Biomanufacturing Global Series

A one page summary focusing on the latest policy developments, targets and investments in biomanufacturing from a different country.





Biomanufacturing Global Series

US in Focus



Introduction

The direct economic inputs from the US bioeconomy, in line with the US bioeconomy definition, were estimated to be \$402 billion, and including indirect and induced effects to be \$959 billion in 2016. According to a recent article, despite not leading in terms of high-quality biotech publications and therefore research, the US has a higher number of biotech companies compared to Europe, 8000 vs 4500. Furthermore, more than the double of the companies receiving funding, 3557 vs 1558, between 2015 and 2021, and the average capital raised is 1.5 times higher. The US also accounted for 65% of the new biotech companies created in the world between 2018 and 2020, while Europe for 24%.

Latest Policy Developments

The US is currently active in developing and releasing policy documents in and around biotech and biomanufacturing. The current strategy was laid down in 2022 by the <u>Executive Order</u> (EO) on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. Following and in accordance with the EO, The White House issued the <u>Bold Goals</u> for US Biotechnology and Biomanufacturing and the <u>Building the Bioworkforce of the Future</u>, both in 2023.

The US policy approach is comprehensive by targeting different challenges, such as climate change or national security, and sectors, such as chemical, agriculture or health. Overall, the US Administration considers biotechnology and biomanufacturing essential activities to develop innovative solutions and foster the American bioeconomy: by taking as a starting example their vital role in the response to the COVID-19 pandemic, but expanding their potential to contribute to other challenges such as climate and energy goals, food sustainability and supply-chains security.

Produce 25% APIs deploy biomanufacturing capabilities to

produce at least 25% of all active pharmaceutical ingredients for small molecule drugs needed in the US.

Replace 90% of plastics

replace more than 90% of today's petrochemical-based plastics and other polymers at scale with bio-based ones.

Produce 20+ bioproducts

produce 20+ commercially viable bioproducts with +70% reduced lifecycle GHG emissions over current production practices.

Produce 30% of (bio)chemicals

produce at least 30% of the US chemical demand via sustainable and cost-effective biomanufacturing pathways.

Find out about all the 50 targets in <u>Bold Goals for US Biotechnology and Biomanufacturing</u>.

\$1 billion in infrastructures

in biomanufacturing domestic infrastructure to catalyse the establishment of the domestic base that is accessible to innovators.

\$40 million in APIs

to expand the role of biomanufacturing for APIs.

\$270 million in bio-based materials investment to support the advanced development of bio-based materials for defence supply chains.

\$178 million in innovative biotech R&D to advance innovative research efforts in biotechnology, bioproducts and biomaterials.

Accounting for more than \$2 billion, find out about other investments and details, <u>here</u>.

5 years

20 years

5 years

Investments

argets



Biomanufacturing Global Series India in Focus



Introduction

India's biotechnology industry valuation was estimated to be \$63 billion in 2019, comprising more than 3500 biotech start-ups and accounting for approximately 5% of the global market according to the <u>Government of</u> <u>India</u>. These figures place India among the top 12 biotech locations in the world and in 3rd place in Asia. The Government also anticipates a significant growth based on the increasing economic prosperity, health consciousness and a billion-plus population and mainly driven by vaccines and recombinant therapeutics. In India, the biotech sector is divided into five segments: bio-pharma, bio-services, bio-agri, bio-industrial and bio-informatics, which together contribute to the Bioeconomy.

Latest Policy Developments

The core of India's biotech and biomanufacturing policies has been delivered since 2007 through the National Biotechnology Development Strategy (NBDS). The latest <u>NBDS</u> version launched in 2020 sets a group of key strategies, instruments for implementation and targets for the period 2021-2025 and supports India's aim to become a \$5 trillion economy.

The NBDS defines biotechnology as a key tool for national development and societal well-being, and assumes as main **mission to ensure India's global competitiveness** throughout the different biotech dimensions: from research and innovation to entrepreneurship and industrial growth. It aims to position India as a strong and global biomanufacturing hub with the capacity to produce **innovative**, **affordable and accessible** products for the internal and international markets. India, like the US, sees biotech strengthened in the wake of the COVID-19 pandemic. The country identifies strengths such as its scientific human capital and cost-effective biomanufacturing capabilities and the need to focus and invest on enhancing R&D expenditure, improving the link between research and commercialisation and ensuring the international quality standards.

2021 - 2025

Targets

Investments

Achieve a \$150 billion biotech industry

grow the biotech industry from \$92 billion in 2019 to \$150 billion, representing 21% of the global market share. Further details on the sectorial contribution can be found here.

Reach **10 000** biotech start-ups

grow the number of biotech start-ups from the >3500 in 2019 to 10 000 by 2024/2025.

Create a \$100 billion biomanufacturing global hub

develop the hub would make India a key biomanufacturing player in the global supplychains.

Create 10 technology clusters

the clusters integrate facilities to support start-ups to move to integrated enterprises: from proof of concept to pilot facility.

Find out about the 13 targets in the <u>National Biotechnology Development Strategy 2021-2025</u>.

The documents accessed to create this summary, such as the National Biotechnology Development Strategy and <u>India Biotech Handbook</u> or sources such as <u>Invest in India</u>, do not provide information regarding the amount invested or its allocation. Nevertheless, this publication acknowledges that the information may be available in other non-consulted sources.



