

Upstream Bioprocessing Market Size and Forecast (2020 - 2030), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Product Type (Bioreactors/Fermenters, Cell Culture, Filters, Bags and Containers, and Others), Workflow (Media Preparation, Cell Culture, and Cell Separation), Usage Type (Single Use and Multiuse), Mode (In-House and Outsourced), and Geography

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Abstracts

The global upstream bioprocessing market is expected to reach US\$ 25.046 billion in 2030 from US\$ 9.174 billion in 2022. The market is estimated to grow with a CAGR of 13.4% from 2022 to 2030.

Key factors driving the upstream bioprocessing market growth include the commercial use of single-use bioreactors, outsourcing of biopharmaceutical manufacturing, and rapid growth of pharmaceutical and biotechnology industries. However, a stringent regulatory framework hinders market growth.

Market Opportunities of Upstream Bioprocessing Market

The upstream bioprocessing market is experiencing a wave of technological advancements, presenting considerable industry opportunities. These advancements include innovative developments in cell culture systems, bioreactor design, process monitoring, and control, as well as the integration of automation and digitalization. In September 2023, Repligen Corporation and Sartorius introduced an integrated bioreactor system. Repligen's XCell Alternating Tangential Flow (ATF) upstream

intensification technology has been integrated into the Sartorius Biostat stirred-tank reactor (STR). This bioreactor technology is designed to make the application of N perfusion and intensified seed train easier for biopharmaceutical firms. An embedded XCell ATF hardware and software module that combines integrated process analytical technologies with predefined advanced control recipes is incorporated into Biostat STR. This module is intended to simplify the management of cell growth and enhance cell retention in perfusion procedures, eliminating the need for a separate cell retention control tower. Such modern products feature enhanced process efficiency, scalability, and adaptability, which are crucial for meeting the evolving demands of biopharmaceutical production.

Advanced cell culture media formulations and next-generation bioreactor technologies are contributing to the optimization of upstream bioprocessing, enabling higher product yields, improved product quality, and the efficient production of complex biologics. The ongoing integration of advanced analytics and real-time process monitoring revolutionizes data-driven decision-making in bioprocessing, driving precision and process optimization opportunities. Progress in biotechnology also fosters the development of flexible and modular manufacturing platforms. Additionally, the convergence of machine learning, artificial intelligence, and predictive analytics is paving the way for predictive bioprocessing, unlocking proactive process control, quality assurance, and cost optimization opportunities. Thus, technological advancements in upstream bioprocessing are reshaping the industry, presenting new avenues for innovation, efficiency, and adaptability.

Factor Hampering Upstream Bioprocessing Market

Regulatory authorities such as the Food & Drug Administration and the European Medicine Agency (EMA) monitor the operations of pharmaceutical manufacturers with consistent stringency. These businesses are thus bound to abide by the updated regulations promoting current good manufacturing practices (cGMP) and good laboratory practices (GLP) for assuring the control and monitoring of manufacturing processes and facilities. Currently, the FDA's CBER regulations do not mention single-use bioreactors. Any diversions from the registered protocols, demands, and requirements of this guidance may lead to the termination of the clinical trials orchestrated by manufacturers or outsourced organizations.

The biggest concern with using SUBs is that the molecules may not generate the same results in clinical trials as they produce in laboratory environments. The mixing mechanisms of SUBs may also lead to difficulties adhering to regulations, which

restricts their use. For instance, in wave-type SUBs, the mixing principle is limited to a rocking movement, leading to uneven mixing and causing errors. Hence, the safety and efficacy of biologics may raise significant concerns in the application of SUBs.

Therefore, stringent regulations associated with the biotechnology industry bolster the demand for bioreactors. Moreover, the lack of regulatory framework in developing nations such as China, India, and Brazil hinders the upstream bioprocessing market growth.

Upstream Bioprocessing Market: Segmental Overview

Based on product type, the upstream bioprocessing market is segmented into bioreactors and fermenters, cell culture media, filters, bags and containers, and others. The bioreactors/fermenters segment held the largest share of the upstream bioprocessing market in 2022. Moreover, the cell culture segment is anticipated to register a significant CAGR during 2022–2030. Bioreactors and fermenters serve as core vessels in which cells and microorganisms are grown for various therapeutic and bioprocessing applications involving the expression and production of biologically derived compounds. These systems are engineered to provide an optimal environment for cell growth, incorporating precise control over parameters such as temperature, pH, dissolved oxygen, and agitation. These are critical for cultivating cells and microorganisms in large-scale bioprocessing operations.

