bharat Biotech International Ltd**, and **Biological E Ltd**—are based in India, underscoring the country's significant contribution to global vaccine production.

Indian manufacturers supplied **25%** of the total vaccine volumes purchased by the WHO, with a considerable portion consumed domestically. Moreover, India exported a substantial quantity of vaccines to the WHO African Region, making up approximately **20%** of its total exports.

Serum Institute of India, Bharat Biotech International Ltd, and Biological E Ltd.—are based in India, underscoring the country's significant contribution to global vaccine production



02 A Boost to Energy Independence

India's Ethanol Blended Petrol (EBP) program has been pivotal in reducing the nation's dependence on imported fuels while promoting domestic ethanol production. Government measures such as price regulation, expanded production routes, tax incentives, and the National Policy on Biofuels have significantly accelerated the growth of India's bioethanol industry.

The country's installed bioethanol capacity saw a remarkable surge, reaching **13.8 billion liters** (1,380 crore liters) in 2023, with projections indicating a further expansion to **14.5 billion liters** India has become the world's thirdlargest producer and consumer of ethanol, with production nearly tripling over the past five years

additional production capacities will only increase.

According to the International Energy Agency, this growth underscores India's emerging leadership in bioethanol. However, the sector's future growth depends on the continued implementation of favorable policies, effective cost control, and securing sustainable

> feedstocks. By prioritizing these factors, India can solidify its position as a global leader in biofuel production and further its energy independence.

The launch of the Global Biofuel Alliance (GBA) during the G20 Summit in New Delhi in 2023 marked a major milestone in the

(1,450 crore liters) in 2024. Industry experts attribute this rapid growth to approximately **\$5 billion** in capacity expansion investments over recent years. As a result, India has become the world's **third-largest producer and consumer of ethanol**, with production nearly tripling over the past five years. As the nation progresses towards the **20% blending ratio** in petrol, from the current **14%**, the requirement for shift toward a sustainable energy future. Led by India, Brazil, and the United States, the alliance seeks to reshape the global biofuels landscape through international collaboration, technology exchange, and enhanced policy frameworks. For India, the GBA presents an opportunity to reduce costly oil imports, boost domestic biofuel production, and enhance economic stability. 18

03 Breakthroughs in Precision Healthcare and Agri–Tech Innovations

00 India's 2023 product launches showcased significant advancements in healthcare, biotechnology, and agriculture, emphasizing personalized care, patientcentric solutions, and sustainable practices.

gene therapy techniques. In Bengaluru, inStem's

reducing transfusion-related risks. Voxelgrids

achieved a major milestone in 2023 of launching

initiatives like INSACOG's genomic sequencing,

Biological Data Centre (IBDC), and the Dare2eraD

a compact MRI scanner under DBT's National

Biopharma Mission (NBM). Additionally,

the establishment of India's first National

novel blood bag technology represented a

breakthrough in medical devices aimed at

In healthcare, Medtronic introduced the Symplicity Spyral renal denervation system, a breakthrough minimally invasive therapy for hypertension, while Indian Immunologicals launched Mabella, a live-attenuated vaccine for measles and rubella. Revvity unveiled the T-SPOT.TB test, an advanced tool for latent tuberculosis screening.

Notable progress in remote health monitoring was marked by LifeSigns' Al-powered solution,

enabling 24×7 patient data streaming from rural areas to healthcare professionals. Terumo introduced Occlusafe, a pioneering Balloon-TACE device for liver cancer management, delivering precise, targeted chemotherapy directly to tumors. Personalized healthcare further expanded with MapMyGenome's BeautyMap and at-home microbiome tests, offering DNA-based insights into skin, hair, and gut health. Other notable diagnostics

These innovations illustrate a broader trend toward integrating advanced technology, AI, and genomics into healthcare while addressing critical agricultural needs. India's sectors are steadily advancing toward a more sustainable and precisionfocused future.

TB program underscore the growing role of data-driven research in advancing healthcare solutions.

> Startups have made remarkable strides in **biotech product development**, with 30 launches highlighted at Global Bio-India 2023 in New Delhi. Key innovations include a **Liraglutide biosimilar** for diabetes, Fibroheal's **hemostatic sponge**, OmniBRx's **automated vaccine production**

include Mylab's **neonatal screening device** and CrisprBits' **CRISPR**-based point-of-care tests, setting new standards in affordability and accuracy.

In agriculture, innovations included Netafim's **Toofan drip irrigation system** and Syngenta's **drone spraying technology** for crop protection, both aimed at boosting efficiency, reducing costs, and promoting sustainable farming practices.

India's biotechnology sector continues to prioritize innovation and self-reliance. Key developments included the **approval of the country's first gene therapy clinical trial for Hemophilia A**, a significant step in advanced system, and India's first circulating tumor cell detection test by Actorius. Other noteworthy products include devices for neurofunction testing, waterless solar panel cleaning, and diagnostic tools tailored for rural areas. These advancements span healthcare, agriculture, and industrial biotechnology, reflecting the rapid growth and diversification of India's biotech ecosystem.

These innovations illustrate a broader trend toward integrating advanced technology, AI, and genomics into healthcare while addressing critical agricultural needs. India's BioEconomy sectors are steadily advancing toward a more sustainable and precision-focused future.

India's Biotech Startups Reach 8,531 in 2023 Amid Rapid Growth

India's biotech startup sector continues its rapid ascent, with the last three years showcasing exponential growth. Between 2021 and 2023, the cumulative number of biotech startups surged from **5,365** to **8,531**—a **59% increase**. This rise reflects a consistent upward trajectory since 2016, with a noticeable surge post-2020.

The biotechnology and life sciences sector added 1,128 startups in 2021, followed by 1,390 in 2022, and a record-breaking 1,776 in 2023. This expansion is driven by increased investments, favorable policy shifts, and rising demand for biotech innovations in healthcare and sustainability. The moving average trend line further highlights this consistent growth. BIRAC's entrepreneurship development and strategy support programs have played a pivotal role.

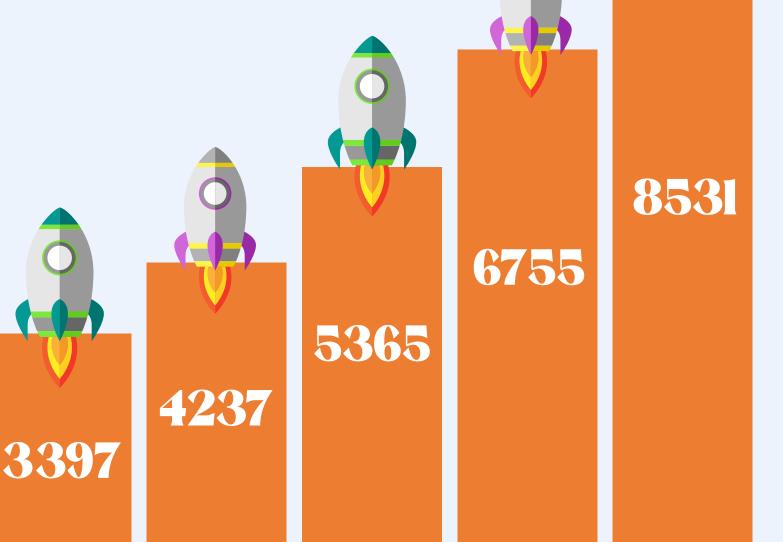
The COVID-19 pandemic acted as a catalyst, turning attention to biopharma, healthtech, and diagnostics. Investors increasingly recognized biotech as a high-impact sector. Government initiatives and global partnerships have also played pivotal roles in sustaining this momentum.



Indian startups have developed over 800 products and raised more than \$600 million in follow-on funding. However, while 2022 saw 31 deals totaling \$938.8 million, 2023 saw a dip, with only 16 deals worth \$199.6 million. On a positive note, the MedTech sector witnessed robust Foreign Direct Investment (FDI) growth, rising from \$370 million in 2022 to \$480

startup activity and increased FDI in MedTech position India as a critical player in the global biotech and health-tech sectors.

million in 2023. In contrast, FDI in pharmaceuticals dropped from \$2 billion to \$1 billion in the same period, signaling shifting investment priorities. Despite these fluctuations, the biotech ecosystem remains vibrant, fueled by domestic innovation and strategic global collaborations. The rising



2022

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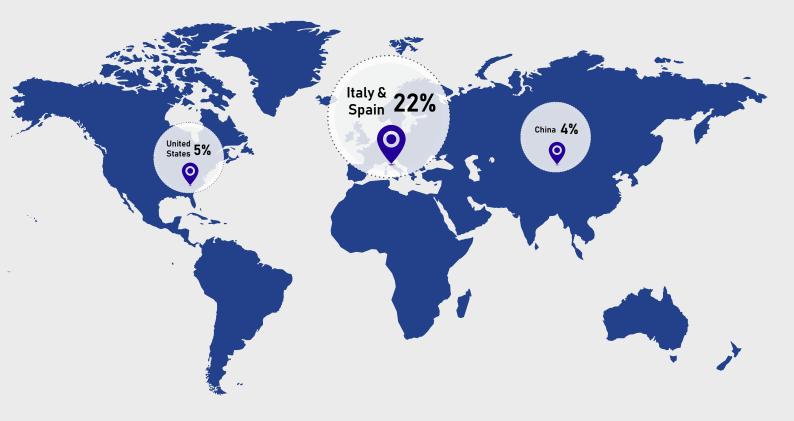
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BioEconomy's Global Impact by 2050

The BioEconomy contributes significantly to various national economies, with **Italy and Spain** leading with **22%** of GDP. The **U.S. and China**, having larger BioEconomy sizes, see lower GDP shares at **5%** and **4%**, respectively. India's BioEconomy share aligns with China at **4.25%**. This data represents the most recent figures available, ranging from 2016 to 2023.

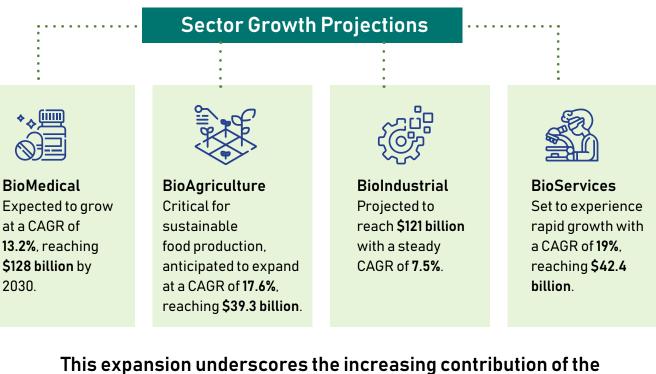
By **2050**, the global BioEconomy is expected to expand significantly, with its contribution to the world economy growing from **\$4 trillion** to **\$30 trillion**, representing nearly **12%** of the projected global GDP of **\$228 trillion**. Emerging markets like India, China, and Indonesia are anticipated to be key drivers of this growth. According to PWC's "The World in 2050" report, emerging markets like India are set to drive global growth, with the **Emerging 7**, or **E7** economies poised to increase their share of world GDP from around **35%** to nearly **50%**. In this context, the BioEconomy is expected to play a pivotal role.

According to projections from Goldman Sachs, visualized by Visual Capitalist, India's real GDP is estimated to reach \$30 trillion, while China's GDP could rise to \$42 trillion and the United States to \$35 trillion by 2050. For India, with its GDP projected at \$22 trillion, the BioEconomy's contribution could range between \$1.4 trillion and \$2.7 trillion, accounting for 6.5% to 12% of the nation's GDP. This growth is poised to play a critical role as India and other nations work toward achieving net-zero carbon emissions, with sustainability initiatives expected to drive economic growth and create millions of high-quality jobs.



06 India's BioEconomy: A Promising Future by 2030

The future of India's BioEconomy looks exceptionally promising, with substantial growth anticipated across key sectors. By **2030**, the India BioEconomy is projected to double to **\$300 billion**, up from **\$151 billion** in 2023, reflecting a robust compound annual growth rate (CAGR) of **12.3%**.



BioEconomy to India's GDP, emphasizing its role as a key driver of sustainable growth and innovation within the country's economic landscape.

Government Initiatives that **boost BioEconomy**

India has embarked on a series of transformative policy reforms to boost its BioEconomy

Here are some of the enabling initiatives



Biomanufacturing Initiative

The Department of Biotechnology (DBT) has launched BioE3 Policy aimed at advancing highperformance biomanufacturing. This initiative focuses on innovation through integrated research and scaleup support, bridging the gap between discovery and commercialization. Key components of the program include Bio-Foundry, Bio-Enabler Hubs such as Bio-Artificial Intelligence Hubs for innovation and Biomanufacturing Hubs for scaling operations. The program is designed to foster the development of biobased products while promoting eco-friendly, lowcarbon-emission manufacturing processes.



Intellectual Property (IP) Guidelines

In September 2023, DBT introduced new IP guidelines to

improve the commercialization of public-funded research. Key reforms include flexible licensing options and protection mechanisms like Marchin Rights to ensure socio-economic benefits. This overhaul aims to bridge the gap between research and practical applications.



Governance and Structural Reforms

The Department of Biotechnology (DBT) has restructured 14 autonomous institutes into the Biotechnology Research and Innovation Council (BRIC). This centralization aims to streamline governance and amplify the impact of biotech research across the nation.



Regulatory Streamlining with BioRRAP

The Biological Research Regulatory Approval Portal (BioRRAP) simplifies the approval process for biological research. This portal streamlines submissions to relevant regulatory agencies, enhancing ease and efficiency in research activities.



These policy initiatives collectively aim to advance India's BioEconomy, promoting innovation, ensuring regulatory efficiency, and fostering sustainable practices to drive economic and environmental progress.



National Medical Device Policy

Announced in May 2023, this policy aims to elevate India's medical device sector by enhancing quality, affordability, and innovation. It introduces a singlewindow clearance system, encourages industry-academia collaborations, and aims to attract investments through targeted incentives.

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National Green Hydrogen Mission

The mission, with nearly a \$2.4 billion budget, positions India as a leader in Green Hydrogen production and utilization. It includes the Strategic Interventions for Green Hydrogen Transition (SIGHT) Programme, promoting domestic manufacturing and international collaboration.



Regional Initiatives

Uttar Pradesh's Pharmaceutical and Medical Devices Industry Policy 2023 and Tamil Nadu's Ethanol Blending Policy exemplify regional efforts to support local industries. Uttar Pradesh's policy aims to streamline regulatory processes and attract investments, while Tamil Nadu's policy focuses on enhancing ethanol production to meet national blending targets.



Guidelines for Genetically Engineered Insects

The new guidelines for research on genetically engineered insects, updated in 2023, ensures stringent biosafety measures while maximizing the benefits of genetic engineering. These guidelines provide a comprehensive regulatory framework for safe and responsible research practices.

Startups and Employment Growth

Complementing this expansion, the number of biotech startups in India is expected to surge from 8,531 in 2023 to an impressive 35,460 by 2030. This growth will significantly boost employment, with the BioEconomy projected to create 35 million jobs.

The sector's development highlights its increasing contribution to India's GDP and its pivotal role in driving sustainable growth, innovation, and large-scale employment across the nation. **35,460** STARTUPS BY 2030

35 MILLION

JOBS TO BE CREATED

Section 3

India BioEconomy Overview

A Comprehensive Analysis of the India BioEconomy and Segment Performance: **Growth, Trends, and Milestones**

India's BioEconomy: Charting New Growth

By the end of 2023, India's BioEconomy reached a valuation of **\$151 billion**, marking a notable **10%** increase from the previous year's figure of **\$137 billion**. This growth underscores the sector's dynamic evolution and expanding influence.

Yearly Growth Overview: From \$137.2 Billion in 2022 to \$151 Billion in 2023. In 2022, the BioEconomy was valued at \$137.2 billion. By the end of 2023, this figure had increased to \$151 billion, marking an overall growth of approximately 10%.

Overall Size & Structure

BIOECONOMY 2023

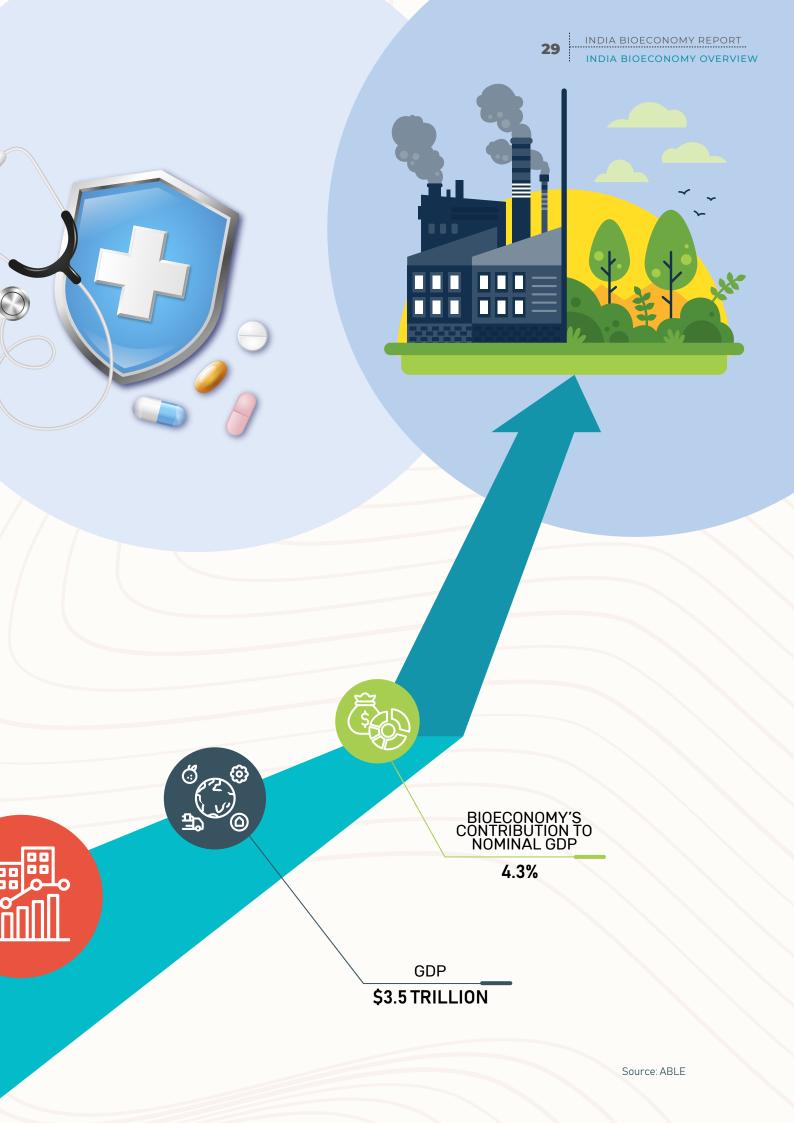
India's bioeconomy has witnessed a phenomenal rise over the past decade, transforming from a fledgling sector to a powerhouse contributing significantly to the nation's economic growth. In 2003, India's bioeconomy stood at a modest \$2 billion. The initial phase witnessed steady growth, reaching \$5 billion by 2008, with the bioeconomy tripling to \$11 billion by 2013. This period marked the beginning of a remarkable upsurge.

From 2013 to 2018, the bioeconomy experienced an exponential surge, reaching a staggering \$55 billion – a phenomenal 400% growth. The momentum continued between 2018 and 2023, with the bioeconomy reaching a colossal \$151 billion, reflecting a robust 174% growth. This translates to a staggering 13.6-fold increase since 2013.

The state governments are setting targets as a factor of national BioEconomy Values and as part of the Gross State Domestic Product (GSDP) considerations. More about such examples will be shared in subsequent sections.

START-UPS 8,531

BIOECONOMY VALUE \$151 BILLION



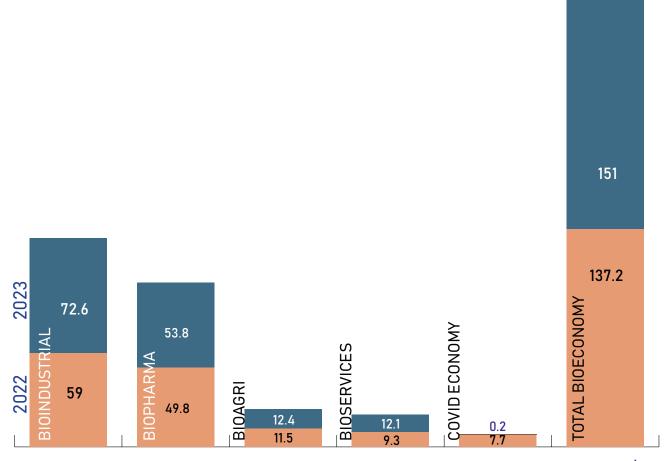
This growth was not uniform across all segments, with BioIndustrial and BioPharma emerging as the primary drivers.

BioIndustrial: The largest segment, BioIndustrial, contributed **\$59.0 billion** to the BioEconomy in 2022, accounting for **43%** of the total. In 2023, this segment grew to **\$72.6 billion**, representing a **23%** increase and solidifying its dominant position with a **48%** share of the total BioEconomy.

BioPharma: The BioPharma sector, the second-largest contributor, saw its value rise from **\$49.8 billion** in 2022 to **\$53.8 billion** in 2023, reflecting a growth of **8%**. Although its overall share slightly decreased from **36%** to **35%**, BioPharma remained a crucial component of the BioEconomy. **BioAgri**: The BioAgri segment experienced modest growth, from \$11.5 billion in 2022 to \$12.4 billion in 2023, an increase of 8%. Its share of the BioEconomy remained relatively stable at around 8% to 9% annually.

BioServices: The BioServices segment also saw growth, increasing from **\$9.3 billion** in **2022** to **\$12.1 billion** in **2023**, a 30% rise. This segment's share of the total BioEconomy grew from 7% to 8%, reflecting its expanding role.

Covid-Related Contributions: In 2022, Covid-related activities contributed \$7.7 billion, accounting for 6% of the total BioEconomy. However, as the pandemic's impact waned, this contribution dropped to zero in 2023, indicating a shift towards a post-pandemic BioEconomy.



Source: ABLE

All figures in \$ bn

Quarterly Performance and Trends: Analyzing the Fluctuations

Quarterly data for 2022 and 2023 reveals fluctuating performance across segments, with certain quarters outperforming others. These fluctuations can be attributed to varying economic conditions, changes in demand, and the evolving focus of different segments.

2023 Quarterly Breakdown

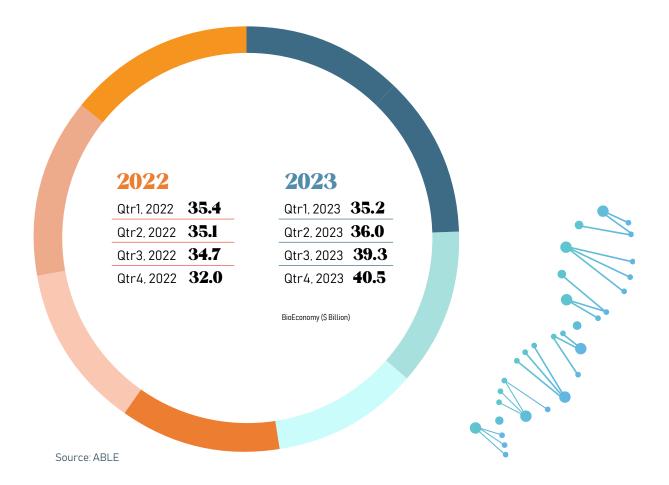
Q1 2023: The year began with a total of **\$35.2 billion**, with BioIndustrial and BioPharma contributing **\$17.2 billion (49%)** and **\$12.4 billion (35%)**, respectively. BioAgri contributed **\$2.9 billion (8%)**, while BioServices added **\$2.6 billion (7%)**.

