

Biopharmaceutical Fermentation Market- Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product Type (Upstream Products, Downstream Products), By Application (Antibiotics, Recombinant Proteins, Others), By End User (Biopharmaceutical Industries, Contract Research Organization, Academic Research Institutes, Others), By Region, and Competition

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Abstracts

Global Biopharmaceutical Fermentation Market has valued at USD 24.82 billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 8.15% through 2028. COVID-19 has impacted the growth of the biopharmaceutical fermentation market. The pandemic resulted in an unprecedented demand for enzymes essential for innovative point-of-care diagnostic kits and mRNA vaccines. For instance, according to the report published by Mass Bio, in December 2022, it has been observed that the COVID-19 epidemic has increased and reinforced the demand for complex fermentation products in the pharmaceutical and biotechnology industries. Globally, companies and populations benefited from crucial supplies of enzymes produced by fermentation. Moreover, the production of new biologic drugs during the pandemic period for the treatment of COVID-19 infection increased which has impacted the market growth. For instance, in December 2021, Samsung Biologics and AstraZeneca expanded a strategic biopharmaceutical production partnership to include therapies for Covid-19. However, the emergence of a new variety of viruses accelerates vaccine production which involves the fermentation step. For instance, in July 2022, CEPI funded USD 30 million to bring a new nanoparticle vaccine offering protection against a range of coronaviruses to clinical trials. Thus, with such initiatives, the studied market is

expected to grow and regain its full potential in the coming years.

Factors such as the increasing demand for biotech-based drugs and rising research and development activities to produce novel biological drugs are boosting market growth. For instance, according to the 2021 annual report of AbbVie, Humira is one of the top-selling biotechnology drugs in the world which accounted for net revenues of USD 20.7 billion and approximately 37% of AbbVie's total net revenues in 2021. Globally, Humira sales increased by 4% in 2021 compared with the previous year. Similarly, as per the 2021 annual report of Merck & Co, the sales of Keytruda, one of the major biotech-based drugs of the company, grew by 20% to USD 17.2 Billion, compared to USD 14.9 Billion in the year 2020. Thus, the increasing sales of biotech-based drugs in the market indicates the increasing demand for these drugs in the market which in turn is anticipated to fuel the market growth over the forecast period.

Furthermore, the rising company focus on developing novel biological drugs is also expected to fuel the demand for fermentation services and products which is anticipated to propel the market growth. For instance, in November 2022, Eikonoklastes Therapeutics, a preclinical biotech company, and Forge Biologics, a gene therapy-focused contract development and manufacturing organization entered a manufacturing partnership that will advance Eikonoklastes' AAV-based gene therapy, ET-101, into clinical trials for the treatment of patients with amyotrophic lateral sclerosis (ALS). Also, in August 2022, Sanofi and Innovent Biologics entered a strategic collaboration to accelerate the development of two biologic oncology medicines (tusamitamab ravtansine, SAR444245) and expand their presence in China.

Therefore, owing to the factors, such as the rising company activities and increasing demand for biotech-based drugs, the studied market is anticipated to grow over the forecast period. However, the high cost of biopharmaceutical fermentation and installation is likely to impede the growth of the biopharmaceutical fermentation market over the forecast period.

Ky Market Drivers

Growing pipeline of biopharmaceuticals

The dominant driver for the Biopharmaceutical Fermentation market is the growing pipeline of biopharmaceuticals. This trend is driven by several key factors that highlight its centrality to the market: Biopharmaceuticals offer innovative solutions for a wide range of diseases, including cancer, autoimmune disorders, and rare diseases. The

expanding therapeutic landscape necessitates the development of new biopharmaceuticals, fueling the pipeline. Biologics, a subset of biopharmaceuticals, are gaining prominence due to their specificity and effectiveness. As research uncovers new targets and mechanisms of action, biologics with diverse applications are being developed. The emergence of biosimilars, which are highly similar to approved biopharmaceuticals, but often more cost-effective, contributes to the growing pipeline. These products aim to provide affordable alternatives to existing biopharmaceuticals.