Biomanufacturing Global Series Japan in Focus

Introduction

Japan's bioindustry market size is estimated to be \$32 billion in 2019 according to the <u>New Energy and Industrial</u> <u>Technology Development Organization</u>. The country is described by the <u>EU-Japan Centre for Industrial</u> <u>Cooperation</u> as having one of the most developed biotech sectors, evidenced by the high number of patents filed. The same source provides other highlights on biotech and biomanufacturing, such as <u>biopharmaceuticals</u> being considered the main innovation pathway to follow in the pharmaceutical industry and <u>bioinformatics</u> as the country hosts the largest database in Asia. The main drivers behind the commitment with the bioeconomy are the growing concern over environmental challenges, security of food supply, increases in lifestyle-related diseases and rising demand for pharmaceuticals.

Latest Policy Developments

Bioeconomy Strategy 2019 is Japan's current strategy for the bioeconomy. According to the <u>US International</u> <u>Trade Administration</u>, the Government of Japan has designed the strategy to develop and advance the biotech sector to realise "the world's most advanced bioeconomy society by 2030". The <u>Strategy</u> has three main points: expansion of the bio-based market, formation of a bio community and establishment of a data platform.

The first sets the goals for an expansion of the biobased market on three key segments that expect significant grow and leverage Japan's strengths: biomanufacturing, such as biorefineries; primary production, such as use of gene editing technology in agriculture; and healthcare, such as biopharmaceuticals and vaccines. The second fosters the creation of bio-clusters and new value chains by gathering stakeholders under the same community. The third targets biological data collection and analysis to enable practical and applicable data linkage.

Achieve a \$837 billion biobased market in biomanufacturing, primary production and healthcare, which consists of an increase of approximately 50% of 2021 market size.

2019 - 2030

Targets

Investments

Produce \$485 billion through biomanufacturing R&D and industrial production of h

R&D and industrial production of highperformance biomaterials and bioplastics.

Primary production of \$15.5 billion exclusively in the biobased market through automated agriculture and gene editing

technology based breeding.

Reach \$30 billion in healthcare biotech through the production of biopharmaceuticals, regenerative medicine, cell therapy and gene therapy.

Find out about the expected <u>market growth</u> and <u>other targets</u> of the Bioeconomy Strategy.

\$56 million in biomanufacturing technologies

In 2019, the <u>Government of Japan</u> invested \$56 million to explore and test biomanufacturing technologies including demonstration and examination of data linkages.

Plan for a \$8 billion fund to support biomanufacturing

According to <u>Ministry of Economy, Trade and Industry</u>, "the field encompasses technologies that leverage genetic technology to maximize the ability of microorganisms to produce substances" and is expected to be key in solving global issues, such as global warming.



Biomanufacturing Global Series China in Focus



Introduction

China's manufacturing industry is the pillar of the national economy and an essential activity to ensure the country's national security, according to the People's Republic of China <u>State Council</u>. In recent years, the country has made significant progress in terms of biotech and biomanufacturing and had consequently narrowed the knowledge and industrial gap with other geographical regions. According to a recent <u>article</u>, despite scoring after Europe and the US in terms of high-quality publications covering health, agriculture, and industrial biotech, China is levelling up the ground and clear evidence is having six of the top ten "young" universities in the world. Furthermore, China granted a similar number of health-biotech patents as Europe in the period 2014-2020, 39 000 vs 40 000, and accounted for 12% of the world's new biotech companies in the period 2018-2020, growing more than Europe and the US. It shows the commitment of the country to "increase the size and strength of the bioeconomy".

Latest Policy Developments

The strategy for biotech and biomanufacturing is the combination of two policy plans: the <u>Made in China</u> (MIC) 2025, released in 2015, and China's Government five-year plans (FYP), currently the <u>14th</u> released in 2021 and covering the period 2021-2025.

The MIC initiative aims to make China a global powerhouse of high-tech industries and reduce its reliance on foreign technology by investing in its own innovations to compete globally and be part of the global manufacturing value-chains, according to the <u>Institute for Security and Development Policy</u>. The same source states that biotech integrates China's list of Strategic Emerging Industries (SEI).

The Government 14th FYP, for the first time, did not a GDP growth target and set biological innovation and biotech as major themes. China addresses biotech from four different angles: R&D, biomanufacturing, regional development and national defence. In R&D, the country prioritises cutting-edge fields such as genetics and biotech with the aim to develop new innovative vaccines, antibody drugs, varieties of crops and poultry. In biomanufacturing, it supports China's industrial powerhouse strategy by addressing competitiveness in high-end new materials including bio-based and biomedical materials. It also proposes expansion of the SEI including through acceleration in development of biotech: biopharmaceuticals, bioengineered breeding, biomaterials and bioenergy. The regional development comes tied with marine biotech and the focuses on building a modern maritime industry system. Lastly, the development of the biotech industry is linked to economic and defence strength and the goal to deepen military-civilian collaboration and innovation.

Fargets

Investments

2025

1.68% share of R&D spending of operating revenue. The starting point is 0.88% in 2013.

4% growth of industrial value-added The starting point is 2% in 2020.

The aforementioned targets are for all industries and are referred in the China Manufacturing 2025 analysis made by the <u>European Chamber of Commerce in China</u>. The documents accessed to create this policy summary do not provide information on specific targets to bioeconomy, biomanufacturing or biotech.

In line with the previous section, the documents accessed, such as the Made in China 2025, China's 14th five-year and <u>UNDP Issue Brief</u>, also do not provide information regarding investments. Nevertheless, this publication acknowledges that the information may be available in other non-consulted sources.



www.europabio.org