Q2 2023: A modest increase to **\$36.0 billion** was recorded, driven by growth in BioIn-

dustrial **(\$17.6 billion, 49%)** and BioPharma **(\$13.2 billion, 37%)**. BioAgri's contribution remained stable at **\$2.7 billion (8%)**, and BioServices held steady at **\$2.5 billion (7%)**.

Q3 2023: This quarter marked a significant boost, with the BioEconomy totaling \$39.3 billion. BioIndustrial led with \$18.6 billion (47%), while BioPharma increased to \$14.0 billion (36%). BioAgri saw an increase to \$3.4 billion (9%), and BioServices rose to \$3.3 billion (8%).

Q4 2023: The upward trend continued in the final quarter, reaching a peak of \$40.5 billion. BioIndustrial contributed \$19.1 billion (47%), BioPharma \$14.2 billion (35%), Bio-Agri \$3.4 billion (8%), and BioServices \$3.7 billion (9%).



Half–Yearly Trends Comparing HI and H2 Performance

The half-yearly analysis provides insights into how the BioEconomy performed in the first and second halves of each year.

2023 Half-Year Analysis:

H1 2023: The first half of 2023 exhibited stronger performance, with the BioEconomy totaling \$71.2 billion. BioIndustrial and BioPharma remained the dominant segments, contributing \$34.9 billion (49%) and \$25.6 billion (36%), respectively. BioAgri added \$5.6 billion (8%), while BioServices contributed \$5.1 billion (7%).

H2 2023: The second half of 2023 marked a significant improvement, with the Bio-Economy reaching \$79.8 billion. Biolndustrial continued to lead with \$37.7 billion (47%), while BioPharma increased to \$28.2 billion (35%). BioAgri grew to \$6.9 billion (9%), and BioServices to \$7.0 billion (9%).

Year	Period	BioEconomy (\$ Billion)
2022	H1	70.5
2022	H2	66.7
2022	Yearly Total	137.2
2023	H1	71.2
2023	H2	79.8
2023	Yearly Total	151.0

Source: ABLE



INDIA BIOECONOMY REPORT

INDIA BIOECONOMY OVERVIEW

Overview of Segments

INDIA BIOECONOMY HIGHLIGHTS (2023)

Based on the latest data for 2023, here's an updated breakdown of the India BioEconomy:



1. BIOINDUSTRIAL BIOECONOMY SIZE: \$72.6 BILLION (48.4% SHARE)

Key Highlights

- Mainstay of the BioEconomy with nearly half the market share.
- O Diverse applications in enzymes, biofuels, and industrial biotechnology.
- Growth driven by government initiatives like Atmanirbhar Bharat and the focus on energy independence.



2. BIOPHARMA BIOECONOMY SIZE: \$53.8 BILLION (35.8% SHARE)

Key Highlights

- \odot Significant contributor, emphasizing pharmaceuticals and biotech advancements.
- ⊘ Growing acceptance of biosimilars in global markets propelling growth.
- Promising trajectory with an expected BioEconomy Size of nearly \$63 billion by 2025.



3. BIOAGRI BIOECONOMY SIZE: \$12.4 BILLION (8.3% SHARE)

Key Highlights

- Solution Focus on agricultural applications like Bt Cotton, biopesticides, and other agricultural biotechnologies.
- Potential for substantial growth with the growing emphasis on circular economy practices.



4. BIOIT / RESEARCH SERVICES BIOECONOMY SIZE: \$11.1 BILLION (7.4% SHARE)

Key Highlights

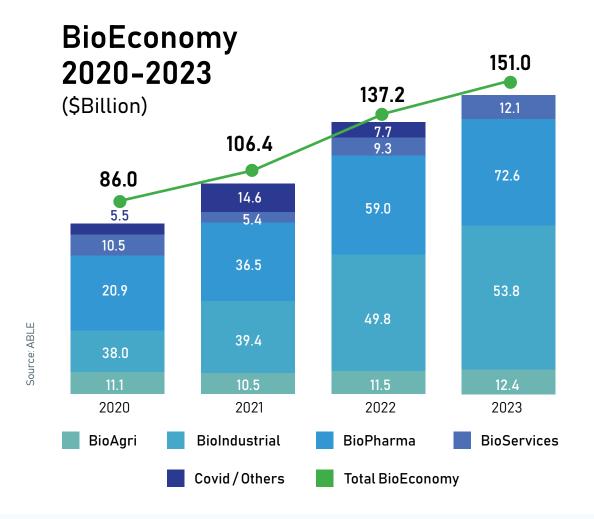
- Rising importance of Information Technology (IT) in the BioTech sector.
- Strong presence in Contract Research Organizations (CROs), Contract Development and Manufacturing Organizations (CDMOs), and BioIT services.
- Projected significant growth, potentially quadrupling to \$26.6 billion by 2025, reflecting the critical role of IT in bio advancements.



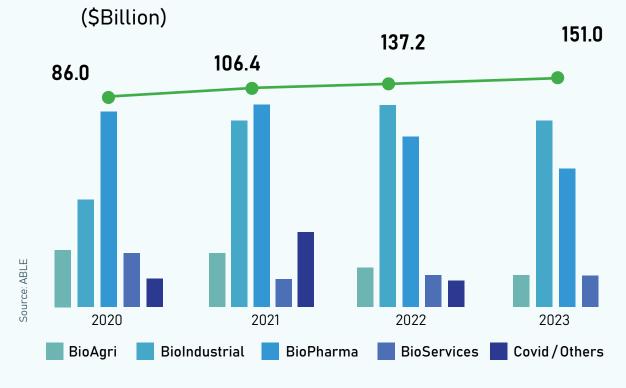
5. COVID ECONOMY BIOECONOMY SIZE: \$0.2 BILLION (0.1% SHARE)

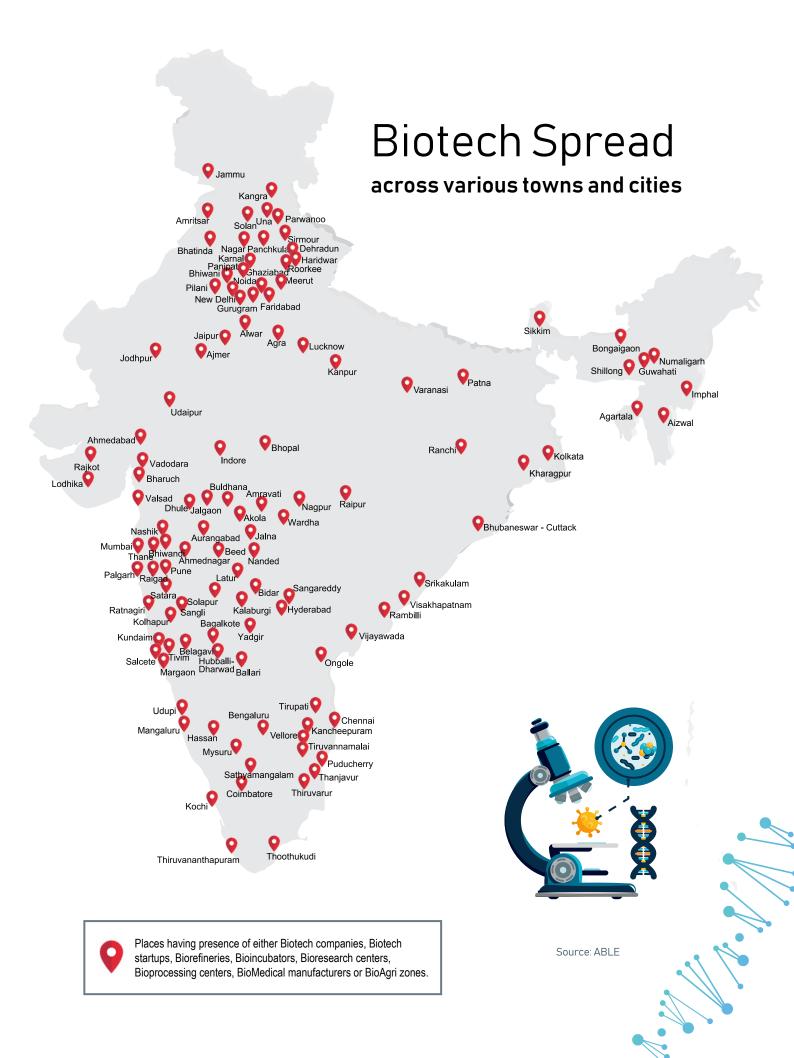
Key Highlights

- Reflects the impact and adaptation during the COVID-19 pandemic.
- ⊘ Contribution from COVID-related vaccines, testing, and services.
- Oemonstrates the BioEconomy's resilience and adaptability during global challenges.



BioEconomy by Segments





KEY GROWTH DRIVERS

Flourishing BioPharma and BioServices
The BioPharma segment witnessed an 8%
increase to \$53.8 billion in 2023, while BioIT/
Research Services/BioServices surged by
19.4% to \$11.1 billion, highlighting the growing
importance of research and development.

BioIndustrial on the Rise

The BioIndustrial segment displayed a steady rise of 23.1% to \$72.6 billion in 2023, indicating increasing adoption of bio-based products and processes in various industries.

- BioAgri Shows Promise BioAgri, though experiencing a modest growth of 7.8% to \$12.4 billion in 2023, holds promise for future development as the focus on sustainable agriculture intensifies.
- Covid-19 Impact
 The Covid Economy segment, which boomed
 during the pandemic, understandably witnessed
 a significant decline of 97.4% to \$0.2 billion in
 2023, reflecting the return to normalcy.







SEGMENT PERFORMANCE ANALYSIS

Delving into the Details

The performance of each segment within the BioEconomy offers a deeper understanding of the dynamics driving growth.

BioAgri: Modest but Steady Growth

The BioAgri segment, while smaller in comparison to others, has shown consistent growth over the two-year period. In 2022, BioAgri contributed \$11.5 billion, representing 8% of the total BioEconomy. By 2023, this segment grew to \$12.4 billion, maintaining its share at around 8%.

2023 Quarterly Performance: In 2023, BioAgri began with a lower contribution of \$2.9 billion in Q1 but showed recovery in Q3 and Q4, reaching \$3.4 billion in both quarters. This rebound was driven by increasing demand for sustainable agricultural practices and innovations in bio-based fertilizers and pest control solutions. Year-on-Year Growth: The BioAgri segment grew by 8% from 2022 to 2023, reflecting the sector's potential for steady expansion as the global focus on sustainable agriculture continues to intensify.

BioIndustrial: The Powerhouse of the BioEconomy

BioIndustrial has consistently been the largest segment within the BioEconomy, and its growth trajectory underscores its critical role.

2023 Performance: BioIndustrial continued to grow in 2023, with its total contribution reaching \$72.6 billion, or 48% of the BioEconomy. The segment's quarterly performance peaked in Q4 with a contribution of \$19.1 billion, reflecting the expanding demand for sustainable industrial solutions. The growth was also fueled by significant investments in bio-manufacturing and the development of biobased alternatives to traditional industrial products.

Ye**ar-on-Year Growth:** The BioIndustrial segment grew by approximately 23% from 2022 to 2023, underscoring its dominance and potential for further expansion as industries continue to transition towards more sustainable practices.

BioPharma: A Vital but Fluctuating Sector

BioPharma: A Critical Sector with Variable Performance BioPharma, the second-largest segment, has shown variable performance over the two years, influenced by both external and internal factors.

2023 Performance: BioPharma showed resilience in 2023, with its total contribution increasing to \$53.8 billion, or 35% of the BioEconomy. The segment saw steady quarterly growth, particularly in the second half of the year, with Q4 contributions reaching \$14.2 billion. This growth was driven by ongoing innovations in biotechnology, personalized medicine, and the expansion of biosimilars in the market.

2023 Share: In 2023, BioPharma's share remained relatively stable, ranging from 35% in Q1 to 35% in Q4. Despite the fluctuations, BioPharma's importance within the BioEconomy is evident, and its potential for future growth remains strong.

Year-on-Year Growth: BioPharma grew by 8% from 2022 to 2023. While this growth was modest compared to other segments, it highlights the sector's ongoing importance and its potential for future expansion as new biopharmaceutical products continue to emerge.

BioServices: An Emerging Force in the BioEconomy

BioServices, while smaller in scale, has shown significant growth, reflecting its increasing role in the BioEconomy.

2023 Performance: BioServices experienced substantial growth in 2023, with its total contribution rising to \$12.1 billion, or 8% of the BioEconomy. The segment's quarterly contributions increased steadily, peaking at \$3.7 billion in Q4. This growth was driven by the expanding demand for outsourced R&D services, clinical trials, and other specialized bio-services that support the development and commercialization of biotechnological products.

Year-on-Year Growth: The BioServices segment grew by 30% from 2022 to 2023, reflecting its growing importance as a support system for the entire BioEconomy. As the demand for biotechnological innovations continues to rise, the BioServices sector is poised for further expansion.

Covid-Related Contributions: A Declining Impact

The Covid-19 pandemic had a significant impact on the BioEconomy in 2022, but its influence waned by 2023.

2023 Performance: By 2023, Covid-related contributions had dwindled to negligible levels, effectively dropping to zero by Q1. This decline reflects the broader shift towards a post-pandemic economy, where the focus has moved away from emergency response and towards longer-term sustainability and innovation within the BioEconomy.

Sub–Sector Movers SUB-SECTOR MOVERS

Biolndustrial Leading the Charge



The BioIndustrial segment, encompassing industries that utilize biological resources for non-food applications, boasts the most impressive growth at 23.1%. This surge suggests a growing demand for bio-based fuels, and growing use of enzymes in other industries like potable alcohol, textiles, and driven by increasing environmental concerns and a push for sustainable alternatives. As awareness of the environmental impact of traditional materials grows, the BioIndustrial segment stands poised for continued expansion.



Biolndustrial BioEconomy Surges to \$72.46 Billion in 2023: Alcoholic Beverages, Biofuels, and Enzymes Drive Growth

The BioIndustrial segment of the global BioEconomy experienced a significant expansion in 2023, reaching a total market value of **\$72.46 billion**. This marks an impressive **22.71%** increase from the previous year, fueled by growth across various sectors, particularly alcoholic beverages, biofuels, and enzymatic applications.

Beverages Lead the Way

The alcoholic beverages sector was a major driver of this growth. Potable and industrial alcohol alone accounted for **\$16.20 billion** of the total BioEconomy value, reflecting an **11.57%** increase from 2022. The rise in value was bolstered by a surge in alcohol content and an 18% rise in volume. Yeast and enzymes played a crucial role in this segment, aiding in the production of alcohol from raw materials like molasses and grain.

The beer industry also showed strong performance, growing by 20% to reach \$6 billion. The complete market value of beer, underpinned by biotechnological processes such as fermentation, contributed significantly to this increase. Meanwhile, the wine segment, though smaller, saw a staggering 56.25% growth, driven by increasing market acceptance and production.

Biofuels See Continued Expansion

Biofuels were another key contributor to the BioIndustrial BioEconomy, with the segment growing by 17.91% to reach **\$7.90 billion**. Ethanol blending increased to **12%** in 2023, up from **10%** the previous year, leading to a substantial rise in value. The total volume of ethanol blended reached **505 crore liters**, emphasizing the sector's critical role in advancing sustainable energy solutions.

Enzymatic Applications Across Industries

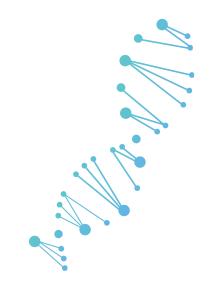
Enzymes continued to be a cornerstone of the BioEconomy, with their applications spanning multiple industries. The textile sector, reliant on detergent enzymes for the production of fabrics like jeans and knits, grew by 18.84% to achieve a market value of \$8.20 billion. Similarly, enzymatic detergents for laundry and dishwashing saw growth, with the latter experiencing an 87.50% surge, reflecting growing consumer adoption. In the food and dairy industry, enzymes and yeast were instrumental in the production of various products. The bread segment, for instance, reached **\$2.68 billion**, while the biscuit segment grew by **33.33%** to hit **\$0.80 billion**. Cheese and ice cream also showed significant growth, driven by the increasing use of enzymes in their production processes.

Probiotics and Feed Enzymes on the Rise

The aquaculture and poultry sectors, both heavily dependent on probiotics and feed enzymes, also contributed to the BioEconomy's growth. The shrimp industry, valued at **\$8.30 billion**, saw a **13.70%** increase as probiotics became integral in avoiding antibiotics. The poultry feed market, valued at **\$12.60 billion**, grew by 22.33%, with enzymes playing a vital role in bird nutrition and growth.

Outlook

The BioIndustrial BioEconomy's robust performance in 2023 underscores the growing importance of biotechnology in various industries. With continued advancements in enzyme and probiotic applications, this segment is poised for further expansion, solidifying its role as a key driver of economic growth in the years to come.





SUB-SECTOR MOVERS

ALCOHOLIC BEVERAGES

The Indian alcohol market is experiencing significant growth, with a projected CAGR of 7.0% until 2033. This is driven by factors like a growing middle class, urbanization, and evolving lifestyles. India's drinking culture is becoming more sophisticated, with a shift towards premium and craft beverages, particularly among young adults. This trend is bolstered by India's position as the global leader in whisky, rum, and brandy consumption, with an expected 61% growth in the premium whisky segment alone.

The influx of a young population reaching legal drinking age (estimated at 100 million in the next five years) further fuels market expansion. Despite the optimistic outlook, the industry faces challenges related to rising input costs, particularly for key ingredients and packaging materials. Complex and varying regulations across different Indian states create operational hurdles and necessitate strategic navigation for brands. The success of Indian single malts signifies a focus on quality and potential for India to become a production and export hub for alcoholic beverages. Overall, the Indian alcohol market presents a compelling case of robust growth. By addressing operational challenges and adapting to evolving consumer preferences, the industry can ensure its long-term success and responsible development.



ETHANOL PRODUCTION CAPACITY ON THE RISE

As of the end of 2023, India was the third largest producer of blended ethanol. India had a significant ethanol production capacity of 1,380 crore liters. The reliance is on molasses-based production which was about 875 crore liters compared to grain-based alcohol of 505 crore liters.

The Indian government's ambitious target of 20% ethanol blending in petrol by 2025 necessitates a substantial increase in capacity. Estimates suggest a requirement of 1,700 crore liters, considering operational efficiency.

The Ethanol Blended with Petrol (EBP) program and various interest subvention schemes implemented since 2018 have demonstrably yielded positive results. Ethanol supply to Oil Marketing Companies (OMCs) has skyrocketed from 38 crore liters in 2013-14 to 505 crore liters in 2023. This translates to a blending percentage increase from 1.53% to a targeted over 12% in the same period.

Overall, India's ethanol production is on a positive trajectory, driven by government initiatives. However, addressing the feedstock mix and scaling up production remain critical for achieving the long-term goals of the EBP program, which accounted for 48.4 percent share of the total BioEconomy.

BIOFUELS REVOLUTIONIZE BIOECONOMY

Biofuels have emerged as a game-changer, propelling the bioeconomy forward. From 2013 to 2023, the average ethanol blending rate with petrol witnessed a staggering 7.7-fold increase, reaching 12%. This period also saw a 3.5-fold growth in the number of bioethanol refineries, along with a 5.4-fold increase in production capacity. Consumption of bioethanol has also skyrocketed, reflecting a remarkable 17.4-fold growth.

India's BioPharma Sector Powers a \$53.8 Billion Surge in BioEconomy Growth



The BioPharma sector has emerged as a cornerstone of the nation's BioEconomy, driving a remarkable \$53.8 billion in economic value. This impressive growth is underpinned by three critical pillars: vaccines, therapeutics, and diagnostics & medical devices, each contributing significantly to the sector's overall impact on both the domestic and global stage.

Vaccines

India's vaccine industry is a global leader, with an unparalleled capacity for largescale production. In 2023 alone, India produced over 3 billion doses of various vaccines, meeting the needs of both domestic and international markets. This extensive production capability not only supports global immunization efforts but also solidifies India's reputation as a vital player in global public health. The economic value generated by this sector goes beyond mere revenue from vaccine sales; it also encompasses the long-term health benefits, such as lives saved and the prevention of diseases, which contribute to a healthier global population. The vaccine segment alone is valued at \$15.5 billion within the BioEconomy, reflecting its critical role in safeguarding public health worldwide.



VACCINE PRODUCTION

India has witnessed a **4-fold increase** in vaccine production from **3 billion doses** (2003-13) to a staggering **11.5 billion doses** (2013-23).

DIAGNOSTIC TESTS

The number of diagnostic tests conducted in India has grown by **5 times**, reaching **5 billion tests** (2013–23) from **1 billion tests** (2003–13).

The therapeutics segment is another major contributor to the BioPharma sector's economic impact, with a total value of **\$19.4 billion**. This segment is anchored by two key subsegments: biosimilars and fermentation-based APIs and formulations. India has become a global leader in biosimilars, producing a wide range of products that have revolutionized the treatment of chronic and life-threatening conditions. With companies like Biocon Biologics, Dr. Reddy's Laboratories, Intas, and Reliance Lifesciences are at the forefront, the biosimilars segment alone contributes **\$13.4 billion** to the BioEconomy. Additionally, the fermentation-based API and formulation industry, which includes the production of critical drugs such as statins, adds another **\$6 billion** in economic value. These contributions highlight India's role as a hub for pharmaceutical innovation, where advancements in therapeutics are driving both economic growth and improved healthcare outcomes.

Diagnostics & ledical Devices

The diagnostics and medical devices segment is also a key pillar of India's BioPharma sector, contributing \$19.4 billion to the BioEconomy. With the rapid advancement of technology and the expansion of healthcare infrastructure, India is making significant strides in this area. The diagnostics segment, in particular, is crucial for early disease detection, which is essential for effective treatment and better health outcomes. As India continues to innovate and expand its capabilities in diagnostics and medical devices, this segment is poised to play an increasingly important role in the global healthcare landscape.



Indian Vaccine Manufacturing: Pioneering Global Health Solutions

In a significant milestone for global health, the World Health Organization (WHO) recently awarded pregualification status to the R21/ Matrix-M malaria vaccine, a collaborative effort between the Serum Institute of India (SII) and the University of Oxford. This groundbreaking vaccine, designed to combat malaria—a disease responsible for over 600,000 deaths annually, mostly among children in Africa—promises to reduce fatalities significantly. SII, the world's largest vaccine manufacturer, is poised to produce 100 million doses annually. Serum Institute's role in global vaccine production is unparalleled. With 3.5 billion doses capacity annually, SII's portfolio includes vaccines for measles, polio, HPV, and now malaria.

