

Next-Generation Biomanufacturing Market Gathers Momentum: 8.5% CAGR Forecast Through 2035

Next-generation biomanufacturing market was valued at USD 24.1 million in 2024 and is projected to grow at a CAGR of 8.5% during the forecast period 2025-2035

INDORE, INDIA, May 1, 2025 /EINPresswire.com/ -- The <u>Next-</u> generation biomanufacturing market is experiencing strong growth, fueled by technological developments in biotechnology and growing demand for biologics. This advanced industry is all about utilizing the latest



technologies, including continuous upstream biomanufacturing and single-use technologies, to make the bioprocesses more efficient and scalable. Recent trends reflect a movement towards greener practices, with businesses embracing green approaches and minimizing resource consumption.

The massive growth in biologics and biosimilars over the last few years has raised the demand for biomanufacturing technologies. According to the Biosimilars Council, biosimilars are generally valued at 10% to 35% less than branded biological medicines, and an amount of \$250 billion could be saved through the application of biosimilars in the next decade. Biomanufacturing is important for the improvement of healthcare as it offers innovative ways to cure and treatment. Additionally, biomanufacturing accelerates scientific research, boosts accelerates scientific research, economic growth, and offers jobs. As it encourages the development of eco-friendly technology and decreases industrial waste, its significance extends more to environmental conservation. The advantages of biomanufacturing are its scalability, cost-effectiveness, and potential for expansion.

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Moreover, companies implementing next-generation biomanufacturing can partner with companies such as Danaher Corporation's life sciences businesses to develop flexible, innovative processes for all stages of production, ranging from research and development to cGMP manufacturing. The scope of flexible manufacturing services and solutions is growing rapidly, offering pharmaceutical manufacturers several options to optimize the manufacture of genetically modified drugs.

Market Trends

Technological Advancements

Biomanufacturing is an essential application in the medical and pharmaceutical industries. It has evolved with a broad scope of applications ranging from the production of antibacterial, regulated, on-demand molecules, drugs, and vaccines. It has significant potential of producing customized, optimal suits for specific patients using "3D printed drugs" such as tissues and even organs on demand. There are promising prospects for next-generation market players of biomanufacturing offering bioprocessing 4.0 services by advances such as real-time access to operations and increasing interest among innovators for paperless manufacturing. This is expected to lead to the creation of a standardized process that has the potential to reduce the consistency of quality between batches.

The shift to continuous bioprocessing has improved efficiency and scalability in biomanufacturing. Continuous bioprocessing enables uninterrupted production, providing benefits in terms of efficiency, quality control, and real-time monitoring. Moreover, the integration of automation and robotics has improved accuracy and efficiency, leading to error minimization and better throughput. The use of AI and ML in biomanufacturing has been revolutionary. The use of technologies allows for predictive maintenance, process optimization, and quality control that result in higher yield and lower costs. Furthermore, digital biomanufacturing platforms have enabled real-time monitoring and data analytics, while improving decision-making and operational effectiveness. For instance, in March 2025, AstraZeneca announced an investment of \$2.5 billion in Beijing to support early-stage research and clinical development by building an AI and data science laboratory. The investment includes collaborations with local biotech businesses and a joint venture with Harbour BioMed, Syneron Bio, and BioKangtai for the improvement of vaccines.

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Government Initiatives for the Development of Biomanufacturing

Governments around the globe are realizing the vast potential of biomanufacturing to drive innovation and economic growth in the healthcare, pharmaceuticals, and biotechnology industries. Therefore, various countries have launched effective programs to support the development and scale-up of next-generation biomanufacturing technologies to ensure economic and healthcare sustainability. For instance, in August 2024, the government of India accepted the proposal of the Department of Biotechnology (DBT) for India's first Policy in Biotechnology, the 'BioE3 (Biotechnology for Economy, Environment and Employment) Policy for 'Fostering High Performance Biomanufacturing'. This Policy sets the framework for the implementation of the Biomanufacturing and Bio-foundry Initiative and supports SMEs, start-ups, industries, and academia with access to common infrastructure/facilities and resources for pilot and pre-commercial scale biomanufacturing of feasible commercial bio-based products. BioE3 Policy towards a clean, green, prosperous, and independent India will facilitate Indian industries and institutions to indulge in cutting-edge innovation under the umbrella of Public-Private Partnership (PPP) and foreign partnerships. Biomanufacturing takes advantage of microbial, plant, animal, and human cell engineering with growing accuracy and control for producing commercially relevant substances. Apart from supporting India's goal of reducing emissions, Biomanufacturing will also bring transformative effects across varied health, agricultural, food, pharmaceutical, chemical, materials, biofuels, and in more sectors.