Biopharmaceutical companies are heavily investing in R&D to bring novel therapies to market. This includes monoclonal antibodies, vaccines, gene therapies, and cell-based therapies. Emerging markets are increasingly adopting biopharmaceuticals, creating new opportunities for drug development. This global expansion of the biopharmaceutical market drives research and innovation. Stringent regulatory approvals necessitate thorough research and testing, encouraging a continuous stream of biopharmaceutical candidates in the pipeline. The shift towards precision medicine, where therapies are tailored to individual patients based on their genetics and biology, requires a diverse array of biopharmaceuticals for various genetic profiles. In summary, the growing pipeline of biopharmaceuticals is dominant in the Biopharmaceutical Fermentation market because it reflects the industry's dynamism and its commitment to addressing unmet medical needs. As biopharmaceutical companies seek to develop more effective and personalized treatments, fermentation processes remain essential for producing these complex and life-changing therapies.

Expanding biosimilars market

The dominance of the expanding biosimilars market in the Biopharmaceutical Fermentation market is a testament to its pivotal role in shaping the biopharmaceutical landscape. Several key factors underline its dominance: Biosimilars are highly similar versions of approved biopharmaceuticals. They offer cost-effective alternatives to expensive reference biologics, increasing patient access to essential therapies. This economic advantage is driving the demand for biosimilars. Many blockbuster biopharmaceuticals have reached or are approaching patent expiration, opening doors for biosimilar manufacturers. As patents expire, biosimilar competition intensifies, encouraging the development and production of these products. Biosimilars are instrumental in containing rising healthcare costs. Governments and healthcare systems globally are incentivized to promote biosimilar adoption to reduce expenditures on biopharmaceuticals. The biosimilars market is expanding rapidly, encompassing a diverse range of therapeutic areas, including oncology, autoimmune diseases, and diabetes. This growth fuels the need for efficient biopharmaceutical fermentation

processes to meet rising demand. Regulatory agencies worldwide have established clear pathways for biosimilar approval. This regulatory clarity has boosted confidence in biosimilars and encouraged investment in their development.

Biosimilars have the potential to provide essential medicines to a global patient population. This accessibility aspect is crucial for improving healthcare outcomes and addressing unmet medical needs. Intense competition in the biosimilars market is driving innovation in biopharmaceutical fermentation technologies. Manufacturers are continually optimizing processes to enhance product quality and cost-effectiveness. In summary, the expanding biosimilars market is dominant in the Biopharmaceutical Fermentation market because it epitomizes the convergence of economic viability, regulatory support, and the imperative to provide affordable and accessible biopharmaceuticals. As biosimilars continue to gain traction and enter new therapeutic areas, fermentation processes play a central role in their production, solidifying their significance in the biopharmaceutical industry.

Key Market Challenges

Regulatory complexities

Regulatory complexities represent a key challenge for the Biopharmaceutical Fermentation market due to the intricate and stringent requirements imposed by regulatory authorities worldwide. Several factors contribute to these complexities: Biopharmaceutical products must meet exceptionally high safety and efficacy standards. Regulatory agencies, such as the U.S. FDA and the European Medicines Agency (EMA), scrutinize every aspect of the manufacturing process, including fermentation, to ensure patient safety. Any deviation or inconsistency can lead to regulatory hurdles. Fermentation processes can exhibit inherent variability, which is a natural challenge when dealing with living organisms. Controlling and minimizing this variability to meet regulatory standards can be complex and resource-intensive. Regulatory authorities demand comprehensive validation of biopharmaceutical manufacturing processes, including fermentation. This entails extensive documentation, data collection, and adherence to strict protocols throughout the product's lifecycle. Regulatory frameworks are not static; they evolve over time. Keeping up with changing regulations, especially in different regions, poses a challenge for manufacturers aiming to ensure compliance with the latest standards.