India has solidified its position as a global vaccine manufacturing powerhouse. SII's share of global vaccine volumes, excluding **COVID-19**, went up from **19%** in **2021** to **24%** in **2023**, reflecting increased production of vaccines such as PCV, MR, and Td. SII's state-of-the-art facilities, including the world's largest pandemic production facility, are critical in addressing health crises and preparing for potential outbreaks like Monkeypox and Ebola.

India's indigenous vaccine successes further illustrate its growing biopharmaceutical prowess. CERVAVAC, India's first indigenously developed quadrivalent Human Papillomavirus (qHPV) vaccine, was developed to combat cervical cancer through a collaboration between SII, DBT, BIRAC, and the Bill and Melinda Gates Foundation. ZyCoV-D, the world's first plasmid DNA COVID-19 vaccine, offers needle-free delivery, while CORBEVAX, the nation's first protein subunit vaccine for COVID-19, played a key role in mass immunization efforts. Additionally, GEMCOVAC-19, India's first mRNA COVID-19 vaccine, and iNCOVACC, the country's first intranasal COVID-19 vaccine, highlight India's capabilities in advanced vaccine technologies. GEMCOVAC-OM, India's first Omicron-specific mRNA booster, contributes to the fight against emerging variants, positioning the country at the forefront of global vaccine innovations.

The vaccine manufacturing sector in India is expanding beyond the regular manufacturers. Some examples include:

Dr. Reddy's: Entered vaccine marketing with Sputnik V and is exploring mRNA technology for future vaccines.

Zydus: Introduced India's first DNA vaccine with a needle-free delivery system for children aged 12 and above.

Biocon: Partnered with SII to access 100 million doses annually and commercialize vaccines globally, including COVID-19 vaccines.

India's vaccine manufacturing sector continues to evolve, with emerging opportunities and innovations shaping the future of global health. As the market grows, India's leadership in vaccine manufacturing is set to enhance its global health impact and drive forward innovative solutions for future public health needs.

SUB-SECTOR MOVERS

Indian Diagnostics and Medical Devices Sector – Poised for Growth Amidst Rising Healthcare Needs

The Indian diagnostics industry is undergoing a major transformation, becoming an increasingly vital component of the nation's healthcare system. Valued at approximately **\$12 billion** in 2023, the sector is experiencing robust growth, driven by a rising prevalence of chronic diseases, an aging population, heightened demand for preventive healthcare, and supportive government initiatives.

The market is notably fragmented, with standalone centers holding **46%** of the market share, private hospital-based labs accounting for **28%**, and national chains representing just **6%**. This fragmentation presents both challenges and opportunities. As the market matures, the trend towards consolidation through strategic mergers and acquisitions is expected to create stronger, more capable entities that can deliver consistent, high-quality diagnostic services nationwide.

Pathology remains the dominant segment, contributing around **58%** of the market. This field,which focuses on the examination of tissues, cells, and body fluids to diagnose diseases, is complemented by radiology, which includes imaging techniques like CT scans, MRIs, and ultrasounds, making up the remaining **42%**. Both areas are projected to continue driving growth as technological advancements enhance diagnostic accuracy and accessibility. The integration of digital technologies is reshaping the diagnostics landscape. Innovations such as telemedicine, AI-driven diagnostic tools, and home-based diagnostics are broadening healthcare access, particularly in remote or underserved regions. These advancements not only improve convenience but also cater to evolving clinical needs, fostering the development of new business models and specialized diagnostic services.

Government policies, including Ayushman Bharat, and increased health insurance coverage are playing a significant role in expanding access to diagnostic services. These initiatives are making healthcare more affordable and driving sector growth by broadening the patient base, which is crucial for the sector's continued expansion. In parallel, the medical devices market in India, valued at around **\$8 billion**, is also poised for substantial growth.

High-growth segments such as clinical chemistry, immunoassay, and histopathology are expected to benefit from the increasing demand for advanced diagnostics and the rising prevalence of non-communicable diseases (NCDs). The expansion of diagnostic labs into tier 2 and 3 cities represents a crucial step towards decentralizing healthcare. Partnerships with small to medium-sized hospitals in these regions are enhancing the accessibility of high-quality diagnostic services beyond major urban centers. This decentralization is essential for addressing the healthcare needs of a broader segment of the population, particularly as India contends with a growing burden of chronic diseases and an aging demographic.

SUB-SECTOR MOVERS

BioIndustrial BioEconomy Surges to \$72.46 Billion in 2023

Alcoholic Beverages, Biofuels, and Enzymes Drive Growth

The BioIndustrial segment of the BioEconomy experienced a significant expansion in 2023, reaching a total market value of **\$72.46 billion**. This marks an impressive **22.71%** increase from the previous year, fueled by growth across various sectors, particularly alcoholic beverages, biofuels, and enzymatic applications.

Beverages Lead the Way

The alcoholic beverages sector was a major driver of this growth. Potable and industrial alcohol alone accounted for **\$16.20 billion** of the total BioEconomy value, reflecting an **11.57%** increase from **2022.** The rise in value was bolstered by a surge in alcohol content and an 18% rise in volume. Yeast and enzymes played a crucial role in this segment, aiding in the production of alcohol from raw materials like molasses and grain.

The beer industry also showed strong performance, growing by **20%** to reach **\$6 billion**. The complete market value of beer, underpinned by biotechnological processes such as fermentation, contributed significantly to this increase. Meanwhile, the wine segment, though smaller, saw a staggering **56.25%** growth, driven by increasing market acceptance and production.

Biofuels See Continued Expansion

Biofuels were another key contributor to the BioIndustrial BioEconomy, with the segment growing by **17.91%** to reach **\$7.90 billion**. Ethanol blending increased to 12% in 2023, up from **10%** the previous year, leading to a substantial rise in value. The total volume of ethanol blended reached **492 crore liters**, emphasizing the sector's critical role in advancing sustainable energy solutions.

Enzymatic Applications Across Industries

Enzymes continued to be a cornerstone of the BioEconomy, with their applications spanning multiple industries. The textile sector, reliant on detergent enzymes for the production of fabrics like jeans and knits, grew by **18.84%** to achieve a market value of **\$8.20 billion**. Similarly, enzymatic detergents for laundry and dishwashing saw growth, with the latter experiencing an **87.50%** surge, reflecting growing consumer adoption.

In the food and dairy industry, enzymes and yeast were instrumental in the production of various products. The bread segment, for instance, reached **\$2.68 billion**, while the biscuit segment grew by **33.33%** to hit **\$0.80 billion**. Cheese and ice cream also showed significant growth, driven by the increasing use of enzymes in their production processes.

Probiotics and Feed Enzymes on the Rise

The aquaculture and poultry sectors, both heavily dependent on probiotics and feed enzymes, also contributed to the BioEconomy's growth. The shrimp industry, valued at \$8.30 billion, saw a 13.70% increase as probiotics became integral in avoiding antibiotics. The poultry feed market, valued at \$12.60 billion, grew by 22.33%, with enzymes playing a vital role in bird nutrition and growth.

Outlook

The BioIndustrial BioEconomy's robust per-

formance in 2023 underscores the growing importance of biotechnology in various industries. With continued advancements in enzyme and probiotic applications, this segment is poised for further expansion, solidifying its role as a key driver of economic growth in the years to come.

2023 BioIndustrial Segment Share Distribution

Segment Category	Segment Share (%)
AlcoBev (Alcoholic Beverages)	31.00%
Biofuels	10.90%
Textiles & Leather	16.40%
Household Care (Laundry & Dishwashing)	3.30%
Baking & Dairy (Breads, Biscuits, Cheese, Ice Cream)	7.00%
Feed (Aqua & Poultry)	28.90%
Starch Derivatives	1.30%
Vegetable Oil (Rice Bran)	1.20%

Source: ABLE



India's Biofuel Expansion

India's biofuel industry is poised for significant expansion, with non-potable ethanol consumption expected to rise by 13 percent to 7.2 billion liters (BL) in 2024. Fuel ethanol continues to dominate this sector, driven by the government's push for higher blending rates to meet the ambitious E-20 target by 2025. Fuel ethanol consumption alone is forecast to reach 6.2 BL in 2024, despite challenges stemming from restricted feedstock availability and lower-than-expected sugarcane and rice production.

The Ethanol Blending with Petrol Program (EBP) has been a cornerstone of India's biofuel strategy, enabling the country to achieve a record 12 percent blending rate with gasoline in October 2023. However, due to feedstock limitations, particularly the government-imposed restrictions on sugar feedstock diversion to stabilize domestic sugar prices, the average blending rate for 2024 is expected to settle at 14 percent. This decline underscores the impact of lower sugarcane output-down 8 percent this year due to adverse weather and pest infestations—and a 2 percent reduction in rice production, which has constrained ethanol production.

India's ethanol production capacity currently stands at 13.8 billion liters per year, with 270 sugarcane/molasses-based distilleries and 140 grain-based distilleries contributing to this output. The government has been promoting maize/corn as an alternative feedstock to address the shortfall and meet the E-20 target. The recent procurement of maize at the Minimum Support Price (MSP) for ethanol production reflects this strategy. Maize production is projected to increase, with estimates reaching 37 million metric tonnes (MMT) for the 2024/2025 marketing year.

Despite these efforts, achieving the E-20 target remains uncertain. Ethanol production from key feedstocks like sugarcane and maize needs to increase significantly, but the ongoing challenges in sugarcane and rice production make this difficult. The government's initiatives, including restrictions on sugar exports and efforts to boost maize production, are steps in the right direction, yet the required 20 percent increase in feedstock availability remains a significant hurdle. India's biodiesel program is also seeing slow progress, with a forecasted blending rate of 0.16 percent for 2024, slightly up from the previous year. Biodiesel production is expected to reach 226 million liters in 2024, but inconsistent feedstock availability continues to limit growth.

India has committed \$72.2 million to the National Green Hydrogen Mission and is advancing plans for Sustainable Aviation Fuel (SAF) blending in domestic flights. These efforts are part of India's broader strategy to reduce carbon emissions and transition to a more sustainable energy landscape.

The launch of the Global Biofuels Alliance in September 2023, in collaboration with the U.S., highlights India's commitment to global decarbonization efforts. However, the path to achieving its ambitious biofuel targets by 2025 remains fraught with challenges, requiring continued government support and industry adaptation. SUB-SECTOR MOVERS

BIOAGRI A Sustainable Future for Agriculture



BioEconomy Size **\$12.4 billion**



The BioAgri segment, encompassing sustainable and genetically modified agricultural practices, showed a promising growth of 7.8%. This trend is reflected in a growing cotton yield. Additionally, the need to improve agricultural yields while minimizing environmental impact fuels the demand for bio-based fertilizers, pest control solutions, and genetically modified crops with enhanced resistance and yield.

India's Cotton Sector Sees Notable Gains Despite Challenges

India's cotton sector demonstrated resilience and growth in 2023, with a significant increase in production despite challenges such as unfavorable weather patterns and declining sowing areas in key regions. Cotton production rose from 31.9 million bales in 2022 to 35.5 million bales in 2023, translating into a total output of 6.04 million metric tonnes. This marks an 11.3% increase compared to the previous year, reflecting a promising outlook for the sector.

This growth is particularly noteworthy given the initial concerns surrounding the delayed monsoon and below-normal rainfall, especially in North and Central India. The slow progress of the monsoon impacted early sowing, leading farmers in some regions to switch to alternative crops like oilseeds and pulses. North India, in particular, experienced a sharp decline in cotton acreage, with areas under cultivation dropping by 35% in Punjab and Haryana and by 53% in Rajasthan.

Despite these regional setbacks, Central and South India have contributed to the overall increase in cotton production. Gujarat, India's top cotton-producing state. saw cautious planting decisions due to high carryover stocks from the previous season. However, timely rains in July improved yields, especially in Maharashtra, helping to balance the losses in the North. Additionally, Southern states like Telangana and Andhra Pradesh benefited from adequate rainfall and robust government support through the minimum support price (MSP) procurement program.

A key driver of India's cotton production growth has been the widespread adoption of Bt. Cotton, the only genetically modified crop approved for commercial cultivation in India by the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forests, and Climate Change (MoEF&CC). Since its introduction in 2002–03, the area under Bt. Cotton cultivation has expanded dramatically from just 29,000 hectares (0.34% of the total cotton area) to 12.669 million hectares in 2022–23, covering 95% of the total cotton area. This widespread adoption has led to a significant increase in cotton production, which rose from 8.6 million bales in 2002–03 to 35.5 million bales in 2022–23.



While Bt. Cotton has played a crucial role in boosting India's cotton production, there are ongoing challenges that need to be addressed to sustain this growth. For instance, countries like Mexico, which have higher cotton yields, have completely adopted genetically modified seeds with Bt+ herbicide-tolerant traits. To stay competitive, it is recommended that India's Ministry of Agriculture and Farmers' Welfare focus on developing early maturing and hybrid seeds that cater to the specific needs of Indian farmers. The Central Institute for Cotton Research, Nagpur, has suggested that early maturing Bt and non-Bt varieties be introduced in 20% of the cotton-growing areas where long-duration Bt hybrid seeds are currently used. Protecting these seed varieties through the Protection of Plant Varieties and Farmers' Rights Authority could also encourage greater private sector participation in their development.

However, the use of certain seeds, particularly Bt cotton hybrid seeds, which are primarily produced by the private sector, has proven to be expensive for farmers. This recurring cost significantly adds to their debt burden. The Committee has recommended that farmers be financially supported to procure quality seeds and adopt best farming practices. Additionally, it suggested that the Ministry of Textiles and the Ministry of Agriculture and Farmers' Welfare consider imposing price caps on seeds and providing further impetus to seed development.

The development of high-quality cotton variants, such as extra-long staple cotton, is also crucial as domestic production currently falls short of demand. The Committee has called for the creation of seeds that are tolerant to droughts and arid conditions and resistant to pests and diseases. The adoption of advanced techniques like drip fertigation (the use of fertilizers in drip irrigation systems) is also recommended. The Committee has emphasized the importance of partnering with the private sector in all aspects of cotton development as a viable option for driving future growth. The BioEconomy value of Cotton is estimated at \$9.8 billion.



India's Growing Agricultural Biologicals Market

The Agricultural Biologicals Market in India, encompassing biofertilizers, biopesticides, and other biologicals, is witnessing significant growth, reflecting the country's commitment to eco-friendly agricultural solutions. This shift

aligns with global trends, as farmers increasingly turn to biological alternatives to enhance crop yield, improve soil health, and reduce the environmental impact of conventional chemical inputs.

Biofertilizers, which use natural microorganisms to enrich the soil and promote plant growth, have become a cornerstone of India's push towards sustainable agriculture. The biofertilizers market in India was valued at approximately \$1.4 billion in 2023 and is projected to growing at a compound annual growth rate (CAGR) of around 12% in the next four-five years. This growth is driven by government initiatives and increasing awareness among farmers about the benefits of organic farming. The demand for biofertilizers is particularly high in regions with intensive farming, where soil degradation has become a pressing issue. With the rise of organic farming practices, biofertilizers are expected to play a pivotal role in rejuvenating soil fertility and promoting healthier crop production.

The Indian pesticide market, traditionally dominated by chemical-based products, is undergoing a significant transformation. The biopesticides segment, which includes natural alternatives for pest control, was valued at about **\$500 million in 2023** and is projected to grow at a CAGR of approximately **17%**. The rising awareness of the envi-



ronmental and health hazards associated with chemical pesticides has led to an increased demand for biopesticides. This shift is supported by regulatory changes that encourage the

use of biological pesticides and restrict the application of certain harmful chemicals. The Indian government's emphasis on sustainable agriculture and integrated pest management practices is further fueling the growth of the biopesticides market.

Biologicals: Beyond biofertilizers and biopesticides, the broader category of agricultural biologicals, which includes bio-stimulants and bio-control agents, is gaining traction in India. This segment, encompassing various products designed to enhance crop productivity, was valued at around \$700 million in 2023. It is expected to register CAGR of approximately 14%. These products improve plant health, stress tolerance, and nutrient uptake. The adoption of biologicals is driven by the need to meet growing food demand while ensuring sustainability. The market is also benefiting from increased investments in research and development, which are leading to the introduction of new and more effective biological products. With continued innovation and support, this market is set to become a key driver of growth in the agricultural sector, contributing to a healthier environment and a more sustainable food system.

SUB-SECTOR MOVERS

BIOIT / RESEARCH SERVICES / BIOSERVICES

Powering Innovation



The BioIT / Research Services / BioServices segment, encompassing research and development activities across the BioEconomy, exhibits the second-highest growth at 19.4%. This significant rise underscores the crucial role of research and innovation in driving advancements across all BioEconomy sectors. Technological advancements in areas like bioinformatics, artificial intelligence, and gene editing contribute to accelerated discovery and optimization in various biological processes.

Outsourcing Trends in the BioServices Segment

The BioEconomy is increasingly leveraging outsourcing to navigate the complex and evolving landscape of drug development and commercialization. This shift is shaping a dynamic service provider ecosystem that addresses diverse needs within the industry. The service provider landscape is categorized into five main segments, each playing a crucial role in supporting biopharma and medical device enterprises:

Contract Research Organizations (CROs) and Contract Sales Organizations (CSOs): CROs and CSOs are essential for managing clinical trials, offering comprehensive end-to-end services. They operate clinical trial facilities and employ medically trained professionals to ensure rigorous monitoring and safety. Prominent players in this category include IQVIA, Syneos Health, and Parexel, which also provide marketing and sales support. enhancing their value proposition across the life sciences value chain. **IT/BPO Service Providers:** Organizations such as Accenture. Cognizant. Infosys, HCL, and TCS offer a broad spectrum of IT and business process services. They support life sciences companies with IT infrastructure, clinical data management, and other domain-specific services. Their business models feature offshore delivery centers and extensive full-time equivalent (FTE) bases, enabling scalable and cost-effective solutions.

Life Sciences Specialists and Digital Engineering Firms: Life sciences specialists leverage deep domain expertise and advanced digital tools to drive clinical trial success and regulatory compliance. Their specialized knowledge in areas such as marketing, regulatory affairs, and pharmacovigilance is crucial for navigating industry complexities. Digital engineering firms, on the other hand, develop technological solutions including platforms, software, and custom applications. facilitating the integration of next-generation technologies into life sciences offerings, driving innovation and efficiency.

Product/Platform Players and BioSuppliers: Companies like Thermo Fisher Scientific and Agilent Technologies are pivotal in accelerating life sciences research, solving complex analytical challenges, and improving patient diagnostics. They provide platforms that offer unified data views and support comprehensive business operations. These companies collaborate with other service providers to deliver customized end-to-end solutions tailored to life sciences enterprises.

BioEconomy Education & Training Services: As the BioEconomy becomes a central topic globally, education and training services are vital for transitioning from a linear economic model to a circular, low-carbon economy. These services are crucial for skill generation and supporting the industry's shift towards renewable, organic-based resources.

Trends Influencing Outsourcing in Life Sciences

Life sciences companies are increasingly outsourcing to address several pressing needs:

Specialized Skills and Domain Knowledge: The rapid evolution of therapies and technologies, such as cell and gene therapies and precision medicine, demands specialized skills. Outsourcing provides access to a qualified talent pool and mitigates the burden of costly and time-consuming reskilling and retraining.

Navigating Regulatory Complexities: The complex and frequently changing regulatory landscape pres-

ents significant challenges. Service providers with expertise in regulatory affairs help companies achieve timely approvals and maintain compliance, reducing risks associated with regulatory changes.

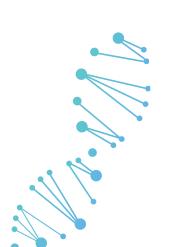
Data Management and Digital Advancements: The proliferation of data and advancements in digital technologies present both opportunities and challenges. Outsourcing partners bring advanced capabilities, such as AI and machine learning, to help companies manage, integrate, and analyze data effectively.

Mergers and Acquisitions: Consolidation in the life sciences sector drives the need for streamlined processes and systems. Agile service providers assist in harmonizing operations and customizing solutions to meet the needs of merged entities.

Cost Management: Rising sales, general and administrative (SG&A), and research and development (R&D) expenses prompt life sciences companies to seek outsourcing solutions to improve efficiency and reduce costs. Outsourcing helps manage these expenses while leveraging specialized expertise.

Valuation and Segmentation

The BioEconomy services segment is valued at approximately \$12.11 billion, with notable contributions from BioEducation services (\$1 billion), BPI/IT Services (\$7 billion), and CROs and clinical trials. As life sciences companies continue to adapt to a rapidly changing environment, the role of outsourcing service providers is expected to grow. By leveraging specialized expertise and advanced technologies, these providers are pivotal in driving innovation, efficiency, and success within the industry.



MILESTONES

A 13.7 Fold Increase

A Breathtaking Trajectory

From a mere \$2 billion in 2003, India's bioeconomy has ballooned to a staggering \$151 billion by 2023, reflecting a remarkable 13.7-fold increase. This growth trajectory can be segmented into distinct phases

Steady Growth (2003-2008) The initial years witnessed a stable rise, with the bioeconomy reaching \$5 billion by 2008, marking a 150% increase.

Significant Acceleration (2008–2013) The next phase saw a significant acceleration, with the bioeconomy reaching \$11 billion by 2013, a 120% growth spurt.

Exponential Surge (2013-2018) This period witnessed an exponential surge, with the bioeconomy reaching a stag-gering \$55 billion by 2018, reflecting a phenomenal 400% growth.

Robust Growth (2018-2023)

The most recent phase saw continued robust growth, with the bioeconomy reaching a colossal \$151 billion by 2023, marking a 174% increase.



RANKS #3 in global ethanol production

670 APPROVALS FDA-approved facilities





25% VACCINES used worldwide comes from India

95 INCUBATORS

India's active bioincubator network



13 MN HECTARES

world's second-largest cotton producer

BEYOND THE NUMBERS Emerging Trends and Challenges

Beyond these segment-specific trends, the BioEconomy as a whole faces both opportunities and challenges. Concerns around intellectual property rights, especially regarding genetically modified organisms, need to be addressed to ensure fair access and encourage innovation. Additionally, regulatory frameworks must adapt to keep pace with the rapid pace of technological advancements in the BioEconomy.

Furthermore, ensuring equitable access to the benefits of the BioEconomy for developing countries requires international cooperation and knowledge-sharing initiatives. Sustainability remains a critical concern, demanding responsible sourcing of biological resources and minimizing the environmental footprint of BioEconomy processes.

BioEconomy's Contribution to India: The BioEconomy remains a significant contributor to India's economic landscape. It employs over **3.3 million people** and accounts for a noteworthy **4.25%** of the nation's GDP. More than 450,000 students and researchers are pursuing biotech studies.



LOOKING AHEAD

Strategic Insights and Future Outlook

The BioEconomy's dynamism is evident in the growth of diverse segments like BioPharma, BioIndustrial, and BioServices. This adaptability positions the India BioEconomy for continued success.