Governments are now becoming more interested in developing supportive regulatory environments for biomanufacturing innovation. For instance, in 2024, the US FDA (Food and Drug Administration) unveiled new guidelines aimed at streamlining approval for biomanufactured therapeutics, specifically biologics and gene therapies. The new policies of the FDA aim to shorten approval times for emerging biologics and offer more clarity on the regulatory pathways for gene-editing tools such as CRISPR, this will further increase the commercialization of innovative therapeutics. The rising interest in biomanufacturing from governments across the globe is driving a healthy ecosystem for technology development, allowing next-generation biomanufacturing solutions to scale and commercialize at high speed. As governments continue to support the industry through regulatory reform, investments, and infrastructure creation, the sector is poised to grow tremendously in the next few years, enabling effective and sustainable healthcare.

Regional Outlook

North America: Leading in Innovation and Adoption

North America dominates the next-generation biomanufacturing market through advanced technologies and widespread adoption. The region is dominated by numerous well-established manufacturing firms that are leading in the development of innovation in biomanufacturing procedures. Besides, favorable government policies and emphasis on R&D strengthen the industry's development in this region. Specifically, the United States is a leading force, with key players developing several methods of biomanufacturing.

Additionally, the industry is fueled by the growing incidence of chronic diseases and increasing demand for innovative biomanufacturing processes. For instance, in January 2025, Telix Pharmaceuticals Ltd. declared that it had finalized the acquisition of antibody engineering firm ImaginAb, Inc. (ImaginAb). The acquisition includes a pipeline of next-generation treatment

applicants, a new innovative biologics technology platform, and a protein engineering and discovery research center to complement existing innovation capabilities. Intellectual property and technology platforms utilize minute, customized forms of antibodies that permit highly discriminative radiation-mediated cancer targeting, nevertheless, have quick tumor uptake and blood clearance.

Asia-Pacific: The Emerging Powerhouse

Asia-Pacific is the region with the fastest-growing region in the next-generation biomanufacturing market. The growth in approved treatments and the rising demand for advanced biomanufacturing facilities that are capable of supporting more target indications for gene and cell therapies are factors that are credited to the next-generation biomanufacturing market growth. The Asia-Pacific region is seeing unprecedented developments in medical treatments through the massive investments by governments, pharmaceutical industries, and universities. China, India, South Korea, and Singapore are making strides by investing in biomanufacturing facilities and adopting innovative platforms to serve their expanding biopharmaceutical markets. For instance, China's 'Made in China 2025' initiative promotes domestic development of biologics and innovative manufacturing technologies.

Market Segmentation and Growth Areas

Upstream Manufacturing is the Favoured Manufacturing Type

Upstream production is the ideal form of manufacturing in the next-generation biomanufacturing market owing to its essential role in cell culture and biologics production. The upstream production step is used to optimize the conditions and cell lines and is responsible for the creation of high-quality, high-volume biologicals such as vaccines and proteins. In addition, segmental growth comes about due to aspects such as enhanced bioreactor technology, enhanced media compositions, and demand for personalized medicines and biologics.

Contract Development and Manufacturing Organizations (CDMOs) are the Major End-User

CDMOs are the major end-users within the next-generation biomanufacturing market. Their significant role in both the development and high-volume production of biopharmaceuticals necessitates them to bring new biologics and novel therapies to the market efficiently. Additionally, segmental growth is fueled by escalating demand for personalized medicine, the requirement for scalable production solutions, and the escalation of complexity within biologics. For instance, in April 2025, Samsung Biologics signed a CDMO deal of \$514 million with a US pharmaceutical company, and for this, Samsung Biologics will manufacture pharmaceutical products for the undisclosed client by 2031.