Different countries have their own regulatory requirements, adding complexity for companies operating on a global scale. Harmonizing these requirements while meeting

local standards is a formidable task. Ensuring consistent product quality is paramount. Manufacturers must implement rigorous quality control measures to comply with regulatory standards, which often necessitates substantial investments in infrastructure and technology. The regulatory approval process can be lengthy, leading to delays in bringing biopharmaceutical products to market. Navigating these timelines and securing approvals can be financially taxing. In summary, regulatory complexities in the Biopharmaceutical Fermentation market stem from the need to maintain the highest safety and efficacy standards while dealing with the inherent variability of living organisms. These complexities require significant expertise, resources, and a proactive approach to ensure compliance with evolving global regulations and to meet the demands of a highly regulated industry.

Ensuring consistent product quality

Ensuring consistent product quality is a paramount challenge in the Biopharmaceutical Fermentation market due to the unique characteristics of biopharmaceuticals and the rigorous demands of the industry. Several factors contribute to the significance of this challenge: Fermentation processes for biopharmaceuticals involve living organisms, such as bacteria, yeast, or mammalian cells, which can exhibit inherent variability. Maintaining consistent conditions, such as temperature, pH, and nutrient supply, is critical to ensure reproducibility and product quality. Biopharmaceuticals are large, complex molecules, often protein-based. Even minor deviations in the fermentation process can lead to changes in the final product's structure, functionality, and efficacy. Ensuring consistent quality requires meticulous control at all stages. Regulatory agencies, such as the FDA and EMA, have stringent quality requirements for biopharmaceuticals. These standards necessitate rigorous documentation, validation, and adherence to Good Manufacturing Practices (GMP) to demonstrate product consistency. Consistency is directly linked to patient safety. Any variation in product quality could lead to adverse effects or compromised therapeutic outcomes. As biopharmaceuticals are often used to treat serious diseases, maintaining quality is of utmost importance.

Achieving batch-to-batch consistency can be challenging, as fermentation processes can be sensitive to small changes in environmental conditions or microbial behavior. Manufacturers must implement robust control strategies to minimize variability.

Continuous monitoring of fermentation processes and advanced analytical techniques are essential to detect and address variations promptly. Investing in state-of-the-art monitoring equipment and analytics is necessary but resource-intensive. Scaling up

fermentation processes from laboratory to commercial production can introduce new complexities. Ensuring that product quality remains consistent at larger scales requires careful planning and process optimization. In summary, ensuring consistent product quality in the Biopharmaceutical Fermentation market is a multifaceted challenge that demands meticulous attention to detail, adherence to regulatory standards, investment in advanced technology, and a deep understanding of the intricacies of bioprocesses. Overcoming this challenge is critical to providing safe and effective biopharmaceutical products to patients worldwide.

Key Market Trends

Continuous fermentation

Continuous fermentation has emerged as a prominent trend in the Biopharmaceutical Fermentation market, revolutionizing the way biopharmaceuticals are produced. Unlike traditional batch processing, continuous fermentation involves the uninterrupted and ongoing production of biopharmaceuticals. This trend is gaining momentum for several compelling reasons: Continuous fermentation offers higher levels of efficiency by maximizing equipment utilization and reducing downtime between batches, resulting in increased productivity. Real-time monitoring and control in continuous processes enhance product consistency and reduce batch-to-batch variability, ensuring a high level of product quality. Continuous fermentation can lead to significant cost savings, including reduced labor and materials costs, making it an economically attractive option for manufacturers. This approach is flexible and can be adapted to various scales, from small laboratory setups to large-scale commercial production, allowing for seamless scalability. Continuous processes often generate less waste and require smaller volumes, aligning with sustainability goals and reducing the environmental footprint of biopharmaceutical production.