KEY DRIVERS FOR FUTURE GROWTH

- Global Biosimilars Market: Expanding global acceptance of Indian-made biosimilars presents a lucrative opportunity for the BioPharma sector to capture a larger market share in developed countries.
- Therapeutics Innovation: Continued advancements in BioPharmaceuticals, personalized medicine, and precision treatments are expected to propel the Therapeutics segment forward.
- Sustainable Biolndustrial Practices: The growing focus on sustainable industrial practices, including biofuel production and enzyme applications, aligns with global environmental trends, creating significant growth potential for Biolndustrial.
- Tech Integration in BioIT/Research Services: Integration of advanced technologies like bioinformatics, data analytics, and artificial intelligence in bioresearch services is poised to accelerate, enhancing research capabilities and driving growth in BioIT/ Research Services.



CHALLENGES AND OVERCOMING STRATEGIES

Pandemic-Induced Volatility: The BioEconomy's vulnerability to global health crises, as witnessed in the Vaccines and Diagnostics segments during the pandemic, necessitates flexible strategies to navigate unforeseen challenges. Continued investment in R&D for rapid response capabilities is critical.

Regulatory and Infrastructure Support: To

capitalize on emerging opportunities, particularly in smart proteins and fermentation capacities, robust regulatory support and infrastructure development are crucial. Collaboration between the government and industry stakeholders is essential to foster sustained growth.

Section 4

Global BioEconomy

Nations Prioritize BioEconomy for Sustainable Growth

A 2050 Projection: Global BioEconomy's \$30 Trillion Future

POLICY FRAMEWORKS

Nations Prioritize BioEconomy for Sustainable Growth

Economic goals take center stage as global adoption of BioEconomy strategies accelerates, driven by economic priorities and increasing environmental considerations. The global landscape is undergoing a transformative shift as countries increasingly adopt BioEconomy strategies to drive sustainable growth. By integrating nature-based solutions across various sectors—from agriculture and forestry to cutting-edge technologies like synthetic biology and artificial intelligence—nations are paving the way for a resilient and eco-friendly future. However, a recent study published in Ambio reveals that economic growth remains the primary focus of these policies, often overshadow-ing environmental and social goals.



Understanding the BioEconomy

The BioEconomy is defined by the utilization of renewable biological resources to produce bio-based products and services, offering significant potential for climate change mitigation and adaptation. It is grounded in the sustainable and circular use of these resources and spans various domains, including BioAgri, BioIndustrial, BioPharma, and BioServices.

Element	Description
Natural Resources	Renewable biomass used as feedstock for biotechnology processes.
Biotechnology	Applies biology to generate products through traditional methods.
Synthetic Biology	Engineers organisms to perform new functions.
Biomanufacturing	Scales biotechnology for large-scale production.
Convergent Technologies	Combines biotechnology with engineering and computerized
	systems (e.g., Al).

These elements combine to deliver innovative bio-solutions, relying on both existing strengths and investments in emerging technologies.

The BioEconomy encompasses the production, trade, distribution, management, and consumption of goods and services derived from biological resources. Although definitions may vary, the BioEconomy consistently focuses on societal goals such as sustainable consumption, climate mitigation, and job creation. Industrialized nations often support the shift from fossil-based systems to bio-based alternatives, emphasizing high-value products and value chain optimization. Regions with large productive landscapes, like Brazil and the African Union, strive to balance ecological and socio-economic needs. Many countries are integrating BioEconomy policies into their industrial strategies and green growth plans, including measures like research funding, tax incentives, and supportive regulations.



Global BioEconomy Strategies

Countries are tailoring their BioEconomy initiatives to leverage unique resources and strengths. For example:

Costa Rica: Focuses on rural development through agriculture and forestry.

Malaysia: Emphasizes producing high-value bio-based products.

Nordic Countries: Capitalize on rich natural resources for sustainable processing.

South Africa: Utilizes biodiversity to drive bioeconomic growth.

US BioEconomy Definitions

US BioEconomy

Economic activity that is driven by research and innovation in the life sciences and biotechnology and that is enabled by technological advances in engineering and in computing and information sciences

Agricultural

Criteria for inclusion include the use of 1. Genetic engineering when creating a strain or seed 2. Advanced molecular biology technique for marker-assisted breeding programs 3. Large informatics databases and computational techniques for either breeding apprication or enhanced land use capabilities

Examples: Genetically modified crops/animals, precision agriculture

Biomedical

Criteria for inclusion include any medical products or services resulting from research and development or innovation in life sciences.

Examples: Pharmaceutical products, lab-grown organoids, Medical devices

BioIndustrial

Criteria for inclusion include any medical products or chemicals produced using a biosynthetic route utilizing recombinant DNA technology.

Examples: Bio-based chemicals, biofuels, biobased plastics

Tools, kits and services

Criteria for inclusion include tools, kits and services that support or enable the advancement of biotechnology of life science research.

Examples: Lifesciences or biotechnology related software and databases, specialized equipment or instruments for use in BioEconomy (e.g.:pippeting robots, mass spectrometers, DNA sequencing and synthesizers, bioscience patent lawyers.

These emerging economies, along with

leading nations like the United States, China, and the United Kingdom, are demonstrating innovative approaches to harnessing biological resources for sustainable development.

Technological Integration and Innovation

The BioEconomy is rapidly evolving beyond traditional sectors, with technologies like synthetic biology and artificial intelligence playing a crucial role. These innovations are creating new opportunities in biomaterials, biofuels, pharmaceuticals, and more. Countries are heavily investing in research and development to unlock the full potential of these technologies, exploring new frontiers in sustainable production and resource optimization.

However, this path is not without challenges. Regulatory frameworks, industry standards, and scalability issues remain significant obstacles. The COVID-19 pandemic highlighted the importance of a resilient BioEconomy infrastructure, prompting countries to strengthen supply chains and improve disaster preparedness.



Expanding the BioEconomy's Impact

Once seen as a minor component of circular economies, the BioEconomy is now a driving force in green transformation. Advanced technologies are leading this expansion, creating new opportunities for rural development and job creation across all skill levels. This shift is especially crucial for developing economies, where the BioEconomy can fuel sustainable growth and provide diverse economic opportunities.



Harnessing Biodiversity and Biomass Countries rich in biodiversity and biomass are utilizing technologies like synthetic biology to transform these resources into high-value products. Brazil and Argentina are leading in the bioenergy sector, producing high-performance biomaterials, bioplastics, pharmaceuticals, and nutraceuticals from natural and residual (waste) biomass. These nations are setting the standard for using biological resources to develop sustainable products that can replace traditional, less eco-friendly alternatives.



Biologizing the Industry Nations with strong scientific and technological capabilities are moving beyond simply adding value to biological resources—they are replacing petrochemical-based energy sources and chemicals with biologically derived alternatives. By leveraging tools like genomics, systems biology, and synthetic biology, these countries are pioneering new, more sustainable industrial processes. This shift towards "biologizing" industries represents a significant move towards a circular economy, where biological processes and materials are central to production.



Building Resilience Post-COVID The COVID-19 pandemic exposed critical weaknesses in global supply chains and underscored the need for better disaster preparedness. In response, many countries are recognizing the importance of a robust BioEconomy infrastructure in building resilience. By strengthening bioeconomic capabilities, these nations can ensure a stable supply of essential resources and reduce reliance on external supply chains, making them better equipped to handle future crisis.



Addressing Environmental and Climate Impacts The expansion of the BioEconomy significantly impacts land use and biodiversity. As demand for bio-based products and biofuels increases, it can compete with food production and affect natural ecosystems. Ensuring sustainability requires responsible land-use planning, regulatory frameworks, and eco-friendly practices. Biodiversity protection must coexist with bioeconomic growth, promoting economic development while conserving natural resources. Bio-based products and bioenergy contribute to climate mitigation by replacing non-renewable materials and fossil fuels. However, the climate impacts vary based on factors like feedstock source and product lifespan. Future efforts should prioritize long-lived bioproducts and waste biomass utilization to enhance climate benefits.



Overcoming Challenges and Fostering Sustainability Despite the promising advancements, challenges remain in regulatory development, industry standards, and scalability. The sustainability of the BioEconomy is also threatened by climate risks, both sudden events like hurricanes and floods, and slow-onset changes such as shifting precipitation patterns. Addressing these risks is crucial for sustainable bioresource management in the face of climate change.



Economic Focus in BioEconomy Policies

Despite these advancements, a new study published in *Ambio* highlights that economic growth remains the dominant focus of BioEconomy strategies. Researchers analyzed 78 policy documents from 50 countries and found that economic objectives accounted for nearly two-thirds (66.7%) of the content. Led by Maria Proestou, Nicolai Schulz, and Peter H. Feindt, the study identifies three primary Bio-Economy visions: bioresource, biotechnology, and bioecology. While economic goals dominate across all these visions, the study notes a positive trend toward incorporating environmental goals, particularly since 2016. This shift is likely influenced by global initiatives like the Sustainable Development Goals (SDGs) and growing concerns about the environmental impact of bioeconomic activities.



The future of the BioEconomy is undeniably tech-driven, with the potential to transform industries, create jobs, and drive sustainable development. As nations continue to invest in advanced technologies and explore new uses for biological resources, the BioEconomy is set to play a central role in the global shift towards a greener, more resilient economy. However, overcoming regulatory and scalability challenges will be essential to unlocking this potential and ensuring that the BioEconomy's benefits reach everyone.



\$

Overview of Bio-based Products, including recent technology developments and their implications

Biomass Utilization Methods

Biomass resource utilization includes energy, raw material, feed, base material, and fertilizer. This section highlights how biomass is converted into various products and its applications.

Bioenergy

Bioenergy is a renewable energy source derived from biomass. It includes solid, liquid, and gas biofuels like biomass briquettes, biogas, and biodiesel. Technology developments focus on enhancing production and efficiency, with mature systems in the EU and ongoing advancements in developing countries.

Bio-based chemicals

Bio-based chemicals are produced from renewable biomass and include categories like acids, alcohols, furans, and bio hydrocarbons. They offer advantages over petroleum-based chemicals, such as reduced environmental impact. Recent technological developments focus on improving production methods and expanding applications.

Bio-based plastics

Bio-based plastics are made from biomass and categorized as biodegradable or non-biodegradable. Innovations include developing new biodegradable materials and improving the efficiency of production processes. The technology for bio-based plastics is advancing, aiming to replace petroleum-based plastics in various applications.

Natural fibers

Natural fibers like cotton, silk, and hemp are renewable and biodegradable. Advances in textile technology are enhancing the durability and functionality of these fibers, making them more competitive with synthetic fibers. The focus is on improving processing techniques and exploring sustainable practices.

Pulp and paper products

Pulp and paper products are derived from cellulose in wood and agricultural straw. Technological developments include advances in recycling processes, alternative fiber sources, and improved production techniques. Innovations aim to increase efficiency and reduce environmental impact.

Global BioEconomy Policy Frameworks

In response to global environmental and economic challenges, countries and regions are increasingly adopting BioEconomy strategies to leverage biological resources for sustainable development. This chapter examines the diverse approaches to BioEconomy policy across different continents, highlighting key strategies and objectives. From the European Union's integrated frameworks to emerging policies in Africa, these efforts reflect a global commitment to fostering innovation and sustainability in the BioEconomy.

EUROPEAN UNION (EU)	The EU has been a leader in developing BioEconomy strategies, guided by its broader environmental and economic goals. The European BioEconomy Strategy, first released in 2012 and updated in 2017 and 2018, aims to promote sustainable growth, enhance resource efficiency, drive innovation, support bio-based industries, and ensure a balanced policy framework. The Europe- an Green Deal (EGD), launched in 2019, targets a resource-efficient econo- my with net-zero greenhouse gas emissions by 2050, integrating initiatives across Research and Innovation, Regional Development, Climate Change, and Circular Economy.
GERMANY	Germany has been at the forefront of BioEconomy policy, starting with the National BioEconomy Research Strategy (2010) and the National BioEcono- my Policy Strategy (2013). These strategies emphasize integrating biological knowledge into industry to drive growth and sustainability. The "From Biology to Innovation" agenda (2018) reinforces the role of the BioEconomy in Germa- ny's transition to a renewable resource-based economy. The 2020 plan under Germany's EU Presidency further highlighted the BioEconomy's importance in education and research.
UNITED KINGDOM (UK)	Despite limited biomass resources, the UK has made significant advancements in BioEconomy policy. The "Natural Environment White Paper" (2011) outlined a vision for sustainable agriculture. This was followed by the Anaerobic Diges- tion Strategy and Action Plan (2020), targeting waste reduction and green- house gas emissions. The "United Kingdom Bioenergy Strategy" (2012) focused on decarbonization through biomass and waste. The 2018 strategy, "Growing the BioEconomy," aimed to build a high-value BioEconomyfrom waste. This strategy has since been succeeded by the 2021 Innovation Strategy and other government initiatives supporting the UK's Net Zero objectives.

ASIA PACIFIC



China has integrated BioEconomy development into its strategic plans from the Tenth to the Fourteenth Five-Year Plans. The Twelfth Five-Year Plan emphasized urban and rural development integration and biomass energy technologies. The Fourteenth Five-Year Plan focuses on clean, efficient energy use, with recent initiatives like the "Three-Year Action Plan" (2023) advancing bioenergy technologies and alternatives to petroleum-based plastics.



AMERICAS



Japan's commitment to biomass utilization began with the "Biomass Japan Strategy" (2002), revised in 2006 to include bioenergy and biomass towns. The Biotechnology Strategy Committee, established in 2002, supports biotech development, and the "Dream BT Japan" strategy (2008) emphasizes high-tech BioEconomy aspects. The National Biomass Utilization Promotion Plan (2010) set targets for biofuels, and Japan's first dedicated BioEconomy strategy (2019, updated 2020) builds on its strong bio-industry and research capabilities.

Costa Rica has been a pioneer in Latin America for BioEconomy strategies, starting with the National Biofuels Plan (2008) aimed at replacing fossil fuels with renewable sources. In 2020, Costa Rica launched the National BioEconomy Strategy Costa Rica 2020–2030, integrating production development with the conservation and sustainable use of biological resources, reflecting a commitment to aligning environmental and production policies.



The USA has been a major player in BioEconomy policy with the release of the "National BioEconomy Blueprint" (2012), covering biotechnology and biomedicine. USDA initiatives from 2014 to 2018 supported bio-based product procurement and biorefining. A 2017 report on modernizing biotechnology regulation and the 2022 National Biotechnology and Biomanufacturing Initiative highlight ongoing efforts to enhance innovation and growth in the US BioEconomy.



Canada's BioEconomy strategy leverages its rich biomass resources and traditional industries. The Paris Agreement and Vancouver Declaration emphasize sustainable agriculture and clean growth. Canada's approach involves converting agricultural outputs and residues into high-value bioproducts, developing stress-tolerant crops, and enhancing environmental sustainability, reflecting adaptation to evolving agricultural and technological landscapes.

AFRICA



SOUTH AFRICA

South Africa introduced its dedicated BioEconomy strategy in 2013, aiming to transition to a knowledge-based BioEconomy by leveraging the country's biodiversity. This strategy builds on the National Biotechnology Strategy and the Ten-Year Innovation Plan, with a vision of significantly contributing to the national GDP by 2030 and engaging in international cooperation within the Southern African Development Community.





Key Components of BioEconomy Strategies: Navigating the Future

As the global focus sharpens on reducing fossil fuel reliance, the BioEconomy emerges as a pivotal area of development. While a unified definition remains elusive, countries worldwide are advancing varied strategies to tap into the BioEconomy's potential. This table elucidates the fundamental components of BioEconomy strategies, highlighting regional approaches, strategic focus areas, and critical development aspects.

Pillar	Summary
Policy Promotion	 EU: Leads with comprehensive national strategies aligned with circular economy and climate goals. Asia-Pacific: Focus on high-tech and industrial innovations; countries like Japan and Thailand have specific strategies. Africa: Growing initiatives, with South Africa and East African countries developing strategies. Latin America & Caribbean: Recent strategies from Argentina, Brazil, and Costa Rica, but slow overall progress. North America: USA emphasizes biotechnology; Canada focuses on agricultural biomass.
Strategic Focus Areas	Embraces life cycle carbon disclosure, trade policies, digital transformation, and carbon pricing. Stresses the importance of holistic and gender-responsive approaches.
Bioresources and Bioproducts	 Biomass: Focus on second- and third-generation resources; addresses food security issues. Bio-jet Fuels: Need policy support and technological advances to be competitive. Bio-based Compounds: Utilizes lignocellulosic feedstocks; advancements reduce costs and pollution. Bioplastics: Viable but require cost-effectiveness and technical improvements. Textiles: Preference for natural fibers; challenges include land use and cost. Paper Industry: Impacted by digitalization; emphasis on recycling and alternative fibers.
Sustainable Land Use and Biodiversity	BioEconomy impacts land use, agriculture, deforestation, and biodiversity. Requires sustainable practices, robust regulatory frameworks, and balanced land-use planning. Focuses on ecosystem conservation and adaptation of legal frameworks.
Interaction with Climate Risk	Climate Mitigation: Bio-based products can help reduce emissions, but their impact varies; biofuels are not always carbon-neutral. Climate Impact: Extreme events affect agriculture and resource availability. Gender Impact: Women, particularly in developing countries, face disproportionate effects but also play a crucial role in climate solutions.

A 2050 PROJECTION

Global BioEconomy's \$30 Trillion Future

BioEconomy Set to Surge: **From \$4 Trillion to \$30 Trillion** by **2050**, Transforming the Global Economic Landscape. This dramatic increase will reshape economic frameworks, emphasizing the BioEconomy's crucial role and its capacity to drive innovation and sustainability across industries.



The BioEconomy is emerging as a critical sector within the global economy, with its current valuation of approximately **US\$4 trillion** poised for dramatic growth. Projections by Boston Consulting Group's Henderson Institute suggest that by 2050, the BioEconomy could reach a remarkable **US\$30 trillion**. This growth underscores the BioEconomy's potential to become a dominant force within the global economic framework.

The correlation between the BioEconomy's expansion and the broader global economy is

striking. With the global economy expected to hit approximately **US\$228 trillion** by **2050**, the BioEconomy's anticipated rise to US\$30 trillion indicates it will occupy a substantial **13%** share of the total economic output. This marks a significant increase from its current **4%** share of the world economy of **\$104 trillion** in **2022**. The projected fourfold increase in the BioEconomy's share reflects a broader trend of integrating biotechnology and sustainable practices into various industries.

Current Contribution and Projected Trends:

The BioEconomy's current contribution to national GDPs varies widely across countries. For instance:

Italy and Spain lead with BioEconomy shares of 22% of GDP, highlighting their strong focus on sustainable and bio-based industries.

France and Germany also exhibit substantial BioEconomy shares at 18% and 16% respectively.

In contrast, major economies like the USA and China have lower BioEconomy shares of 5% and 4% respectively, due to their broader and more diversified economic bases.

By 2030, the BioEconomy is expected to see considerable growth. Projections suggest:

European countries could see BioEconomy contributions rise to 30–40% of GDP, driven by ongoing investment and policy focus.

Major economies like the USA and China might achieve BioEconomy shares of 10–15% as they adopt more sustainable practices and technologies.

Emerging markets such as India and Brazil are expected to increase their BioEconomy shares significantly, driven by policy shifts and the push for sustainable development.

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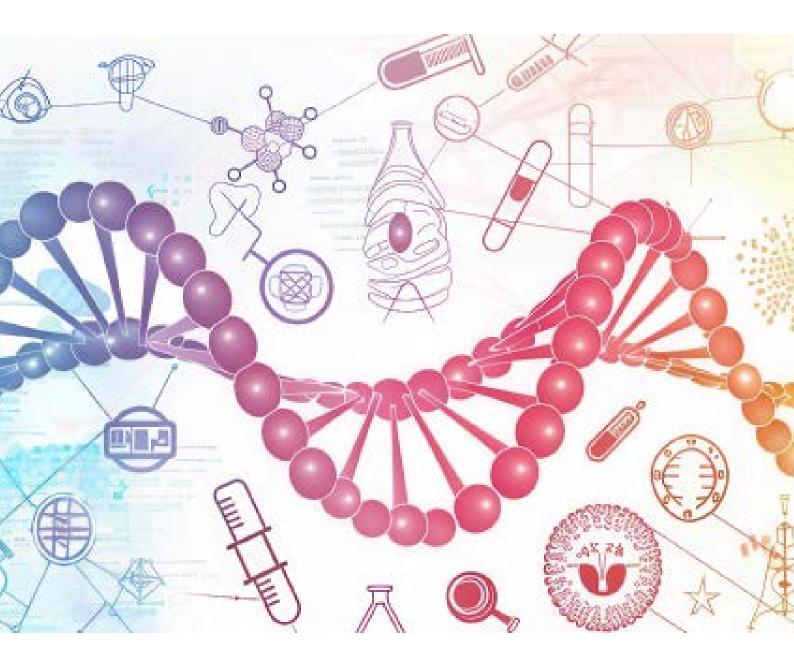
Global BioEconomy in 2050

As the BioEconomy expands, its role in the global economy will become increasingly prominent. The projected rise from **US\$4 trillion** to **US\$30 trillion** by **2050** reflects its potential to drive significant economic growth and innovation. This expansion will likely be supported by:

Increased Investment: Accelerated development in biotechnologies, bio-based materials, and green energy solutions.

Policy Support: Enhanced funding for research and development, supportive regulations, and incentives for sustainable practices.

Technological Advancements: Continued advancements in biotechnology and sustainable practices, making bio-based industries more competitive.



Country	BioEconomy (\$ Billion)	Economy (\$ Billion)	BioEconomy Share of GDP (%)
USA	959	18715	5
China	750	17700	4
Germany	642	4077	16
Japan	541	5041	11
France	497	2775	18
Italy	457	2047	22
UK	363	3065	12
Spain	318	1416	22
India	150	3466	4
Brazil	125	1920	7

Country Comparison: BioEconomy Size and GDP Share

Source: ABLE

Implications for the Global BioEconomy in 2050

Increased Economic Influence: The BioEconomy's expanded share signifies its growing importance, influencing global economic policies, driving innovation, and reshaping market dynamics.

Integration of Biotechnology and Sustainability: The shift reflects an increasing trend towards biotechnology and sustainable practices across industries, central to future economic strategies.

Enhanced Investment Opportunities: As the BioEconomy grows, it will attract more investment, fostering development in biotechnologies, green technologies, and sustainable solutions.

Policy and Regulatory Changes: Governments will need to adapt policies to support this growth, including increased funding, supportive regulations, and incentives.

Global Economic Shifts: The prominence of the BioEconomy will influence global trade patterns, supply chains, and economic relationships, potentially reshaping global economic alliances.

In summary, the BioEconomy's projected rise to US\$30 trillion by 2050, within a global economy valued at US\$228 trillion, represents a significant increase in its economic share from 4% to 13%. This transformation highlights the BioEconomy's expanding role in driving sustainable economic development and underscores the need for strategic investments and supportive policies to maximize its potential and integrate it into the broader economic framework.