Market Limitations and Challenges

•High Cost of Biologic Therapies and Difficulty in Manufacturing these Medications: Biologics are powerful medicines that are tough to manufacture. They are capable of targeting harmful elements, such as certain cancer cells, with exceptional accuracy as they tend to look for similar proteins and other chemicals that occur naturally in living beings. Some of the most promising new drugs for cancer and other diseases are part of this group. In comparison to drugs produced through chemical synthesis, biologics tend to be larger, more complicated molecules that raise the challenges of synthesis and drive their cost. Several biological drugs were mostly valued at \$10,000 for a single dose. Hence, this aspect can hamper the development of the nextgeneration biomanufacturing market.

•Lack of Skilled and Knowledgeable Professionals: The biomanufacturing sector is increasingly dependent on innovative technologies such as synthetic biology and automation that require a skilled and knowledgeable workforce. However, the sector has to address the shortage of skilled and knowledgeable professionals who can handle the intricacies of these new-age processes. This shortage of talent can hinder innovation, as businesses might not be able to create new products or improve existing production methods without the proper expertise.

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Market Players Outlook

The major companies operating in the global next-generation biomanufacturing market include Danaher Corp., GE Healthcare, Merck KGaA, Sartorius AG, and Thermo Fisher Scientific Inc., among others. Developments in bioprocessing technology and AI-powered production systems are driving rapid growth in the next-generation biomanufacturing market. Through continuous production, single-use bioreactors and cell-free synthesis are gaining ground, biologics manufacturers have improved their mass and economic scales, and the control over their production processes.

Recent Developments

•In April 2025, Sartorius Stedim Biotech signed an agreement with Tulip Interfaces to speed digitalization in biopharmaceutical production. According to the alliance's terms, the firms are merging their strengths to create Biobrain Operate, a next-generation set of digital manufacturing software that will directly communicate with Sartorius Stedim Biotech process equipment.

•In December 2024, Nature's Toolbox, Inc. (NTx), a life science company that designs domestically manufactured biomanufacturing solutions for the delivery of customized therapies and biologics, raised \$15 million in venture loans from J.P. Morgan. The capital will be used to implement NTx systems in large pharmaceutical, government, and clinical organizations. NTx platforms will employ raw materials produced in the US and help to create a full domestic supply

chain for critical biomaterials. The method not only reduces cost and streamlines the process, however eliminates toxic byproducts, making it significantly more sustainable than earlier batch processes.

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Some of the Key Companies in the Next-generation Biomanufacturing Market Include-

- Allogene Therapeutics
- Amgen Inc.
- AstraZeneca
- Azenta US, Inc.
- BioMarin
- Bio-Techne
- Boehringer Ingelheim International GmbH.
- Bluebird Bio, Inc.
- BSP Pharmaceuticals S.p.A
- Catalent, Inc.
- Charles River Laboratories
- Danaher Corp/
- GE Healthcare
- Genentech, Inc.
- Ginkgo Bioworks, Inc.
- Global Life Sciences Solutions USA LLC
- Jubilant Biosys Ltd.
- KBI Biopharma, Inc.
- Lonza
- Merck KGaA
- NantKwest, Inc.
- Recipharm AB
- Samsung Biologics
- Sartorius AG
- Thermo Fisher Scientific Inc.
- WuXi Biologics Co., Ltd.

Next-generation Biomanufacturing Market Segmentation Analysis

Global Next-Generation Biomanufacturing Market by Manufacturing Type

- Upstream Manufacturing
- Downstream Manufacturing

Global Next-Generation Biomanufacturing Market by Product Type

- Biopharmaceuticals
- Vaccines
- Biofuels
- Biopolymers
- Others (Recombinant Proteins, Monoclonal Antibodies)

Global Next-Generation Biomanufacturing Market by End-User

- Pharmaceutical Companies
- Contract Manufacturing Organizations (CMOs)
- Contract Development and Manufacturing Organizations (CDMOs)
- Others (Biotechnology Companies, Research, and Academic Institutions)

Regional Analysis

- North America
- o United States
- o Canada
- Europe
- o UK
- o Germany
- o Italy
- o Spain
- o France
- o Rest of Europe
- Asia-Pacific
- o China
- o India
- o Japan
- o South Korea
- o ASEAN Economies (Singapore, Thailand, Vietnam, Indonesia, and Other)
- o Australia and New Zealand
- o Rest of Asia-Pacific
- Rest of the World
- o Latin America
- o Middle East and Africa

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Anurag Tiwari Orion Market Research Pvt Ltd + +91 91798 28694 email us here Visit us on social media: LinkedIn Facebook X

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