Advances in automation, sensors, and process control technologies have made continuous fermentation more feasible and accessible to biopharmaceutical manufacturers. With the increasing demand for biologics in the healthcare sector, continuous fermentation holds the potential to meet these market needs more efficiently and effectively. In conclusion, continuous fermentation represents a transformative trend driven by the pursuit of improved efficiency, product quality, and cost-effectiveness in biopharmaceutical manufacturing. As bioprocessing technologies continue to evolve, continuous fermentation is poised to play a pivotal role in optimizing the production of critical biopharmaceuticals and meeting the growing global demand for these life-saving therapies.

Single-use bioreactors

Single-use bioreactors have emerged as a prominent and transformative trend in the Biopharmaceutical Fermentation market. These bioreactors replace traditional stainless-steel systems with disposable, pre-sterilized plastic bags and components for cell cultivation and bioprocessing. Here's why single-use bioreactors are gaining traction: They offer greater flexibility in terms of process scalability and adaptability. Manufacturers can easily switch between different production scales without the need for extensive cleaning and validation. Single-use systems minimize the risk of contamination, as they are sterile and disposable, reducing the need for time-consuming cleaning and sterilization procedures. The elimination of cleaning, maintenance, and validation procedures results in cost savings. It also reduces the risk of cross-contamination between batches.

Single-use bioreactors streamline the production process, accelerating time to market for biopharmaceutical products. They are considered more environmentally friendly due to reduced water and energy consumption compared to traditional bioreactors. Single-use systems offer high-quality and consistent production, contributing to better product quality and patient safety.

As the demand for biologics and personalized medicine grows, single-use bioreactors facilitate rapid and flexible bioprocess development to meet these evolving needs. In conclusion, single-use bioreactors are a transformative trend driven by their versatility, cost-efficiency, and suitability for a wide range of biopharmaceutical applications. They enable manufacturers to respond quickly to market demands while ensuring product quality and safety, making them a critical component in the biopharmaceutical industry's future.

Segmental Insights

Product Type Insights

Based on the Product Type, Downstream products play a dominant role in the Biopharmaceutical Fermentation market due to their critical importance in the bioprocessing chain. Downstream processing encompasses purification, separation, and recovery of biopharmaceutical products after fermentation. Here's why downstream products are of paramount significance:

Downstream processes are essential for achieving the required purity and quality of biopharmaceuticals. They remove impurities, aggregates, and contaminants to ensure the final product meets stringent regulatory standards. Ensuring the safety of biopharmaceutical products is a top priority. Downstream processing removes any potential harmful components, ensuring patient safety. Downstream products and technologies are crucial for optimizing product yield, reducing product loss, and maximizing the efficiency of bioproduction.

Regulatory agencies require thorough downstream processing to demonstrate product safety, efficacy, and consistency, making it a critical component for market compliance and approvals. Downstream processes help control product variability, ensuring each batch of biopharmaceuticals is consistent in terms of efficacy and safety. Downstream products are designed to be scalable, enabling biopharmaceutical manufacturers to transition from small-scale laboratory production to large-scale commercial manufacturing seamlessly. Efficient downstream processing minimizes production costs by optimizing resource utilization, reducing the need for reprocessing, and enhancing process efficiency. In summary, downstream products are dominant in the Biopharmaceutical Fermentation market as they are integral to ensuring the quality, safety, and market compliance of biopharmaceutical products. They contribute significantly to the success of bioprocessing, making it possible to deliver safe and effective therapies to patients worldwide.

End User Insights

Biopharmaceutical industries wield significant dominance within the Biopharmaceutical Fermentation market. These industries encompass a wide array of companies engaged in the development and production of biologically derived therapeutics and vaccines. Their prominence is rooted in several key factors: Biopharmaceutical industries are hubs of innovation, continually pioneering new biologic treatments and therapies for various diseases and medical conditions.

The surging global demand for biopharmaceuticals to address diverse health challenges propels industry growth, making it a dominant market force. These industries allocate substantial resources to research and development, driving advancements in bioprocessing techniques, including fermentation.