Section 5

BIOTECHNOLOGY LANDSCAPE & INVESTMENTS 78 BIOTECHNOLOGY LANDSCAPE & INVESTMENTS

TOP STATES

Comparative Analysis of BioClusters

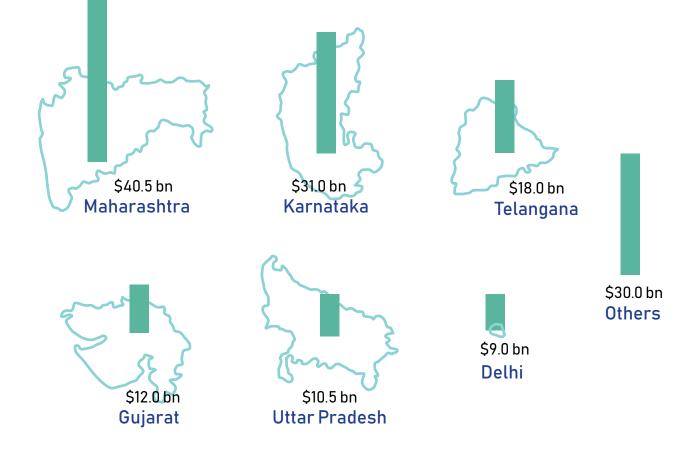
The India BioEconomy thrives on collaboration, with various states playing a crucial role in driving growth, innovation, and sustainability. Maharashtra, Karnataka, and Telangana continue to be key contributors, showcasing diverse strengths across biotechnology, research, pharmaceuticals, and bioIndustrial sectors.

- Maharashtra: Retains its position as the leading state with a substantial contribution across diverse bio-based sectors.
- Karnataka: Maintains its prominence in biotechnology and research, significantly impacting the national BioEconomy.
- Telangana: Continues to make notable contributions from the pharmaceutical and biotech sectors, fostering innovation.
- Gujarat, Uttar Pradesh, and Delhi: Each hold a steady share, with Gujarat focusing on BioIndustrial applications, Uttar Pradesh showcasing diversified contributions, and Delhi leveraging its resources in research and healthcare.
- Other States: Other states collectively hold a significant 20% share and a combined BioEconomy value of \$28.02 billion, highlighting the pan-India nature of the BioEconomy.

	State
	Maha
	Karn
	Telar
•	Guia

State	Share (%)	BioEconomy Contribution (\$ Bn)
Maharashtra	27	40.5
Karnataka	20	31.0
Telangana	12	18.0
Gujarat	8	12.0
Uttar Pradesh	7	10.5
Delhi	6	9.0
Others	20	30.0
Total		151.0

Source: ABLE



BioClusters, BioEconomy, and Capacity

India's key BioEconomy activities are spread over 90 cities in different states. Here's a brief over of the significant BioEconomy infrastructure in various sectors across the country.



BioPharma spread

Ranked third globally for pharmaceutical production by volume and 14th by value. India's BioPharma spread pharmaceutical industry features a robust network of approximately **3,000 drug companies** and around **10,500 manufacturing units**. Here we are considering pharmaceutical sector as a whole because a large number of these units also have considerable presence with a range of biotechnology based drugs. The future outlook is promising, with projections indicating that the Indian pharmaceutical products market will reach a value of approximately **US\$130 billion** by **2030**. The global market, in contrast, is expected to surpass the **US\$1 trillion** mark in **2023**.

India's pharmaceutical industry is supported by an extensive network of over **118 pharmaceutical clusters** spread across **19 states** and union territories. These clusters are vital hubs for production, innovation, and research, driving the industry forward.

The state of **Maharashtra** leads with the highest number of pharmaceutical clusters, totaling **40**. **Gujarat** follows with **13** clusters, and **Andhra Pradesh** has 8.

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The state of Maharashtra leads with the highest number of pharmaceutical clusters, totaling 40. **Gujarat follows with 13** clusters. and Andhra Pradesh has 8.

Additional clusters are located in Punjab, Chhattisgarh, Madhya Pradesh, Odisha, Puducherry, Sikkim, West Bengal, and Jharkhand. These pharmaceutical clusters collectively host 7,673 pharmaceutical industries, averaging **65 units** per cluster.

The annual domestic pharmaceutical production by the industries in 118 pharma clusters in the country is approximately 611,120 tonnes. Apart from that, the annual export amount of pharmaceutical products from these clusters is about **576,140 tonnes**. The annual total output is approximately **1,187,260 tonne**. The value of



Source: ABLE

products ranging from orthopedic implants to advanced coronary stent systems.



Government Support and Growth Drivers

The Government of India has introduced several Production Linked Incentive (PLI) Schemes aimed at enhancing domestic manufacturing and attracting significant investments in the sector. These initiatives, coupled with the expected expiration of major global drug patents and the rising demand for healthcare services, position India's pharmaceutical industry for sustained growth.

India's pharmaceutical clusters, coupled with strong government support and foreign investment, are set to solidify the country's status as a global pharmaceutical leader, driving innovation, production, and exports well into the next decade.

In a landmark achievement for India's healthcare sector, the nation has made significant strides under the Production Linked Incentive (PLI) Scheme, successfully completing 32 crucial projects that have established a cumulative installed capacity of 56,679 metric tonnes per annum (MT per annum) for the domestic manufacturing of Key Starting Materials (KSMs), Drug Intermediates, and Active Pharmaceutical Ingredients (APIs). This development is pivotal in reducing India's dependence on imports and fortifying the pharmaceutical supply chain, signaling a new era of self-reliance and industrial growth in the country.

PLI Scheme: A Strategic Initiative for Pharmaceutical Manufacturing



The PLI Scheme for Pharmaceuticals, introduced by the Government of India, represents a strategic initiative aimed at bolstering domestic manufacturing capabilities for 41 essential bulk drugs that are vital to the pharmaceutical industry. With a total financial outlay of ₹6,940 crores, the scheme is designed to provide financial incentives to manufacturers over six years, encouraging investments, scaling up production capacities, and ensuring that India achieves self-sufficiency in the production of critical drugs.

Since its inception, the PLI scheme has seen remarkable progress. In the first phase, which spans from FY 2022-23 to FY 2028-29, the response from the industry has been overwhelmingly positive. Against the initially targeted investment of ₹3,938 crores, the pharmaceutical sector has already attracted ₹4,024 crores, surpassing expectations and underscoring the industry's commitment to this initiative. These investments have led to the completion of 32 projects, which together boast a production capacity of 56,679 MT per annum, a significant boost to the country's pharmaceutical infrastructure.

Furthermore, 16 additional projects are currently under development, backed by critical regulatory approvals such as environmental clearances and drug manufacturing licenses, which have been streamlined with the active support of state governments. This proactive regulatory environment has been instrumental in accelerating project timelines and ensuring that the manufacturing capacities come online as swiftly as possible.

Geographical Distribution and Impact on States

The projects under the PLI scheme are strategically distributed across various states, with Andhra Pradesh, Gujarat, Karnataka, and Telangana emerging as the major hubs for pharmaceutical manufacturing. This geographical distribution not only balances regional industrial growth but also aligns with the government's vision of a more decentralized and equitable industrial ecosystem.

For instance, in Andhra Pradesh, Lyfius Pharma Pvt. Ltd. has successfully commenced the production of Penicillin G, a critical antibiotic. Similarly, Macleods Pharmaceutical Limited in Gujarat has begun producing Rifampicin, another essential drug, while Hetero Drugs Limited in Telangana has started manufacturing a range of APIs. These developments highlight the scheme's effectiveness in fostering a robust pharmaceutical manufacturing base across multiple states, thereby contributing to regional economic growth and job creation.

In total, 48 projects have been selected under the PLI scheme, including 13 projects being implemented by Micro, Small, and Medium Enterprises (MSMEs). This inclusion of MSMEs is particularly noteworthy, as it ensures that smaller enterprises also benefit from the scheme, promoting a more inclusive industrial growth model that supports a diverse range of players within the sector.

Significant Expansion in Medical Devices Manufacturing

Parallel to the pharmaceutical sector, the PLI scheme for medical devices has also witnessed substantial progress, further reinforcing India's position as a critical player in the global healthcare market. With a financial outlay of ₹3,420 crores, this component of the PLI scheme is dedicated to enhancing the domestic manufacturing capabilities of medical devices, which are crucial for the country's healthcare infrastructure.

As of September 2023, the PLI scheme for medical devices has approved **26 projects**, with 16 projects already commissioned. These projects have led to the production of 39 different medical devices, ranging from diagnostic equipment to advanced surgical tools, contributing significantly to the enhancement of India's healthcare system. The cumulative investment in these projects stands at **₹879 crores**, a clear indication of the sector's growth trajectory. Moreover, these projects have created employment opportunities for **4,546 individuals**, showcasing the scheme's role in generating jobs and driving economic growth.

The impact of these investments is also reflected in the financial outcomes. The total sales generated from these projects amount to ₹3,251.76 crores, with a significant portion, ₹1,654.09 crores, coming from exports. This not only underscores the quality and competitiveness of Indian-manufactured medical devices in the global market but also highlights the country's potential to become a leading exporter of healthcare products.



Regional Focus and Key Projects in Medical Devices



The medical devices sector has seen substantial investments across key states, with Gujarat, Maharashtra, and Karnataka emerging as leading centers for manufacturing. Gujarat, in particular, has become a hub for medical device production, with Meghmani LLP leading the way with the manufacturing of Para Amino Phenol, a critical input for many pharmaceutical products. In Punjab, Centrient Pharmaceuticals India Pvt. Ltd. has commenced the production of Atorvastatin, a widely used medication for managing cholesterol levels, further expanding the range of critical healthcare products being manufactured domestically.

These developments not only enhance the country's healthcare infrastructure but also reduce dependency on imports, particularly from countries like China, thereby contributing to national security and public health.

Sector	Total Projects	Completed Projects	Ongoing Projects	Cumulative Capacity	Investment (₹ Crores)
Pharmaceuticals	48	32	16	56,679 MT per annum	4,024
Medical Devices	26	16	10	39 Types of Medical Devices	879

Quick Glimpse of Achievements under the PLI Scheme

Source: ABLE



Biofuels Capacity

India's ethanol policy aims to increase the use of biofuels to reduce dependence on imported fuels, enhance environmental sustainability, and support the agricultural sector. The key target is to blend 20% ethanol with petrol (E20) by 2025, advancing from the initial 2030 goal. This policy also aims to utilize diverse feedstocks, including grains, to optimize distillery capacity and flexibility.

The increase in production is driven by government incentives, expansion of existing facilities, and establishment of new distilleries. The ethanol sector significantly impacts the Indian economy by providing markets for surplus agricultural produce and creating rural employment opportunities.



Current Ethanol Production Capacity and Statistics

Total Production Capacity 13.8 billion litres

- Sugarcane Feedstock
 8.8 billion litres
- ⊘ Grain Feedstock
 5 billion litres

Source: ABLE

The increase in production is driven by government incentives, expansion of existing facilities, and establishment of new distilleries. The ethanol sector significantly impacts the Indian economy by providing markets for surplus agricultural produce and creating rural employment opportunities.



Ethanol Production Targets for 2025

- Blending Target: 20% ethanol with petrol
- Required Production Capacity: 17.0 billion litres
- Current Production Level: 13.8 billion litres

Achieving the E20 target will reduce crude oil dependency, cut greenhouse gas emissions, and bolster the agricultural sector.

Upcoming Ethanol Projects

The Indian government has approved several new ethanol projects:

Capacity AdditionInvestme47 CRORE₹1,31LITRESCROI	 ⊘ Grain-Based: 10 projects (using rice, wheat, corn)
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Source: ABLE

These projects are crucial for meeting the E20 target and involve significant investment in infrastructure.

Ethanol Capacity Requirements for 2025

Ethanol Capacity	Molasses-Based	Grain-Based	Total
Current Capacity	880 crore litres	470 crore litres	1,350 crore litres
Required by 2025	970 crore litres	638 crore litres	1,608 crore litres
Additional Capacity Needed	90 crore litres	168 crore litres	258 crore litres

Source: ABLE



Biofuel Dispensing Stations

- ⊘ Ethanol Blending Rate (May 2024): ~15%
- ◎ E20 Fuel Dispensing Stations: 12,000
- ⊘ ETHANOL100 Launch: 183 outlets of IOCL
- ⊘ E85 and E93 Fuels: Introduction of advanced blends, including E93 ethanol in vehicles like Toyota Innova and TVS Apache RTE 200Fi.

Source: ABLE





Source: ABLE

Sustainable Aviation Fuel (SAF)

- ⊘ Current Status: Nascent stage with research and development ongoing.
- ⊘ SAF Blending Targets:
 - o 1% by 2027 for international flights
 - o 2% by 2028
 - o 5% by 2030
- ⊘ Indian Oil SAF Plant: Investment of \$122 million, aiming for an annual output of 88,000 MT of SAF by 2030.

Biodiesel Production and Targets

- 2024 Production Forecast: 226 million litres (13% increase from previous year)
- ✓ Current Capacity: 820 million litres
- ✓ Aspirational Blending Target (2030): 5%
- ✓ Challenges: Import restrictions, feedstock shortages, and inconsistent availability.

Source: ABLE

Socio-Economic Impact Analysis

Driving Employment, Affordability, Innovation, and Sustainable Growth

India's BioEconomy touches many aspects of people's lives daily. Because BioEconomy has products and services that fuel, feed and heal the people in a variety of ways. Some of the key biotech products that touch our lives daily are bread and other dairy and more such products we consume, beverages, clothes we wear that are produced using highly advance water-saving and environment friendly enzymes, the biofuels that help us commute with less carbon footprint, vaccines that keep us away from deadly viruses, hundreds of medicines that we take to ward off many illnesses, the dozens of medical tests we do to diagnose what is making us sick very quickly so that doctors can start right medication and so on. The list of biotech products that we engage with daily is too long.

And as we consume every such product, there are millions of people who are getting these ready for our instant use. The economic value chains are too numerous. It's a large BioEconomy that drives these daily interactions between people and the products.

BioEconomy supports 2 crore people

First some numbers. The country's BioEconomy employs slightly more than 1 million (10 lakh) highly skilled people directly in the 600+ large, medium and small enterprises that produce a host of biotech products. There are few thousand enterprises of varying sizes that employ thousands of highly skilled workers who use these biotech-based raw materials into highly useful finished products. For every job in the BioEconomy, at least 3 to 4 indirect jobs are created in the larger economy. So, we are talking about an employment figure of 3 to 4 million (30 to 40 lakh) jobs in the entire biotech across several downstream sector. In addition, these 4 million Bio-Economy jobs support 4 million families or 20 million (2 crore) family members. Thus, BioEconomy is a significant employment generator for the country.

Bio impact of biosimilars

Biosimilar Trastuzumab: A Global Game-Changer

Biocon's pioneering role in the development of biosimilar Trastuzumab has had a profound impact on global healthcare. The original biologic, priced at an average of \$20,000, was often out of reach for many patients, particularly in developing countries. Biocon's biosimilar version, which is generally 65% cheaper, has significantly increased access to this life-saving therapy. The WHO listing of biosimilar Trastuzumab in is a testament to affordability of Biosimilars. As more biosimilars enter the market, it is expected that the cost of cancer treatments will continue to decrease, improving outcomes for patients around the globe.

CAR-T cell Therapy

Cellular therapies to treat a large number of dis-

eases for which no standard cure exists have been around for more than a decade in many countries. As these are complex medical products the costs are very high and even in the case of many debilitating diseases, not every one gets these latest treatments due to unaffordability. Just take the case of CAR-T Cell therapy developed by a team of researchers and their startup named Immuno-Act in Indian Institute of Technology in Mumbai.

Last year, President of India honoured the team that developed the country's first approved CAR-T cell therapy. Therapy costs about \$40,000 (₹35 lakh in the country. The same treatment abroad costs about 5 times more at \$200,000 (₹1.9 crore). By making available the same world class product at a lower cost, the IIT-Mumbai team has already treated more than 25 people, thus saving precious lives and also the foreign exchange of the country.

There are hundreds of such biotech products developed by companies in India whose products focus on affordability so that access to such cutting-edge technologies become easier for our citizens who need it urgently.

Biofuel and Beverages

The country consumed more than 5.15 billion liters (515 crore liters) of biofuels mainly as ethanol blended upto 13% of petrol used in in 2023. Biofuels are primarily now produced from maize and molasses and in the next stage with newer technologies agricultural wastes could be the key raw materials for bioethanol production.

Biofuel production has many societal benefits. It directly reduces the greenhouse gas emissions from the amount of conventional petroleum product is displaces. As a nation that imports more than 85% of its petroleum products, increase use of alternative biofuels produced within the country enhances our energy security.

As biofuels are sourced from agricultural products, the increased use of home-grown raw materials improves income levels in rural areas.

Various studies indicate that the biofuel component of petrol used in transport has 'net zero' impact on carbon emissions. Use of ethanol has substituted import of 17.3 million metric tonnes of petroleum since 2014. Also carbon emissions have been reduced by 51.9 million metric tonnes in the past decade. There could be some carbon emission during the processes involved in the life cycle assessment of biofuel production. Experts are still working on methodologies to measure the full impact of biofuels.

Another example, according to experts, is ethanol production. Considering the yields of grains such as millets and barley, in addition to other grains used in ethanol production, the average feedstock (grain) yield is assumed to be 2.5 kilos per liter of ethanol. Thus, producing 700 million liters of ethanol requires 1.8 billion kgs or 1.8 million tonnes of grain. According to experts, nearly 3.6 million farmers are engaged in or employed for the grain production used for ethanol.

Vaccines

Serum Institute of India (SII) makes vaccines against diphtheria, tetanus, pertussis, hepatitis B, measles, mumps and rubella, and ships out more than 1.5 billion vaccine doses annually at affordable prices. It is estimated that about 65% of the children in the world receive at least one vaccine manufactured by SII. These vaccines are used in around 170 countries for national immunization programs, saving millions of lives throughout the world. Hyderabad-based Bharat Biotech has over 145 patents and produces hepatitis B, rotavirus and typhoid vaccines, and is developing vaccines for viral diseases like chikungunya and Zika.

According to the WHO, Indian vaccine manufacturers including SII, Bharat Biotech, Panacea Biotec, Sanofi Shantha Biotechnics, Biological E, Hester Biosciences and Zydus Cadila have an installed capacity to manufacture 8.2 billion doses of different vaccines every year. FDI

Foreign Direct Investment (FDI)

The Government has established an investorfriendly FDI policy to encourage investment in the pharmaceutical sector. In Medical Devices, 100% foreign investment is permitted under the automatic route. In pharmaceuticals, up to 100% FDI is allowed in greenfield projects, and up to 74% FDI in brownfield projects is permitted under the automatic route. Government approval is required for foreign investment beyond 74% in brownfield projects.

The pharmaceutical sector contributes approximately 3.71% to the total FDI inflows in the country. From April 2000 to March 2024, FDI inflows in Drugs & Pharmaceuticals (Pharma) and Medtech Sectors reached \$7.74 billion.

The FDI inflows in the pharmaceutical sector, including both drugs & pharmaceuticals and medtech activities, have seen significant growth over the years. In the financial year 2023–24, FDI inflows in the pharmaceutical sector amounted to \$1.06 billion from drugs & pharmaceuticals activities and \$477 million from medtech activities, totaling \$1.54 billion. This represents a decrease from the previous year, where the sector saw a total inflow of \$2.37 billion. However, there was a notable increase in Medtech FDI, rising from \$375 million in 2022-23 to \$477 million in 2023-24. Additionally, biotech FDI constitutes an estimated 40% of the total FDI in Drugs & Pharmaceuticals activities.

The combined FDI in medical devices and drugs & pharmaceutical activities continues to play a crucial role in bolstering the sector's growth, even amidst fluctuating annual inflows.

FDI Inflows (\$ Million)

Year	Drugs & Pharmaceuticals	Medtech
2018-19	221	133
2019-20	438	264
2020-21	1,322	61
2021-22	1,266	185
2022-23	1,998	375
2023-24	1,061	477
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Source: ABLE

Inflows in \$ mn

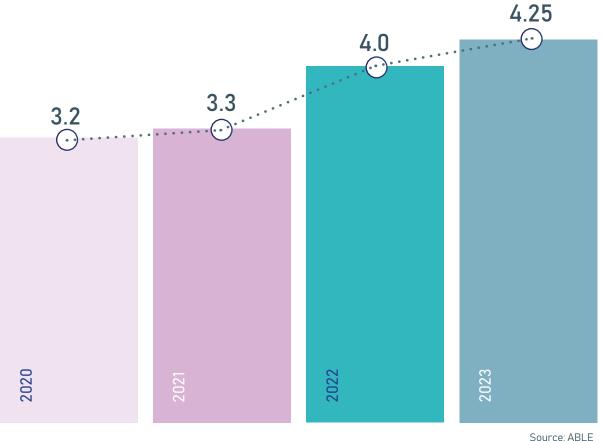
Source: FDI Linked Compliance Monitoring Portal (pharmaceuticals.gov.in)

CONTRIBUTION TO GDP BioEconomy: 4.25% of GDP

The national BioEconomy value stood at \$151 billion or about 4.25% of the national GDP (Gross Domestic Product) of \$3.5 trillion in 2023. The BioEconomy's contribution to the national GDP in 2022 was at 4% of the GDP of (\$3.4 trillion) in 2022.

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BIOTECHNOLOGY



BioEconomy's share of GDP

Source: ABLE

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START-UPS

Incorporation of new Biotechs and Overall Performance Highlights

India's biotech start-ups base (i.e., total number of companies registered since 2010) continued to grow in 2023 as well. The country's total biotech start-up base has expanded to 8,531 companies. The base grew from 3,397 companies in 2019.

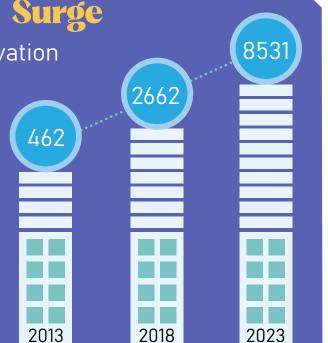




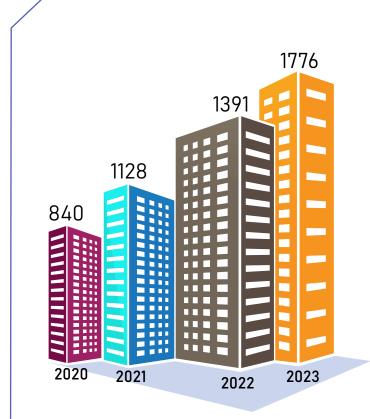
Explosive Startup Surge

A breeding ground for innovation

India's bioeconomy is not just about large-scale figures; it's also about fostering a vibrant startup ecosystem. The number of biotech startups has witnessed an 18-fold increase from 2013-2023, reflecting a staggering Compound Annual Growth Rate (CAGR) of 33.85% This period can be further divided into two sub-phases.