Based on workflow, the upstream bioprocessing market is classified into media preparation, cell culture, and cell separation. The cell separation segment held the largest share of the upstream bioprocessing market in 2022. It is further anticipated that a significant CAGR will be registered from 2022 to 2030. Cell separation is the initial stage of segregating protein products (cells) from the culture. The amount and quality of the product collected in the bioreactors will determine whether to terminate the cell culture, which is an important decision.

Based on usage type, the global upstream bioprocessing market is classified into single use and multi-use. The single-use segment held a larger share of the market in 2022. The same segment will record a significant CAGR in the upstream bioprocessing market during 2022–2030. The upstream bioprocessing market has experienced a transformative shift with the widespread adoption of single-use technologies. Single-use systems, including bioreactors, bags, and connectors, have gained prominence for their flexibility, cost-effectiveness, and reduced risk of cross-contamination. These disposable components replace traditional stainless-steel equipment, offering a more agile and scalable approach to bioproduction. The single-use trend accelerates process

development, minimizes cleaning and validation efforts, and facilitates quick changeovers between production runs.

The upstream bioprocessing market is segmented into in-house and outsourced based on mode. In 2022, the in-house segment held a larger market share. The outsourced segment is expected to record a higher CAGR during 2022–2030. In-house manufacturing is gaining traction in the upstream bioprocessing market as biopharmaceutical companies seek greater control over their production processes. Establishing in-house upstream bioprocessing facilities enables companies to tailor processes to their needs, ensuring a more customized and efficient approach. This move often involves investment in state-of-the-art bioreactors, cell culture systems, and associated technologies.

Upstream Bioprocessing Market: Geographical Overview

North America accounted for the largest global upstream bioprocessing market share in 2022. The US held the largest upstream bioprocessing market share in the region and is anticipated to register the highest CAGR during 2022-2030. The US is the largest market for bioreactors—several market players in the US manufacture bioreactors for pharmaceutical and biotechnology companies. Launch of new bioreactors, geographic expansion strategies, and partnerships among market players bolster the upstream bioprocessing market growth in the US. In April 2023, BioMADE announced five new projects focused on addressing gaps in the US' research and adoption of bioreactors in bio-industrial manufacturing. With a funding commitment of US\$ 10.5 million, these projects would span engineering, hardware development, and scalability to address the barriers to accelerating an economy. These projects would focus on innovation to introduce advanced bioreactor designs supported by Schmidt Futures. In April 2023, Cytiva launched X-platform bioreactors to simplify upstream bioprocessing operations with single-use products. Initially, bioreactors were available in 50 L and 200 L sizes. The X-Platform bioreactors are equipped with Figurate automation solution software, and they can increase process efficiency through ergonomic improvements, production capacity, and simplified supply chain operations.

The growth of the biopharmaceutical sector, mainly due to technological advancements, increasing flexibility, and low operational costs, also benefits the upstream bioprocessing market in the US. As per the International Trade Administration (ITA), the US is the largest market for biopharmaceuticals and the global leader in biopharmaceutical R&D. According to the Pharmaceutical Research and Manufacturers Association (PhRMA), companies in the US account for nearly 50% of the global

pharmaceutical R&D work, and they have succeeded in developing many novel medicines for which they hold intellectual property rights. A continuous increase in the development of new biologics, resulting in the approval of more new molecular entities (NME) by regulatory authorities, creates opportunities for the growth of the upstream bioprocessing market in the US. According to the Chemical & Engineering News, the US Food and Drug Administration (FDA) approved ~37, 50, and 53 new NMEs in 2022, 2021, and 2020, respectively.

Furthermore, Increasing R&D investments by US-based pharmaceutical and biotechnology companies to improve outcomes of clinical trials and ensure patient safety contributes to the growth of the upstream bioprocessing market in the US. In addition, growing traction toward precision medicine with rising investments by the US government will likely contribute to market growth in the coming years.

A few of the major primary and secondary sources referred to while preparing the report on the upstream bioprocessing market are the World Bank Data, National Health Service (NHS), FDA (Food and Drug Administration), EMA (European Medicines Agency), and WHO (World Health Organization).

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