Maintaining diverse portfolios of biologic products necessitates robust fermentation capabilities to produce a broad range of biopharmaceuticals. Biopharmaceutical industries operate on a global scale, ensuring the widespread availability of biologic

medications and treatments. Adhering to stringent regulatory standards, they lead in ensuring product safety, efficacy, and quality. These industries consistently explore emerging markets, further cementing their dominance in the global biopharmaceutical fermentation landscape. In essence, biopharmaceutical industries' dominance is a testament to their pivotal role in advancing healthcare through cutting-edge bioprocessing technologies and the production of life-saving biopharmaceuticals. They drive industry growth, establish standards, and are instrumental in delivering innovative therapies to patients worldwide.

Regional Insights

North America is expected to witness significant growth in the biopharmaceutical market over the forecast period owing to the factors such as the increasing demand for biotech-based drugs, rising research and development activities, and growing expenditure for the development and advancements in biopharmaceutical fermentation. In addition, the rise in the frequency of chronic diseases rises the consumption of medicines which in turn helps to grow the biopharmaceutical industry and offers growth opportunities for the market players by increasing demand for biologics and biotech drugs which will ultimately propel the utility of biopharmaceutical fermentation.

The rising demand for biopharmaceutical fermentation in the biopharmaceutical sector to reduce the toxicity of drugs and bacterial resistance and increase its efficacy attracts various companies to research and development using biopharmaceutical fermentation. For instance, in August 2022, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) of the United States granted funding of USD 15.8 million for 14 new technology and workforce development projects that address key opportunities for innovation in the biopharmaceutical sector.

Additionally, the growing prevalence of diseases, such as diabetes, rheumatoid arthritis, and cancer in the region is contributing to the market's growth owing to the use of biopharmaceutical fermentation in manufacturing biotech drugs and biological drugs. For instance, about 32 million and 14 million living in the United States and Mexico were suffering from diabetes in 2021 and this number is projected to reach 36.2 million and 21.8 million by 2045, respectively. Also, as per the 2022 statistics published by ACS, about 1.9 million people living in America were diagnosed with cancer in the United States in 2022. Thus, the high burden of cancer and diabetes among the population raises the demand for effective biological drugs which in turn is anticipated to fuel the market growth over the forecast period.

Furthermore, the rising company focuses on adopting various business strategies such as product launches, approvals, fundraising, and partnerships to expand their offerings in the biopharmaceutical industry are expected to drive the growth of this market. For instance, in February 2022, Kerry Group plc acquired Enmex S.A., an enzyme manufacturer based in Mexico for EUR 62 million. The acquisition accelerates Kerry's innovation capabilities in enzyme engineering, fermentation, and bioprocess development. Also, in September 2021, Thermo Fisher Scientific announced its plan to expand its Nashville, Tenn. site by establishing a dedicated single-use technology manufacturing facility at the site, doubling capacity. The expansion is likely to use bioreactors on a large scale for the manufacturing of biological drugs.

Therefore, owing to the factors such as the high burden of diabetes, and cancer, growing demand for biopharmaceutical fermentation, and rising company activities, the studied market is anticipated to grow over the forecast period.

Key Market Players

Agilent Technologies Inc

Thermo Fisher Scientific Inc.

Lonza Group AG

Sartorius Stedim Biotech GmbH

Eppendorf Inc

Danaher Corporation

F. Hoffmann-La Roche Ltd.

Nova Biomedical Corporation

Merck KGaA

Becton, Dickinson and Company

Report Scope:

In this report, the Global Biopharmaceutical Fermentation Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Biopharmaceutical Fermentation Market, By Product Type:

Upstream Products

Downstream Products

Biopharmaceutical Fermentation Market, By Application:

Antibiotics

Recombinant Proteins

Others

Biopharmaceutical Fermentation Market, By End User:

Biopharmaceutical Industries

Contract Research Organization

Academic Research Institutes

Others

Biopharmaceutical Fermentation Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Biopharmaceutical Fermentation Market.

Available Customizations:

Global Biopharmaceutical Fermentation market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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