Source: ABLE



New Registrations

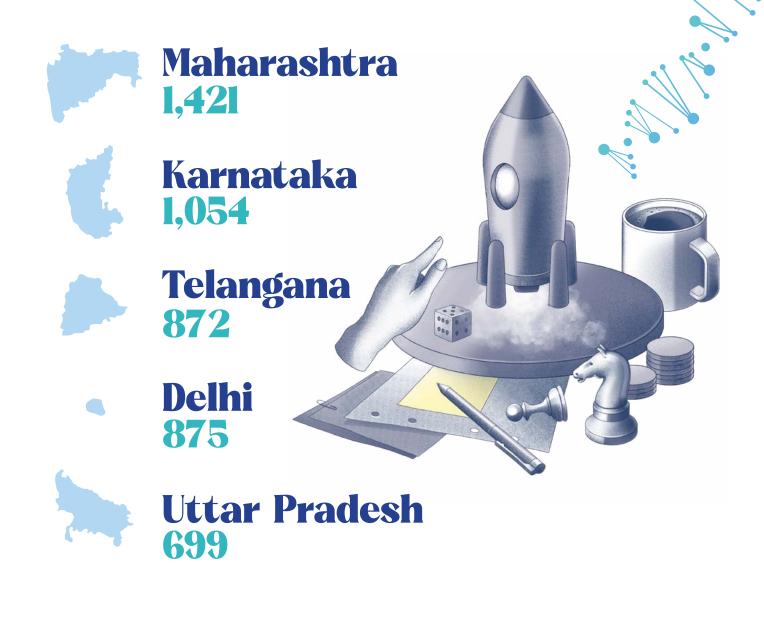
This surge in startups highlights their dynamism and potential as key drivers of innovation and economic growth.

Source: ABLE

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Regional Presence

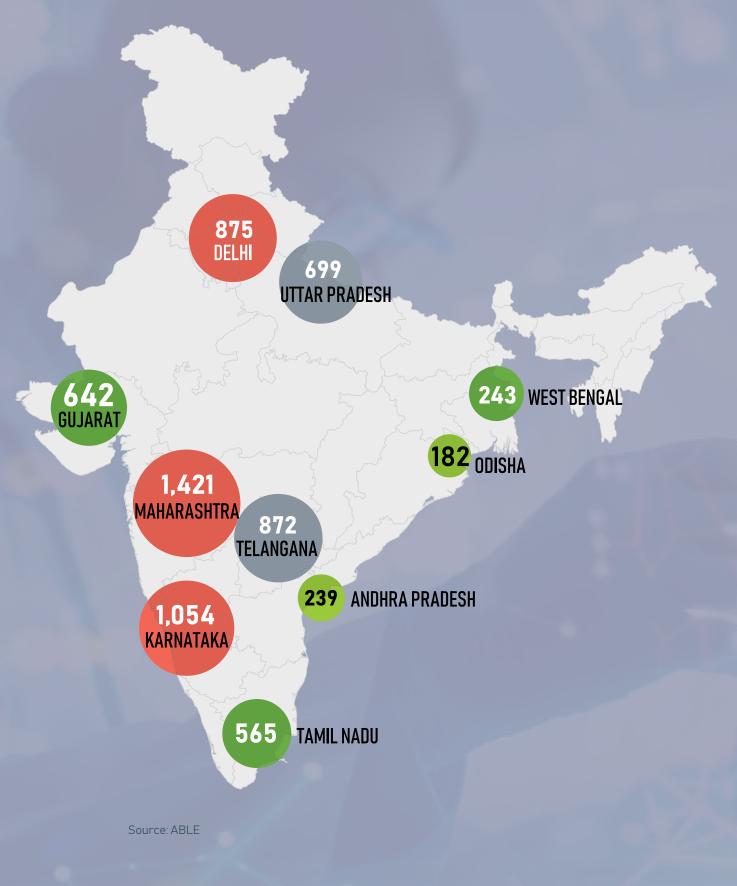
The top five states for Biotech startups are **Maharashtra** (1,421), **Karnataka** (1,054), **Telangana** (872), **Delhi** (875), and **Uttar Pradesh** (699). These states account for over **50%** of all biotech startups in India. The other states have a relatively smaller number of biotech startups, with the exception of Gujarat (642) and Tamil Nadu (565).



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SCAPE

Cumulative Base



The Role of MSMEs in India's BioEconomy

India's BioEconomy, with nearly **10,000** companies ranging from large firms to micro startups, showcases a robust and diverse landscape. The BioPharma and ethanol sector, in particular, have a strong manufacturing base, complemented by a growing number of startups focusing on innovative platforms, research services, and devices. Notably, Micro, Small, and Medium Enterprises (MSMEs) form a significant majority, constituting approximately **90-91%** of the total sector, underscoring their critical role in the broader BioEconomy.

Micro companies are defined as those with turnovers under \$0.6 million (Rs 5 crore), Small companies fall between \$0.6 million and \$6 million (Rs 5-50 crore), while Medium Enterprises report turnovers between \$6 million and \$30 million (Rs 50-250 crore). Companies above \$30 million (Rs 250 crore) in turnover are categorized as large enterprises.

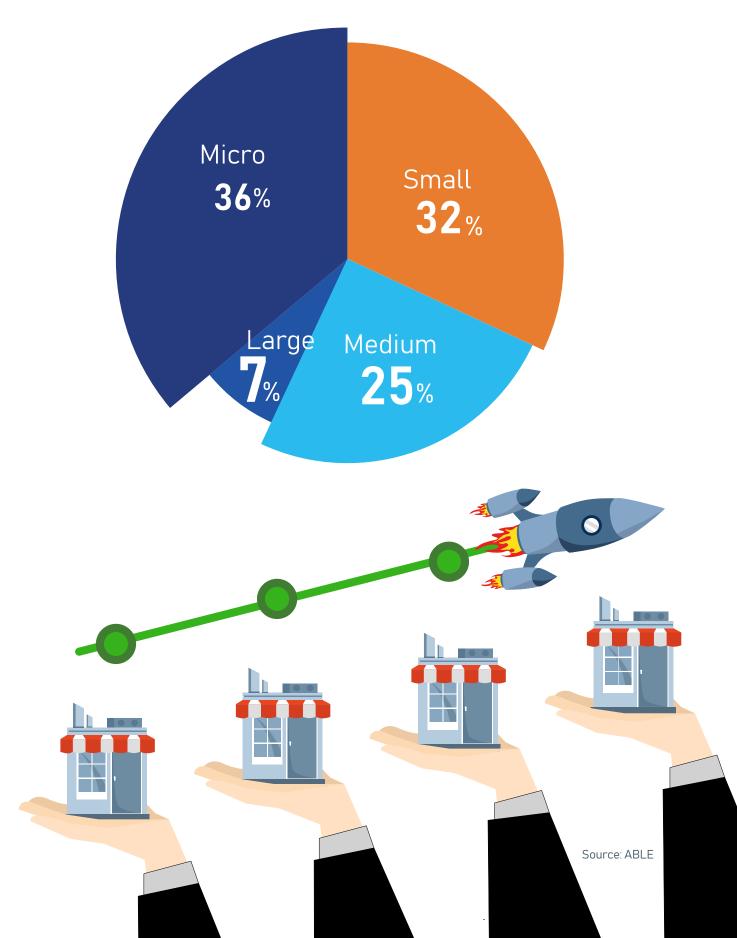
A detailed breakdown of the sector reveals that micro industries constitute 36%, small industries account for 32%, and medium-scale industries make up 25%. Large industries represent just 7% of the total, with most of them concentrated in industrial hubs like Mumbai, Pune, Bengaluru, Baddi, NCR, and Chennai. MSMEs play a critical role in the sector, serving as essential suppliers to larger pharmaceutical and biotech firms, as well as other industries within the green economy. They provide crucial raw materials, intermediary products, platforms, and services essential for the operations of these larger entities.

MSMEs face several challenges, particularly in scaling their operations to meet both national and international regulatory standards. Many MSMEs struggle with inadequate infrastructure, including highend research and development facilities, digital laboratories, and advanced testing centers. Further, limited access to advanced R&D facilities, digital labs, testing centers, and even basic needs like captive power plants restrict their ability to improve efficiency and maintain quality.

Despite these challenges, MSMEs remain the backbone of India's BioEconomy. Their contributions are vital for the sector's growth and resilience, and with continued support and development, they are well-positioned to sustain their crucial role in the industry's future.



Distribution of enterprises in India's BioEconomy



FUNDING TRENDS

Biotech Investments A Shift in Momentum

The biotech industry, which experienced a record-breaking surge in 2022, saw a significant shift in 2023. Total investments plummeted from \$938.8 million across 31 deals in 2022 to just \$199.61 million across 16 deals in 2023. This 79% decline in investment value, coupled with a halving of the number of deals, underscores a marked change in investor sentiment and market conditions within the sector.

Geographic Distribution of Investments (2013-2023)

Over the decade from 2013 to 2023, Karnataka emerged as the clear leader in India's investment landscape, securing a substantial \$1.52 billion in deals, which accounted for 30% of the total \$5.1 billion raised across the country. This reflects the state's strong startup ecosystem, driven by the presence of technology hubs in cities like Bengaluru, which continues to attract significant venture capital.

Telangana and Gujarat also showed strong performance, each attracting \$710 million in investments, representing 14% of the total deals for each state. Telangana, with its thriving tech sector centered around Hyderabad, has become a notable player in the investment scene. Gujarat's equal share reflects its industrial strength and growing focus on innovation and entrepreneurship.

Maharashtra, home to the financial capital Mumbai, secured \$660 million, capturing a 13% share of the total investments. The state's diverse economy and significant business activity make it a key destination for investors. The National Capital Region (NCR), including Delhi, attracted \$410 million in deals, making up 8% of the total. This reflects the region's importance as a business hub with a strong startup culture.

Haryana followed closely with \$300 million, accounting for 6% of the total investments. Tamil Nadu and Uttar Pradesh each secured \$150 million, representing 3% of the total, showing moderate activity in these regions.

Smaller states like Goa contributed \$50 million, representing just 1% of the total, indicating limited but present investment interest. Notably, states like Kerala and Andhra Pradesh reported no investment deals during this period, highlighting regional disparities in investment activity. The remaining states collectively captured 8% of the total investment amount, underscoring the concentration of funding in a few key regions across India.

2023 Funding Landscape: Mixed Trends Across Stages

In 2023, the funding landscape witnessed significant shifts, with average funding sizes showing mixed trends across various investment stages. Angel investments experienced a dramatic decline, plummeting from \$510,000 in 2022 to just \$90,000 in 2023. This sharp drop may indicate a growing caution among earlystage investors, possibly due to heightened market volatility or a recalibration of risk appetite.

Seed funding, which serves as the initial capital to help startups establish their operations, also saw a slight decrease. The average funding size dipped from \$470,000 in 2022 to \$440,000 in 2023. While this decline is less severe compared to angel investments, it reflects a cautious approach among investors, possibly influenced by macroeconomic factors or changing market conditions.

In contrast, later-stage investments showed a more positive trend. Series A funding, which typically supports the scaling of operations, increased from \$5.55 million in 2022 to \$7.15 million in 2023. This rise suggests that investors are more willing to back companies with proven potential, focusing on those that have already established a solid foundation and are ready for growth.

The average Series B funding also experienced a substantial increase, jumping from \$8.49 million in 2022 to \$14.6 million in 2023. This growth indicates strong investor confidence in companies that are in the expansion phase, where funds are needed to boost market reach, product development, and scaling of operations.

However, Series C funding, which often supports companies preparing for major expansion or a potential exit, saw a significant downturn. The average funding size dropped from \$76.5 million in 2022 to \$17.1 million in 2023. This stark decline could be attributed to a more cautious approach among investors, possibly due to uncertainties in exit

Percent Share of Total Deals

State	Deal Amount* \$million	%Share
Karnataka	1520	30%
Telangana	710	14%
Gujarat	710	14%
Maharashtra	660	13%
Delhi	410	8%
Haryana	300	6%
Tamil Nadu	150	3%
Uttar Pradesh	150	3%
Goa	50	1%
Rest of the States	410	8%
Total	5070	100%

*(2013-2023)

Source: ABLE

opportunities or shifting market dynamics.

Overall, these trends highlight a complex and evolving funding environment, where early-stage investments are becoming more conservative, while later-stage funding remains robust, particularly for companies demonstrating strong growth potential. The mixed signals across different stages underscore the need for startups to strategically position themselves to attract the right level of investment amid a changing financial landscape. 100 INDIA BIOECONOMY REPORT BIOTECHNOLOGY LANDSCAPE & INVESTMENTS

INVESTMENT & GROWTH DRIVERS

Strengthening India's Biotech Ecosystem

BIRAC's Decade of Impact



Over the past decade, the Biotechnology Industry Research Assistance Council (BIRAC) has been a cornerstone in the growth of India's biotech ecosystem. Since its establishment in 2012 as a Section 8 Public Sector Enterprise, BIRAC has played a pivotal role in empowering emerging biotech enterprises across the country. Through its unwavering support, BIRAC has nurtured a thriving Biotech Innovation Ecosystem, driving the development of globally competitive and affordable products that address pressing societal needs.

BIRAC's initiatives are comprehensive, ranging from funding high-risk translational research and supporting nascent ideas to building capacity through bioincubation centers and providing mentorship and training. The organization is also deeply involved in policy advocacy, working to further strengthen India's biotech ecosystem.

12+ YEARS OF BIRAC

NURTURING & STRENGTHENING BIOTECH INNOVATION ENTERPRISE

95 incubation centres	7.1 LAKH+ Sq. ft. incubation Space	15 LAKH+ students entrepreneurs engaged	800+ Products in Market	1300+ IP'S FILED
28,000+ proposals assessed	4,800+ Startups Entrepreneurs Supported	₹5,500 CR+ Follow-on-funding Raised by >130 Startups	100+ National & International Partnerships	400+ Academia Supported
35,000+ High skilled jobs created	10,000+ Mentor pool	₹6,600 CR+ Total investment	₹ 4,000 CR+ Birac funding	₹ 2,600 CR+ CO-FUNDING BY INDUSTRY & OTHERS

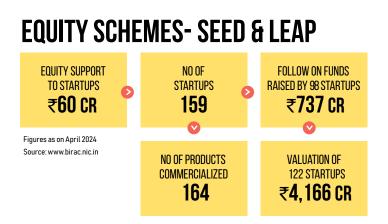
Figures as on April 2024

Aligned with Government of India initiatives like "Make in India" and "Startup India," BIRAC has been instrumental in positioning India as a global hub for biotechnology innovation and bio-manufacturing. The country is on track to meet its BioEconomy target of \$300 billion by 2030, with significant growth expected in sectors such as Bio-pharma, Diagnostics, Medical Devices, and Bio-industrials, both in domestic consumption and exports.

BIRAC envisions a future where innovative biotech-based solutions reduce reliance on non-renewable resources. Key initiatives include promoting ethanol production from natural resources for fuel blending, developing bioplastics, and encouraging the use of biofertilizers and biopesticides as sustainable alternatives to traditional chemicals. The biotech innovation ecosystem, largely driven by startups, continues to grow annually, bolstered by BIRAC's steadfast support.

The success of BIRAC's model is a testament to the visionary approach of the Department of Biotechnology (DBT) in fostering innovation and research and development (R&D). BIRAC's programs and schemes are meticulously designed to foster ecosystem growth, creating a pipeline of entrepreneurs and startups by providing comprehensive support

Source: www.birac.nic.in



FUND OF FUNDS- BIOTECHNOLOGY INNOVATION ACE FUND



from idea conception to product commercialization.

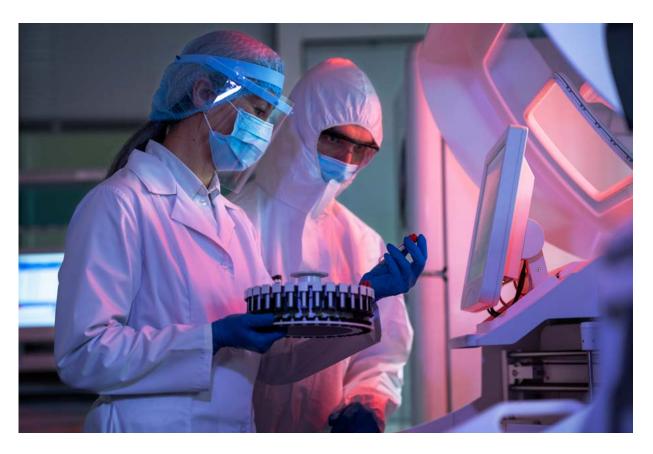
BIRAC's impact is evident in the growing number of funding applications, the increasing count of biotech startups, and the successful commercialization of Made-in-India products. National and international recognition of Indian startups further underscores BIRAC's contributions.

Over the past 12 years, BIRAC has supported more than 4,800 beneficiaries through various programs. The Biotechnology Ignition Grant (BIG) program nurtures a pipeline of biotech startups. More than 1000 innovative ideas have received support, reflecting BIRAC's extensive reach across 550+ cities and 38 aspirational districts in India. Early-stage schemes like E-YUVA and SPARSH create a robust pipeline of innovators for the BIG scheme.

BIRAC's Bioincubation (BioNEST) and pre-incubation (EYUVA) programs have successfully established and supported over 95 bioincubation facilities nationwide, serving as incubators for nascent ideas. These facilities provide access to high-end infrastructure, specialized equipment, business mentorship, intellectual property (IP), legal and regulatory guidance, and networking opportunities, strategically located within universities, research institutes, research hospitals, or as standalone centers.

These centers provide entrepreneurs with the space and resources needed to test ideas, run operations, access highend instrumentation, and connect with mentors and peers. From 2014 to 2023, the number of BIO-NEST incubators





increased from six to 75, creating a dynamic environment for entrepreneurial minds.

Under the umbrella of i4: Intensifying the Impact of Industrial Innovation, BIRAC's Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Program (BIPP) continue to enhance R&D capabilities for biotechnological product and technology development.

BIRAC's PACE Scheme (Promoting Academic Research Conversion to Enterprise) nurtures translational research within academia. Additionally, equity schemes such as SEED (Sustainable Entrepreneurship and Enterprise Development) Fund, LEAP (Launching Entrepreneurial Driven Affordable Products) Fund, and Biotechnology Innovation Fund of funds AcE – (Accelerating Entrepreneurs) further contribute to BIRAC's holistic approach. While BIRAC supports the entire biotechnology sector, it has also launched niche initiatives aligned with national missions, such as those focused on antimicrobial resistance, anti-snake venom, and preclinical models for drug discovery. The recently announced Biomanufacturing and Bio-AI Metabolic Hubs program is another step towards strengthening India's position in biomanufacturing.

Looking ahead, BIRAC is focused on consolidating its achievements and developing strategies for critical components such as infrastructure, regulatory frameworks, and intellectual property. The organization will continue to sustain, support, and scale innovative biotech-based solutions, fostering partnerships with government agencies, venture capitalists, angel investors, and international organizations to collectively contribute to the growth of the innovation ecosystem.

INVESTMENT & GROWTH DRIVERS

State and Union Territory Startup Investment Promotion

Most Indian states are actively promoting startups and investments through dedicated policies. Each state and Union Territory has its own approach to supporting incubators and innovation centers. These policies offer a range of financial incentives, grants, and infrastructure support aimed at stimulating entrepreneurial growth and fostering a vibrant startup ecosystem. From capital grants to land leases, these diverse measures reflect the varied strategies adopted by regional governments to encourage innovation and support startups across India.

State/UT	Policy Details
Andaman & Nicobar	₹1 Crore innovation fund by ANIIDCO Ltd for startup incubators and coworking spaces.
Assam	75% grant up to ₹5 Crore for incubation centers at IITs, engineering colleges, etc.
Andhra Pradesh	Lease of land/space for 90 years at Government-owned IT Parks for NSTEDB-recognized TBIs.
Bihar	Fiscal grant @3% for tech startups, @5% for social sector startups, and 1:1 financial assistance matching Government of India or donor funding.
Chhattisgarh	Innovation Fund for core incubator-cum-accelerator setup for three years, covering infrastructure, operating costs, and events.
Goa	One-time grant of ₹10 lakhs for educational institutes to set up incu- bators for student-founded startups.
Gujarat	Eligible incubators can choose between startup policies and receive one-time capital assistance of 50% of Gross Fixed Capital Investment.

State and Union Territory Startup Policies for Startup Support in India

Haryana	Establishment of at least 22 Technology Business Incubators and Accelerators across different sectors.
Himachal Pradesh	Financial assistance of ₹30 lakh per incubator per year for three years.
Jharkhand	Government-funded institutes receive ₹50 lakh annually for the first 5 years for setting up incubation/innovation centers.
Karnataka	State support for initial capital cost, recurring costs for management of TBIs for 3–5 years.
Madhya Pradesh	Capital grant of max 50% for fixed cost investment, up to ₹50 lakh for setting up an incubator.
Maharashtra	Infrastructure Fund to assist incubators, accelerators, CoEs, and tinkering labs with capital and operational expenditures.
Manipur	Special fiscal incentive @2% for incubators on investments received by incubates from SEBI registered VC/PE.
Nagaland	Financial assistance up to ₹25 Lakh as capital grant to incubators.
Odisha	Approved educational institutions eligible for a one-time grant of 50% of capital cost up to ₹1 crore for incubator facilities.
Puducherry	Land or built-up space allotted on a preferential basis in Industrial Estates/IT Parks for setting up incubators, coworking spaces, etc.
Punjab	100% capital grant subject to a maximum of ₹1 crore for setting up incubators.
Rajasthan	One-time grant for capital items up to ₹50 lakh for host institutes for entrepreneurship development and startup events.
Tamil Nadu	Land allotted at nominal lease for 99 years to establish 'Startup Parks' for entrepreneurs/NRIs.
Telangana	Matching funding raised by the incubator from Government of India on a 1:1 basis as matching grants.
Uttar Pradesh	Capital grant of max 50% for IT infrastructure setup, up to ₹25 lakh, with similar grants for expanding existing incubators.
Uttarakhand	Capital grant of max 50% for IT infrastructure setup, up to ₹25 lakh, and 50% of capital cost up to ₹1 crore for incubators.
West Bengal	Support of ₹10 lakh to universities for creating a central Entrepreneurship Development Centre (EDC).

Comparative Overview of Bioincubators and Biotech Parks

India's leading incubators have been pivotal in advancing biotech innovation and supporting diverse startups

Most Indian states are actively promoting startups and investments through dedicated policies. Each state and Union Territory has its own approach to supporting incubators and innovation centers. These policies offer a range of financial incentives, grants, and infrastructure support aimed at stimulating entrepreneurial growth and fostering a vibrant startup ecosystem. From capital grants to land leases, these diverse measures reflect the varied strategies adopted by regional governments to encourage innovation and support startups across India.

Trends in Biotechnology Incubation Across India

With India's biotechnology sector booming, the incubation spaces are rapidly expanding across regions, offering diverse facilities and catering to a variety of focus areas.

South India leads the biotechnology incubation landscape, accounting for the largest share of the total incubation space in the country. With major hubs such as Hyderabad, Bengaluru, and Chennai, the region dominates with state-of-the-art infrastructure and focus areas ranging from life sciences and MedTech to bio-industrial innovations. West India follows, with significant contributions from cities like Mumbai, Pune, and Ahmedabad. The Society for Innovation and Entrepreneurship (SINE) at IIT Bombay and Venture Center in Pune are key players, offering large and versatile incubation spaces, particularly for MedTech and technology startups. The Savli Technology & Business Incubator in Vadodara, Gujarat,

Top Regions adds to this, focusing on biotechnology dedicated to multi-sector advancements.

India's biotech ecosystem is robustly supported by 95 incubators across various regions. The highest concentration is in South India, hosting 53% of these facilities, including key hubs in Bengaluru and Hyderabad. North India follows with 21%, featuring prominent incubators like the Indian Institute of Technology (IIT) in Delhi. West India houses 12% of the facilities, including notable centers in Pune and Mumbai. North East India, with 7%, and East India, with 4%, also contribute significantly to the sector. Central India holds a modest 2%, reflecting the diverse geographical spread of biotech support across the country.

Top States and Cities for Incubation

Karnataka, Telangana, and Maharashtra emerge as the leading states, housing multiple worldclass incubation centers. Bengaluru, often referred to as the biotech capital of India, is home to various prestigious incubators like the Bangalore Bioinnovation Centre (BBC) and C-CAMP, each contributing significantly to Med-Tech, healthcare, and bio-industrial sectors.

Hyderabad also stands out, with incubators like IKP Knowledge Park, T-Hub, and Society for BioTechnology Incubation Centre (SBTIC), which together offer over 100,000 sq. ft. of cutting-edge infrastructure, particularly in life sciences, healthcare, and agri-tech. The city's facilities provide shared equipment, co-working spaces, and partnerships with industry leaders, making it a major biotech ecosystem. In Maharashtra, Mumbai and Pune are significant biotech incubator hubs, especially in MedTech and technology startups. SINE at IIT Bombay and Venture Center in Pune are examples of how Maharashtra is fostering a thriving startup environment.

Telangana and Tamil Nadu lead the country in the number of incubation facilities, with 14 and 13 locations respectively.

India's incubation sector is characterized by a mix of concentrated hubs and broader regional support.



Infrastructural Services: Building the Future of Biotech

One of the major trends observed in India's biotech incubation landscape is the emphasis on comprehensive infrastructural services. Incubators across the country are offering high-end facilities designed to support biotech startups at every stage of their growth.

Many incubators, such as TICEL BioPark Ltd. in Chennai, are equipped with clean rooms, industrial HVAC systems, and fume hoods, providing an ideal environment for bio-industrial research and manufacturing. Similarly, KIIT-TBI in Bhubaneswar offers specialized technology and testing labs, ensuring startups have access to the latest tools and resources to innovate effectively. Other infrastructure offerings include advanced wet labs, prototyping spaces, and shared equipment facilities, available in incubators like IKP Knowledge Park in Hyderabad and Bangalore Bioinnovation Centre. These facilities enable startups to prototype and test their innovations rapidly, significantly reducing the time to market.

A key driver of this ecosystem is Biotechnology Industry Research Assistance Council (BI-RAC), which has played a pivotal role in establishing incubation spaces across India. BIRAC has created a vibrant ecosystem comprising 95 bioincubators.

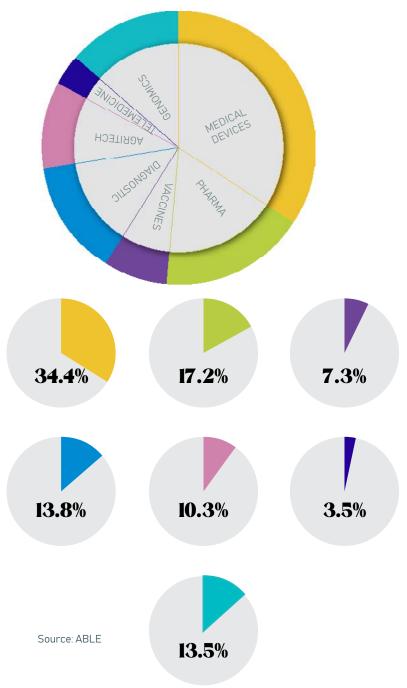
PRODUCTS India Welcomes New Biotech Products

New Product Releases Drive Innovation

The year 2023 saw a wave of innovative new product releases in India's healthcare sector, revolutionizing diagnostics, therapeutics, and preventive care.

The year was marked by a surge in groundbreaking medical innovations. Al-powered solutions, like LifeSigns' remote patient monitoring platform, and innovative devices, such as the 3D printed device for UTI diagnosis, showcased India's technological advancements. Preventive healthcare also witnessed significant progress with the introduction of various vaccines, DNA tests, and early screening solutions. These new product releases have the potential to improve healthcare outcomes, enhance accessibility, and drive overall progress in the Indian healthcare landscape. This is a sample list of notable product launches and may not include all the significant innovations introduced during the year. A quick analysis of the products launched in 2023 reveals a strong emphasis on technological innovation and a focus on improving healthcare outcomes in India.





Medical devices account for the largest share of new product releases at 34.4%, followed by pharmaceuticals 17.2%, vaccines 7.3%, and genomics solutions 13.8%. This highlights a concerted effort to incorporate cuttingedge technologies and groundbreaking solutions into medical devices. Although agricultural technology 10.3% and telemedicine/ others 3.5% are showing growth, medical devices and pharmaceuticals continue to be the primary drivers of new product launches in the Indian healthcare market

THERAPIES

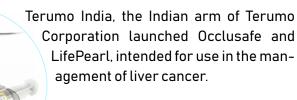
Alkem launches novel antibiotic for multiple drug resistance infections

Alkem (Intenza, critical care division) has announced the launch of its novel anti-infective in India under the brand name, Zidavi, which is novel combination of ceftazidime and avibactamrecommended by the Infectious Disease Society of America (IDSA) and the Indian Council of Medical Research (ICMR) as a preferred treatment against OXA-48-like and Klebsiella pneumoniae carbapenemase (KPC)-producing carbapenem-resistant Enterobacteriaceae (CRE) for pyelonephritis or Complicated Urinary Tract Infections (cUTI) and in other CRE infections caused by KPC and OXA-48 producers.

Medtronic launches 'Symplicity' blood pressure procedure for hypertension in India

India Medtronic Private Limited launched Symplicity Spyral renal denervation system (RDN) for treating high blood pressure.RDN is a minimally invasive therapy that targets nerves near the kidneys that can become overactive and cause high blood pressure. Medtronic received the US Food and Drug Administration's (FDA) approval of the system which is a culmination of ten years of clinical research and development, and the system has approval of the Indian regulatory authorities too.

Terumo India advances liver cancer care in India with launch of Occlusafe & LifePearl



For the first time in India, a Japan based company, Terumo, had introduced an advanced therapy called Balloon-TACE (B-TACE) for the management of liver cancer. WithOcclusafe, Terumo's B-TACE device, patients benefit from more precise and targeted delivery of chemotherapy drug to the tumour.

VACCINES

GSK introduces shingles vaccine Shingrix in India

British firm GlaxoSmithKline (GSK) Pharmaceuticals has announced the launch of Shingrix (Zoster Vaccine Recombinant, Adjuvanted) in India, for the prevention of shingles (herpes zoster) and post-herpetic neuralgia in adults aged 50 years and above. Shingrix is the world's first non-live, recombinant subunit vaccine to be given intramuscularly in two doses.

India Launches First Made-in-India Cervical Cancer Vaccine 'CERVAVAC'

The Serum Institute of India (SII) has launched the country's first indigenously developed Quadrivalent Human Papillomavirus (qHPV) vaccine, CERVAVAC, marking



a significant milestone in healthcare and women's well-being. Developed through a partnership between SII, the Department of Biotechnology (DBT), the Biotechnology Industry Research Assistance Council (BIRAC), and the Bill and Melinda Gates Foundation, CERVAVAC places India at the forefront of the global fight against cervical cancer by offering affordable and accessible healthcare solutions.

Indian Immunologicals unveils Measles and Rubella vaccine for children

Vaccine maker Indian Immunologicals (IIL) launched measles and rubella vaccine Mabella for children. A live-attenuated MR vaccine developed in an exclusive partnership with Polyvac Institute of Vietnam, Mabella was launched as part of the 25th celebrations of the IIL division Human Biologicals Institute (HBI) in Udhagamandalam (Ooty), Tamil Nadu.

World's first and only oral cholera vaccine in LDPE unidose pack launched in India

TechInventionLifecare has partnered with Eubiologics Co. in South Korea, to launch Euvichol-Plus, the world's first and only oral cholera vaccine (OCV), in a low-density polyethylene (LDPE) unidose pack in India.

DIAGNOSTICS & **MEDICAL DEVICES**

CrisprBits, Molbio Diagnostics launch CRISPRbased Point-of-Care tests

CrisprBits and Molbio Diagnostics launched point of care diagnostics by the introduction of CRISPR in Point-of-Care (POC) tests. The strategic partnership between CrisprBits and Molbio Diagnostics represents a significant milestone in the advancement of accessible, cost effective and accurate diagnostic testing in the frontline. The collaboration is set to identify and capitalize on market opportunities, bringing together their respective strengths and expertise. By harnessing the unprecedented sensitivity and specificity of RNA guide-based target identification of nucleic acid, and the presence of both cis and trans-cleavage property of certain Cas enzymes, CrisprBits has developed a platform to build rapid, precise, and affordable POC tests for a wide range of disease and health conditions.

Healthium Medtech launches TRUMAS

Healthium Medtech launched TRU-MAS, a range of sutures designed to address challenges faced during suturing in minimal access surgeries. Minimal access surgery, a technique that has gained remarkable momentum over the last two decades, is now consid-

ered the gold standard for performing surgeries across various medical specialties.

GenWorks Health launches IVD tests for Dengue & Malaria

To improve the offering in the IVD field, GenWorks launched In-Vitro Diagnostic tests including Rapid Card test kits for Dengue and Malaria.iScreen Malaria Card Antigen (Pf/Pv) by GenWorks is a visual lateral flow immunoassay designed for the qualitative and differential detection of P. falciparum specific histidine-rich protein-2 (Pf. HRP-2) and P. Vivax specific lactate dehydrogenase (pLDH) in human whole blood with 98.5% sensitivity & 95% specificity.

IIT Guwahati researchers develop 3D printed device for rapid diagnosis of Urinary Tract Infection

Indian Institute of Technology Guwahati(IIT Guwahati) Research team led by Dr. Partho Sarathi Gooh Pattader developed a fast, accurate, and reliable device to detect specific bacteria that cause Urinary Tract infection (UTI).The estimated cost of manufacturing the device is ₹608 while testing a single sample will cost ₹8 only.The device can measure and identify the type of bacteria in a UTI suspected patient in 5 minutes compared to conventional detection, which uses urine culture that requires a few days.

LifeSigns launches first-of-its-kind Al-powered uninterrupted health monitoring solution

LifeSigns' solution for the first time provides 24×7 real-time, uninterrupted streaming of patient data to doctors and healthcare professionals, whether the patient is at home, in the ambulance or at the hospital. The company deploys remote patient monitoring solutions in 1000 rural and tier III cities across India, in the next 1000

days. LifeSigns also inked a strategic partnership with RailTel Corporation, a leading provider of optic fiber network services. LifeSigns will leverage Rail-Tel's optic fiber cable network spanning more than 62,000 km to provide enhanced connectivity across rural India, enabling remote monitoring of patients.

Lord's Mark Industries launches Microbiotech to pioneer genome testing in India

Mumbai-based Lord's Mark Industries has launched a new wholly owned subsidiary – Lord's Mark Microbiotech – to champion genome testing in India with their first online lab. The new subsidiary has been established as a part of celebrations to mark the successful completion of 25 years of excellence in business by Lord's Mark Industries. With the launch of Lord's Mark Microbiotech, the company is also introducing saliva-based technology for genome testing through its brand MyDNA, which results 99% accuracy. The saliva-based test does not require the extraction of blood or a phlebotomist. An individual can do it after reading the enclosed instructions in the kit at their home.

Lord's Mark Industries also has its patented algorithm called SNAPPY for calculating the Polygenic Risk Score (PRS), which estimates an individual's genetic risk (predisposition) for a trait or condition. PRS takes the sum (aggregate) of all known common variants to calculate an overall genetic risk for a particular disease.

MapMyGenome announces launch of at-home microbiome test

MapMyGenome, a Hyderabad-based preventive genomics company, has announced the launch of Mapmybiome, a DNA based at-home test for understanding and improving your gut health. The test gives you a detailed view of the microbial species in your gut and how they affect your health, energy, and mood.

MapMyGenome launches DNA test for personalised skin and hair care

MapMyGenome launched BeautyMap, a DNAbased test that provides personalised recommendations for skin and hair care products based on an individual's unique genetic makeup. The test will be available in the Indian market at a price of ₹6999.

BeautyMap is the first of its kind in India and aims to help people achieve their beauty goals by understanding their genetic predispositions to 40 conditions related to skin and hair care such as acne, hair loss, sun damage, hydration, sleep habits, and vitamin levels, among others.

Mylab launches Point-of-Care solution for newborn screening

Mylab Discovery Solutions launched a Point-of-Care Device named MyNeoShield for New-born Screening.This device makes screening faster, more accessible, and more affordable, ultimately saving lives and preventing lifelong illnesses. The device supports all the seven tests done for New-born screening globally.

Roche Diagnostics launches dual antigen & antibody diagnostic test for hepatitis C

Roche Diagnostics India launched Elecsys HCV Duo, India's first commercially available fully automated immunoassay that allows simultaneous and independent determination of the hepatitis C virus (HCV) antigen and antibody status from a single human plasma or serum sample. This means that the test canbeused to detect the early stage of infection, as well as when the patient is recovering from the virus, or even during chronic infection.

Roche Diabetes Care manufactures blood glucose monitoring meters in India

Roche Diabetes Care India (RDC India)blood glucose monitoring device 'Accu-Chek Active' is now manufactured in Indiain collaboration with their manufacturing partner Sanmina-SCI India Pvt. Ltd. and assembly & distribution partner Parekh Integrated Services Pvt. Ltd. (PISPL).

The production of Accu-Chek Active meters will take place in Sanmina's state-of-the-art multi-client manufacturing site in Chennai, India, in line with the globally approved quality standards synonymous with the brand.The new Accu-Chek Active product packs will now proudly display the 'Made in India' tag.

Thermo Fisher launches PCR kits for detection of infectious diseases

Thermo Fisher Scientific designed the Applied Biosystems TaqPath PCR kits for infectious diseases such as Multi-Drug Resistant Tuberculosis (MTB MDR), M. Tuberculosis complex (MTB), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and for genetic analysis (HLA B27), have received licensing rights by the Central Drugs Standard Control Organisation (CD-SCO) and will be manufactured in India in association with Mylab Discovery Solutions, India's leading healthcare company.

The Applied Biosystems TaqPath PCR kits have been analytically- and clinically-validated for use in patient care for disease screening and diagnosis, monitoring of therapeutic response and disease progression, and identification of genetic risk factors.

BIOSUPPLIERS & SERVICES

Beckman Coulter unveils Next Gen Immunoassay Analyzer

Beckman Coulter unveiled the Dxl 9000 Access Immunoassay Analyzer which can run up to 215 tests per hour per square meter (tests/hr/m2). The platform has been independently verified to perform at the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) optimal level, the highest level of EFLM performance evaluation. At the same time, the novel Lumi-Phos PRO Substrate has shown the capability to develop increasingly sensitive and clinically relevant assays, ensuring the system is able to meet the healthcare needs of tomorrow.

Medanta & GE HealthCare launch Tele-ICU services in India

Medanta group of hospitals launched Tele-ICU services in India as Medanta e-ICU project, in association withGE HealthCare. This association address the existing gaps in critical care, with high level knowledge transfer via 24×7Medanta e-ICU Command Centre, powered by cutting edge technology from GE HealthCare that equips both central and bedside medical teams.This medical-techni-

Revvity launches its T-SPOT.TB test for latent TB screening in India

Revvity launched T-SPOT.TB test for latent TB screening, at MICROCON in Lucknow.Revvity's T-SPOT.TB is the only FDA-approved, commercially available IGRA (interferon gamma release assay) based on the ELISPOT technology.

This technology includes the isolation, washing and counting of peripheral blood mononuclear cells (PBMCs) from whole blood to standardize the test and provide reproducible results for reliable detection — even in challenging-to-screen groups, such as the immunosuppressed.

cal platform will provide a near real-time patient monitoring, even during the odd hours like midnight, enabling early patient interventions.

PerkinElmer launches EnVison Nexus Multimode Plate Reader

PerkinElmer launched EnVisionNexus system, its fastest and most sensitive multimode plate readerto date, designed for demanding high-throughput screening (HTS) applications and to accelerate drug discovery efforts. The EnVision Nexus platform, with complementary microplates and optimized reagents from PerkinElmer's drug discovery reagents portfolio, including proprietary HTR and AlphaLISAtechnologies and latest reagent kits, provides researchers increased assay flexibility.

The EnVision Nexus system features high-throughput, exceptionally fast dual detectors, enabling researchers to screen millions of samples with the increased accuracy, speed and sensitivity. For walkaway convenience, the system can be equipped with a plate stacker for 20 or 50 plates or can also be fully automated and integrated for 24/7 workflow-driven automation.

BIOAGRI

Garuda Aerospace, Ninjacart launch agri-tech solutions

Garuda Aerospace, a leading manufacturer of drones for the Agritech sector and Ninjacart an Agritech e-commerce startup, brought together advanced dronetechnology to farmers across India.Through

t h is partnership, Garuda Aerospace and Ninjacart will offer short-term financing options to farmers, enabling them to access the latest drone technology at affordable rates.Using drones in the fields helps improve crop yields, reduce costs and increase efficiency. By partnering with Ninjacart, Garuda Aerospace will be able to reach more farmers and provide them with the benefits of this emerging technology.

Netafim India launches latest drip technology, aims to reach 35,000 farmers by 2025



tive drip technology is now available to farmers of all scales, from large to small holdings, regardless of subsidy eligibility. The drip line is engineered for swift deployment, allowing farmers to cover up to 10 acres in a single day. This revolutionary feature saves both time and resources.

Syngenta India launches agriculture drone spraying awareness drive



Syngenta India launched a special awareness drive by simultaneously using 100 drones across Punjab and Haryana to spray its advanced crop protection solution – Incipio. With this Syngenta has taken another pioneering step towards advancing sustainable agriculture.

With the increasing role of drones in boosting agricultural productivity and empowering farmers, this initiative aims to equip farmers of Punjab and Haryana with benefits and implications of modern farming practices and also educate farmers about the transformative potential of drones in farming, including efficiency improvements, cost reductions, and the promotion of sustainable practices.

Syngenta India launches Incipio and Simodis

While Incipio effectively combats stem borers and leaf folders in rice, Simodis saves vegetables against sucking and lepidoptera insects as well as protects paddy crops. These advanced products, based on the innova-



tive PLINAZOLIN technology, offer

effective defence against various pests, ensuring improved yields and crop quality. These are developed to efficiently meet the challenges arising from climate change and pest resistance, which are responsible for major crop losses every year.

Section 6

POLICY AND REGULATORY ENVIRONMENT



Policies

Major Policy Reforms Enhance Governance and Impact

The Department of Biotechnology (DBT) has successfully executed the rationalization of autonomous bodies, subsuming **14 institutes** under the Biotechnology Research and Innovation Council (BRIC). This restructuring aims to centralize governance for maximum impact in biotech research across India.

Policy Measures Fueling the Bioengine

The Government's proactive policy interventions have played a pivotal role in propelling this growth. Key measures include:



Biofuel Policy Introduction of biofuel policies promoting 10% and 20% blending of ethanol with petrol.



Startup Support BIRAC's support for over 4500 startups, entrepreneurs and government-backed development of over 750 products.



Product Linked Incentives Schemes incentivising the production of pharmaceutical products within India.



Regulatory Advancements Formulation of globally acclaimed Biosimilar guidelines and gene editing guidelines.



Mission-Oriented Approach

Launching of the National Biopharma Mission for indigenous vaccine development and the National Medical Devices Policy 2023.



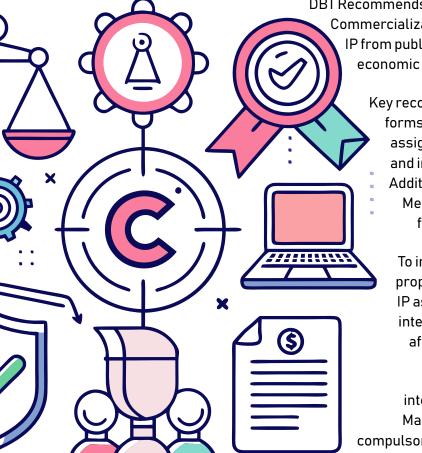
Strategic Vision

Unveiling the National Biotechnology Development Strategy 2020-2025, aiming for India's recognition as a Global Biomanufacturing Hub by 2025.

To incentivize industry involvement, DBT proposes allowing exclusive licensing and IP assignment for products/technologies intended for large-scale public deployment, with affordability clauses for the Indian market.

Strengthening Intellectual Property Guidelines in September 2023

The Department of Biotechnology (DBT), in consultation with stakeholders, has notified Intellectual Property (IP) guidelines to facilitate seamless transfer of IP from research organizations to commercialization, thereby enhancing societal impact.



DBT Recommends Overhauling IP Policies to Boost Commercialization. DBT emphasized the need to harness IP from public-funded research for maximum socioeconomic impact.

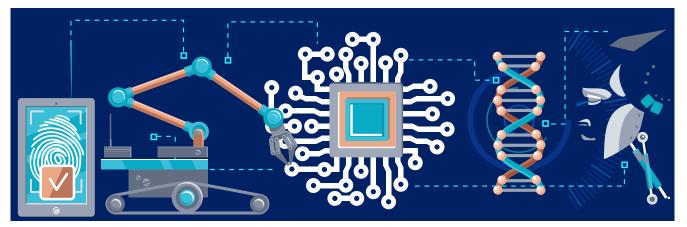
Key recommendations include allowing various forms of licensing- non-exclusive, exclusive, or IP assignment - based on the inventor's discretion and institutional IP committees' decisions.
Additionally, DBT suggests amending grant Memoranda of Agreement (MoA) to provide flexibility in licensing options.

To incentivize industry involvement, DBT proposes allowing exclusive licensing and IP assignment for products/technologies intended for large-scale public deployment, with affordability clauses for the Indian market.

Moreover, DBT assures protection of publicinterest issues through mechanisms like March-in Rights, including the option of compulsory licensing under patent law.

These reforms aim to streamline the transfer of IP from institutes to commercialization, fostering technological innovation for larger societal impact.





National Consultation Meeting Propels Policy Framework on Biomanufacturing

A major initiative has been launched to promote high-performance Biomanufacturing, fostering innovation, scale-up, and manufacturing facilities for bio-based commercial products. This initiative is expected to drive growth in India's Bioeconomy.

This is a bid to capitalize on India's burgeoning bioeconomy set to reach **\$300 bn** by 2030, and align with the vision of Green Growth outlined in the Union Budget 2023-2024. The Department of Biotechnology (DBT) is spearheading a pioneering initiative. Termed **"Fostering High Performance Biomanufacturing: An Integrated Approach towards Promoting Circular Economy for Green, Clean, and Prosperous India**," this national endeavor aims to cultivate world-class expertise, infrastructure, and workforce in synthetic biologybased sustainable manufacturing practices.

At the core of this initiative lies the concept of a cutting-edge 'plug and play' manufacturing model for Industry 4.0. Leveraging advanced biotechnological tools like synthetic biology, genome editing, and metabolic engineering, DBT envisions a comprehensive national infrastructure platform to propel the synthetic biology capacity of a bio-manufacturing program. Central to this infrastructure are biofoundries, high-throughput facilities equipped with state-of-the-art automation methods, including robotics, Al algorithms, and high-throughput analytical equipment.

Biofoundries play a pivotal role in implementing a Design-Build-Test-Learn (DBTL) approach, facilitating the rapid development of tools and datasets for rational strain improvement in biomanufacturing. Pilot-scale biomanufacturing units, employing fermentation with enhanced microbial cell factories and utilizing sugar, biomass, or waste-based raw materials, are envisioned to produce a wide array of bio-based products across sectors like biopharmaceuticals, bulk chemicals, biomaterials, and more.

With its potential for innovation, energy efficiency, and reduced pollution, biomanufacturing aligns with the ethos of 'Lifestyle for the Environment (LiFE)' advocated by the Honorable Prime Minister. By harnessing biomass and waste resources, a pan-India biomanufacturing program can cater to burgeoning consumer demands, bolster the nation's economy, and steer towards net-zero carbon emissions. In light of these prospects, establishing a robust national strategy for advancing biomanufacturing is imperative to enhance India's scientific and economic competitiveness. The proposed policy framework aims to catalyze the transition towards a sustainable, circular economy, driving India's progress towards a greener and more prosperous future.

Streamlining Regulatory Approval Processes

DBT has launched the Biological Research Regulatory Approval Portal (BioRRAP), simplifying regulatory approval processes for biological research activities in India, fostering ease of scientific research.BioRRAP provides a single route to direct the applicant to regulatory agencies providing requisite approval relevant to the

biological research. Based on a succinct set of questions responded in affirmative by the applicant, the list of regulatory agencies from whom approvals may be required for biological research, is determined and attached to the unique BioRRAP ID generated on the submission.Mandatory registration at BioRRAP is required for all organizations and researchers conducting biological research in India. The portal enables researchers to submit their proposals, which are subsequently forwarded to the relevant regulatory authorities for necessary approvals.

India Introduces Guidelines for Research on Genetically Engineered Insects

In compliance with the "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered

Organisms or Cells 1989," established by the Ministry of Environment, Forest and Climate Change (MoEF&CC), the Government of India regulates all activities concerning Genetically Engineered (GE) organisms and hazardous microorganisms. Recognizing the diverse applications of genetic engineering in insects and the need for stringent biosafety measures, the "Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023" have been meticulously crafted. These guidelines ensure the safety of organisms and the environment while maximizing the benefits of genetic engineering.

Following extensive deliberations by an expert committee and the Review Committee on Genetic Manipulation (RCGM), the Guidelines received approval and endorsement during RCGM's 252nd meeting held on 22.02.2023. The Department of Biotechnology officially notifies the adoption of the "Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023." Offering a comprehensive regulatory roadmap, the Guidelines delineate standard operating procedures and data requirements essential for conducting research with GE insects within controlled environments.

These Guidelines and SOPs are binding for all public and private entities engaged in the research and handling of GE insects under containment facilities. The introduction of the "Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023" marks a significant step towards ensuring responsible and safe practices in genetic engineering research, fostering innovation while safeguarding environmental and public health interests.





Government of India Unveils National Medical Device Policy to Revolutionize Healthcare Sector

On May 2, 2023, the Government of India announced the National Medical Device Policy, 2023, with a vision to transform the medical device sector into a key driver of public health objectives. The policy aims to ensure the production of quality medical devices, promote accessibility and affordability,

and foster innovation and growth in a coordinated manner.

The policy sets ambitious missions to achieve universal access to quality healthcare, enhance domestic manufacturing capacity, ensure global competitiveness, improve clinical outcomes, promote healthier lifestyles, foster innovation, and develop resilient supply chains. It emphasizes a patient-centric approach and envisions an ecosystem supported by robust infrastructure, a streamlined regulatory framework, and skilled manpower.

Strategic Focus Areas

- 1. **Regulatory Streamlining:** The policy proposes a Single Window Clearance System for licensing, protocols for quality control, pricing regulations for affordability, and regulatory compliance assistance for research and innovation.
- 2. Enabling Infrastructure: It calls for establishing medical device parks and

clusters with world-class infrastructure, strengthening testing laboratories, and ensuring continuous access to critical components through phased manufacturing.

3. Facilitating R&D and Innovation: The policy encourages industry-academia collaboration, setting up Centers of Excellence, providing infrastructure for health technology ecosystems, and promoting innovation commercialization.

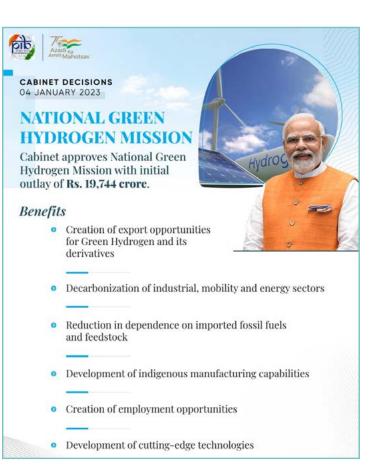
- 4. Attracting Investments: It aims to attract private investments through venture capital outreach, funding for startups, and leveraging existing government initiatives to promote domestic manufacturing.
- 5. Human Resources Development: Focuses on developing skilled labor, multidisciplinary courses, national skill databases, and partnerships with foreign institutions for technology development.
- 6. **Brand Positioning and Awareness:** Aims to adapt global best practices, raise awareness about safety requirements, and promote knowledge-sharing among stakeholders.

The National Medical Device Policy reflects India's commitment to revolutionizing its healthcare sector by fostering innovation, promoting accessibility, and ensuring quality healthcare services for all.

National Green Hydrogen Mission Gains Momentum

The Ministry of New and Renewable Energy's ambitious National Green Hydrogen Mission, sanctioned by the Union Cabinet on January 4, 2023, with a budget of **₹19,744 crore** (\$2.4 Billion), is rapidly advancing towards its objectives. Anchored on the vision to position India as a global leader in the production, utilization, and export of Green Hydrogen and its derivatives, the Mission is making significant strides. Spearheaded by a Working Group chaired by the Secretary of MNRE, the Mission recently shared its first set of regulatory recommendations with key ministries including the Ministry of Road Transport and Highways, Ministry of Consumer Affairs, Department for Promotion of Industry and Internal Trade, and Ministry of Petroleum & Natural Gas.

A pivotal financial measure under the Mission, the Strategic Interventions for Green Hydrogen Transition (SIGHT) Programme, with an allocation of ₹17,490 crore (\$2.1 billion), aims to bolster domestic manufacturing of electrolysers and the production of Green Hydrogen. Initiatives like issuing Requests for Selection (RfS) for Green Hydrogen Producers and Electrolyser Manufacturers signify tangible progress towards achieving the Mission's objectives. Moreover, the recent International Conference on Green Hydrogen (ICGH - 2023), organized in collaboration with key stakeholders including the Ministry of Petroleum & Natural Gas and the



Council of Scientific & Industrial Research, witnessed robust participation from over 10 countries. With insightful plenary talks, panel discussions, and technical sessions, the conference served as a catalyst for fostering international collaboration and showcasing innovative advancements in hydrogen utilization. Country round tables with prominent stakeholders from Europe, Japan, Singapore, and Korea further enriched the discourse, propelling India towards its Green Hydrogen aspirations.

Other Policy Interventions by DBT

Promoting International Collaborations

DBT has signed MoUs with organizations like Armed Forces Medical Services (AFMS), National Science Foundation (NSF) of the USA, and World Intellectual Property Organization (WIPO) to promote healthcare research and international collaborations.

Advancements in Research and Development

DBT has made significant research breakthroughs, such as decoding genome sequences of bacterial pathogens and developing host-directed therapeutics for mitigating diseases like SARS-CoV-2 infection.

Human Resources Development Programme

DBT's Human Resources Development Programme has supported initiatives like the Star College Program, Postgraduate Teaching Program, Research Associateship Program, and Biotechnology Career Advancement and Re-orientation Programme (BioCARe).

North East Biotechnology Programme

In the Northeast region, DBT has established facilities for certified scion material generation, developed natural packaging solutions, and set up eight BioNEST bioincubators to promote entrepreneurship and sustainable development.This has augmented nurturing of a local startup ecosystem in the Northeast Region.



Uttar Pradesh Unveils Pharmaceutical and Medical Devices Industry Policy 2023 to Foster Growth and Innovation

In a bid to bolster its pharmaceutical and medical devices sector, the Uttar Pradesh government has rolled out the Pharmaceutical and Medical Devices Industry Policy 2023. Development Cell (UPPDC) will provide technical guidance and support. Additionally, an Empowered Committee, chaired by the Chief Secretary, will oversee policy development and scheme implementation,

Championing the cause of ease of doing business, the policy introduces a single window clearance mechanism under the direct purview of the Chief Minister's office. With a focus on expeditious clearances, preconsultation of project plans, and dedicated technical advisory support, the policy aims to streamline regulatory processes and attract investments.

Under the new regulations, the state will establish a single window clearance system supervised by the Chief Minister's office, ensuring swift delivery of services and permits. The Food and Drug Administration (FSDA) will appoint a nodal officer to facilitate investors in obtaining necessary certifications, while the newly formed Uttar Pradesh Pharmaceutical further enhancing accountability and efficiency.

The policy's overarching objective is to invigorate the local pharmaceutical and medical device industry by fostering local production, research, and development. Incentives such as subsidies and land allocation for manufacturing units aim to attract investments, with **217 companies** expressing interest to invest approximately **₹28,500 crore** (\$3.4 billion). These investments are anticipated to generate around **57,000 job opportunities**, fortify the local economy, and catalyze sectoral growth. With a robust talent pool and a conducive regulatory framework, Uttar Pradesh is poised to emerge as a hub for pharmaceutical innovation and manufacturing.

Tamil Nadu Unveils Ambitious Ethanol Blending Policy to Accelerate Green Fuel Adoption

Tamil Nadu, known as the automotive manufacturing hub of India, has launched a comprehensive Ethanol Blending Policy aimed at revolutionizing its fuel landscape. The policy, set against the backdrop of increasing urbanization and escalating petrol demand, seeks to harness indigenous resources to meet energy needs sustainably.

With a robust roadmap outlined, the government aims to achieve self-sufficiency in ethanol production, targeting an estimated blending requirement of 1**30 crore liters**. To catalyze this transition, the policy envisions attracting investments totaling **₹5000 crore** in molasses and grain-based ethanol production capacity within the state.

Driving Force Behind the Policy: The policy draws inspiration from Tamil Nadu's status as a key player in the automotive sector, coupled with its commitment to environmental sustainability. As the third-largest consumer of petrol in the country, the state recognizes the urgent need to shift towards greener alternatives to mitigate climate change.

Aligned with the National Biofuels Policy's vision of achieving 20% ethanol blending by 2025, Tamil Nadu aims to leverage its agricultural abundance to bolster ethanol production. With a rich agricultural landscape spanning sugarcane, paddy, maize, tapioca, and sweet sorghum, the state is poised to tap into diverse feedstock resources for ethanol generation.

BIOFUEL

Investment Opportunities and Regulatory Support: The policy presents lucrative investment prospects. The government has introduced several relaxations and incentives to incentivize the sugar industry's expansion and encourage new ethanol production units. Relaxations in environmental clearance procedures for distilleries and sugar mills, along with waivers for incidental increases in ethanol production, underscore the government's commitment to facilitating a conducive business environment. Tamil Nadu's Ethanol Blending Policy represents a significant stride towards achieving energy security, reducing import dependency, and curbing greenhouse gas emissions. By capitalizing on its agricultural prowess and fostering indigenous ethanol production, the state aims to pave the way for a greener, more sustainable future while bolstering economic prosperity.

IMPORTANT DEVELOPMENTS

Key Trends

India's BioEconomy is advancing rapidly with breakthroughs in gene therapy, diagnostics, and biomanufacturing. The country's focus on self-reliance is driving innovations in vaccines and biotech, reshaping its economic and healthcare landscape through significant local research and development.

BioPharmaceutical Breakthroughs and Vaccine Development

- CERVAVAC: The nation's first indigenously developed quadrivalent Human Papillomavirus (qHPV) vaccine, launched to combat cervical cancer, was developed through a collaborative effort between Serum Institute of India (SII), DBT, BIRAC, and the Bill and Melinda Gates Foundation.
- ZyCoV-D: India's DNA-based COVID-19 vaccine, ZyCoV-D, is the world's first plasmid DNA vaccine against COVID-19. This vaccine represents a major milestone, offering a needle-free delivery system and broad coverage for individuals.
- CORBEVAX: India's first protein subunit vaccine for COVID-19, CORBEVAX, was developed for mass immunization. This low-cost and easyto-manufacture vaccine is a key part of India's COVID-19 vaccination strategy.
- Ø GEMCOVAC-19: India's first mRNA COVID-19 vaccine, GEMCOVAC-19, sets a new standard for developing

variant-resistant vaccines. This achievement highlights the country's capacity for advanced biopharmaceutical innovation and showcases the mRNA technology's potential to create safe and effective vaccines.

- iNCOVACC: India's first intranasal COVID-19 vaccine, designed to induce mucosal immunity and prevent infection at the site of viral entry, offering a novel administration route without the need for injections.
- GEMCOVAC-OM: India's first Omicron-specific booster vaccine, based on the mRNA platform, provides targeted protection against newer variants of the virus, contributing to ongoing efforts in COVID-19 management.
- Liraglutide Biosimilar Approval: A biosimilar of Victoza, a treatment for diabetes, was approved after Phase III trials, marking its market introduction in India.

Advanced Waste Treatment Technologies

- Anaerobic Bioreactor for Textile Waste: A ceramic membrane integrated anaerobic bioreactor (CMIAR) has been developed to improve the treatment of textile industry wastewater. This technology enhances the efficiency of effluent treatment, helping reduce environmental impact.
- Coal-to-Liquid (CTL) Technology: An innovative process has been created to convert municipal solid waste into liquid fuel, achieving an 80% conversion rate. This offers a sustainable energy solution by turning waste into valuable resources.

Gene Therapy and Healthcare Innovations

- Gene Therapy Clinical Trial for Hemophilia A: The Central Drugs Standard Control Organisation (CDSCO) has approved India's first gene therapy clinical trial for Hemophilia A, utilizing a novel hematopoietic stem cell-based lentiviral vector technology, which marks a significant advancement in treating genetic blood disorders.
- Blood Bag Technology: The Institute for Stem Cell Science and Regenerative Medicine (inStem) has developed novel electrospun-nanofibroussheets that reduce damage to stored red blood

cells (RBCs). This innovation could lead to the development of advanced blood bags, reducing transfusion-related risks.

MRI Scanner Development: A compact, lightweight next-generation MRI scanner, developed under the National Biopharma Mission (NBM), is poised to transform diagnostic imaging. This disruptive technology, produced by an Indian company, received a commercial sale and manufacture license from CDSCO.

Technological Innovations in Food Safety and Environment

- Iron and Zinc Enrichment in Lentils: A breakthrough process was developed to infuse iron and zinc into lentils, significantly improving their micronutrient bioavailability and offering a practical solution to address nutritional deficiencies.
- Wearable Electrochemical Glove for Drug Detection: A novel glove-based sensor has been designed

to detect methamphetamine, showcasing advancements in portable diagnostic tools for law enforcement and healthcare.

 Food Safety Device: A prototype device has been created to detect harmful bacteria in food, including S. typhimurium and E. coli, ensuring food safety through rapid and accurate testing.

Crop Improvement and Breeding Innovations

- ADVIKA, Drought-Tolerant Chickpea Variety: ADVIKA (NC 7) is a new chickpea variety developed through genetic introgression, offering 7% higher yield under drought conditions. Approved for nationwide cultivation, it is specifically suited for India's Central Zone.
- AccelBreed at PAU, Ludhiana: The Punjab Agricultural University's AccelBreed

facility enables speed breeding with precise environmental control, accelerating crop development.

 IRRI's SpeedFlower Protocol for Rice: The International Rice Research Institute's SpeedFlower Protocol combines advanced light and climate controls to expedite the breeding of rice varieties, contributing to global food security.

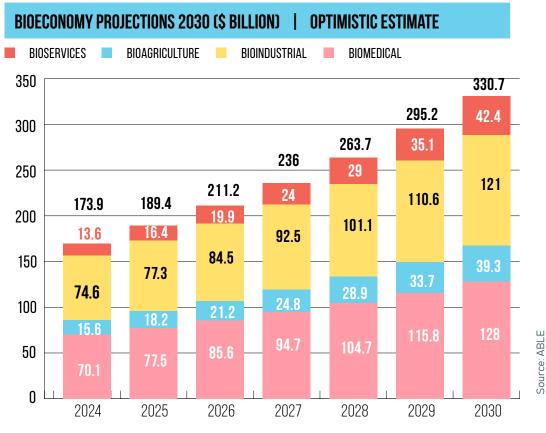
THE FUTURE BIOECONOMY A Collaborative Approach

Looking ahead, the BioEconomy is poised for continued growth. Collaboration between academia, industry, and policymakers will be crucial to harness the full potential of this sector. Continued investment in research and development, coupled with robust regulatory frameworks, will drive innovation and ensure the BioEconomy thrives in a sustainable and equitable manner.

The BioIndustrial segment presents a significant opportunity to address climate change through the development and widespread adoption of bio-based materials. The BioPharma sector holds the promise of personalized medicine and more effective treatments for various ailments. BioAgri offers a path towards sustainable food production and improved food security for a growing global population. BioIT / Research Services / BioServices will continue to be the engine driving innovation across the BioEconomy.

The BioEconomy holds the potential to revolutionize various sectors, from healthcare and agriculture to energy and materials. By recognizing the opportunities and addressing the challenges, stakeholders can ensure this exciting field continues to flourish for the benefit of society and the environment.

In conclusion, the BioEconomy is experiencing a period of remarkable growth. Segment-specific analysis reveals impressive growth trajectories in BioIndustrial, BioIT / Research Services / BioServices, and BioAgri segments. While the decline in the Covid Economy segment reflects a return to normalcy, the lessons learned from this rapid response are invaluable.



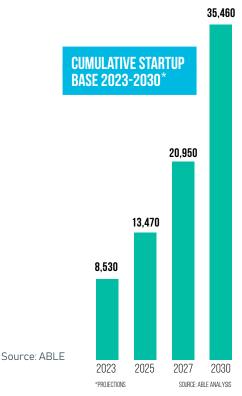
NOTES ON SEGMENTS

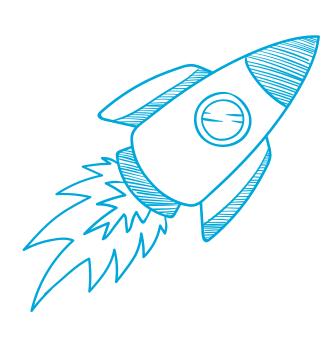
BioMedical: Biopharmaceuticals, diagnostics, medical devices

BioAgriculture: Bt Crops, Animal biotech, Biomass, Pesticides, Fertilizers

BioIndustrial: Aqua - Shrimp industry, Food and Beverage industry, Industrial sector, Laundry and Cleaning industry, Paper and Pulp, Poultry Industry, Textile Industry, Vegetable Oils industry

35,460 CUMULATIVE STARTUPS PROJECTED FOR 2030







ACKNOWLEDGEMENTS AND SOURCES

This report has been compiled by sourcing information from a variety of reputable web sources and publicly available data. The comprehensive nature of the research involved accessing diverse online platforms and mining publicly accessible information to ensure the accuracy and breadth of the content presented. The acknowledgment extends to the wealth of data contributed by these sources, enabling a thorough and well-informed report.

- Biotechnology Industry Research Assistance Council (BIRAC), a public sector enterprise of DBT, Government of India.
- Department for Biotechnology (DBT), Ministry of Science and Technology, Government of India.
- Department of Commerce, Ministry of Commerce & Industry, Government of India.
- Directorate of Economics and Statistics (DES), Department of Agriculture, Cooperation and Farmers Welfare (DAC&FW), Government of India.
- Ministry of Petroleum & Natural Gas, Government of India.
- Ministry of Statistics & Programme Implementa tion National Statistical Office.
- Ministry of Textiles, Government of India.
- The Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India.
- World Health Organization.

Information has been gathered from diverse sourc es, including reports from Industry Associations, Market Research organizations, Investment Track ers, Press Releases, Newspapers, Magazines, pre sentations at Leading Events and conferences. The Food and Agriculture Organization (FAO) of the United Nations, European Commission's BioEconomy - Research & Innovation, press releases from various organizations, and reports from Market Research agencies and Media Publications have contributed to the compilation of data.

CONTRIBUTORS

This report has been prepared for the "Make In India Facilitation Cell for Biotechnology" of Biotechnology Industry Research Assistance Council (BIRAC) by the Association of Biotechnology Led Enterprises (ABLE).

ABLE is a non-profit nationwide forum dedicated to representing the Indian Biotechnology Sector. With a membership exceeding 400, ABLE (www.ableindia. in, Twitter @able_ indiabio) encompasses diverse stakeholders from across India. including Agribiotech, Bio-pharma, Industrial biotech. Bioinformatics. Investment banks, Venture Capital firms, leading Research and Academic Institutes, Law Firms, and Equipment Suppliers, collectively representing all verticals within the sector

The creation of this report was made possible through the collaborative efforts of ABLE and BIRAC.



The Annual India BioEconomy Report has been tracking the evolution of the country's bioeconomy for several years. It has now become a key reference for national and international stakeholders, as well as policymakers.

> — **Dr. Manish Diwan** Mission Director - Make In India PMU for biotech sector, BIRAC Head — BioFoundry, NCR Biotech Cluster & IVCOL

LINKS TO SOME REFERENCE WEBSITES SOURCE

www.ableindia.in www.eai.in www.kitven.com www.mospi.nic.in www.txcindia.gov.in www.agricoop.nic.in www.agritech.tnau.ac.in www.apps.fas.usda.gov www.bioplasticsnews.com www.birac.nic.in www.cdsco.gov.in www.commerce-app.gov.in www.covid19.trackvaccines.org www.dbtindia.gov.in www.dfpd.gov.in www.dpiit.gov.in www.eands.dacnet.nic.in www.ec.europa.eu economictimes.indiatimes.com www.egrowfoundation.org www.eximmitra.in www.fincomindia.nic.in www.gain.fas.usda.gov www.indiabioscience.org www.indianexpress.com www.indiansugar.com www.indxauth.ccamp.res.in www.karunadu.karnataka.gov.in www.mea.gov.in www.mnre.gov.in www.mopng.gov.in www.mospi.gov.in www.newprojectstracker.com www.niti.gov.in www.pharmaceuticals.gov.in

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