

## **Bioprocess Validation Market - Growth, Trends, Covid-19 Impact, and Forecasts (2023 - 2028)**

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### **Report description:**

Bioprocess Validation Market is expected to witness a healthy CAGR of 9.5% during the forecast period (2022-2027).

The bioprocess validation market is significantly impacted by COVID-19. This can be attributed to significant disruptions in their respective manufacturing and supply-chain operations as a result of various precautionary lockdowns and other restrictions imposed by governments all over the world. The demand for bioprocess validation increased during the pandemic because validation is required at all phases of drug development to monitor accuracy, efficiency, and safety. Due to the uncontrolled and sudden increase in covid-19 cases, the development of biosimilars, combination molecules, and other innovative vaccines and medicines has grown, which has resulted in an increased demand for significant bioprocess validation. Companies such as SGS offer a full range of bioprocess validation for both small molecules and biologics. In November 2020, SGS, the world's leading inspection, verification, testing, and certification company, invested in its Biosafety Center of Excellence in Glasgow, boosting its capacity to support scientists and manufacturers in the development of effective vaccines, cell and gene therapies, and other biological medicines.

The market's growth is being driven by the high demand for bioprocess validation services, as well as stringent safety and quality regulations governing product certifications and testing beyond the biopharmaceutical and pharmaceutical industries, and increasing demand for outsourcing bioprocess validation coupled with rising R&D expenditure.

According to the Food and Drug Administration (FDA) Drug Recall Statistics published in July 2021, approximately 1,279 drugs are recalled each year globally, with 94 percent of FDA drug recalls occurring in the United States, followed by 4% in Canada. The FDA issued 12,028 drug recalls in the United States between 2012 and 2021. This necessitates the validation of products and the assurance of public safety before they are marketed. Medicines are designed to improve outcomes in humans and animals, as

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low-quality medicines have a negative impact on patient health and funding systems. As a result, bioprocess validation is critical in ensuring the safety and efficacy data of drugs.

The increased need for specific types of tests in R&D activities, as well as the growing trend of outsourcing laboratory testing services, are two major factors driving the market's growth. Companies are expanding their market share by offering a variety of services and solutions in response to the growing trend of outsourcing laboratory testing services. Major players are also concentrating on various strategies such as mergers, acquisitions, and other developments. For example, in August 2021, Eurofins Scientific agreed to buy GeneTech Inc., a leading Japanese player in genetic analysis, from Noritsu Koki Co. Ltd, to expand Eurofins' testing portfolio in Japan. Because bioprocess validation plays such an important role, the market is expected to expand significantly.

Furthermore, increase in research and development expenditure in pharmaceutical research the market is expected to see a surge over the forecast period. For instance, according to the Pharmaceutical Research and Manufacturers of America data updates from September 2021, since 2000, PhRMA member companies have invested more than USD 1.1 Trillion in the search for new treatments and cures, including USD 102.3 Billion in 2021 alone. Furthermore, these are expected to increase further over the forecast period. Thus, the rising research and development expenditure is expected to boost the bioprocess validation market.

Therefore, the above factors are expected to drive the market's growth. However, the issues related to extractables and leachables is expected to hinder market growth.

### Bioprocess Validation Market Trends

#### Bioreactor is Expected to Hold Significant Market Share in the Process Component Segment

The pharmaceutical sector uses bioreactors for the manufacture of medicines, vaccines, and other pharmaceutical components. Bioreactors are also used for the production of monoclonal antibodies for the treatment of cancer, rheumatoid arthritis, and other diseases. Bioreactors have been utilized in many different areas of industry and research and for the progression of in vitro models of 2D cultures and suspensions to 3D constructs, mimicking the natural physiological state in situ.

In the pharmaceutical sector, bioreactors are used to hold organisms for the purpose of harnessing their natural biochemical processes. Bioreactors are designed to allow microorganisms to thrive, causing the contents of the tank to ferment and creating a usable end product. In a batch bioreactor, everything is added at once to a controlled and sealed environment, and the biochemical reactions are allowed to run their course before the reactor is opened so that the contents can be extracted and utilized, disposed of, or further processed. Others operate on a continuous flow method, in which materials constantly flow through the bioreactor.?

In April 2020, researchers from Ology Bioservices and Univercells SA announced that they had developed a high-yield live-virus vaccine production platform by using a novel fixed-bed bioreactor in a paper published in the 'Vaccine' magazine. The scientists from these companies further stated that their bioreactor platform allows for a cost-effective and scalable process for viral vaccine production. Initiatives such as these are expected to boost segment growth.?

Initiatives by major companies are also boosting segment growth. For instance, in February 2020, Eppendorf introduced its latest bioreactor control system for small- and bench-scale applications called the SciVario system. The new system has been designed for academic and industrial applications.?

Therefore, the rising demand and use of bioreactors for applications in the pharmaceutical sector are expected to boost the innovation and usage of bioreactors, thus propelling the segment growth.

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## North America Holds a Significant Share in the Market and Expected to do Same during the Forecast Period

North America is expected to be a dominant region in the bioprocess validation market owing to the increasing number of R&D activities and investments as well as rising demand for biopharmaceuticals and increasing demand for outsourcing bioprocess validation.

According to the data published by the National Center for Biotechnology Information (NCBI), Biotechnology funding by the National Institute of Health (NIH) was around USD 7.77 Billion during the fiscal year 2020. Also, the data published by the Federation of American scientists reported that federal funding for research and development grew 5.9% in 2020 compared to 2019, which was USD 138.9 Billion. The Nation's 42 federally funded research and development centers spend around USD 23.5 Billion on research and development in the fiscal year 2020.

According to a report published in September 2021 by the Pharmaceutical Research and Manufacturers of America (PhRMA), in the last decade, biopharmaceutical companies invested more than a trillion dollars in research and development, including a record-breaking year in 2020 where PhRMA member companies invested about USD 91 billion in the research and development. Outsourcing drug development helps the biotechnology firms a proper utilization of their resources and limit the financial risks. As a result, the bioprocess validation market is anticipated to grow over the forecast period.

Thus, owing to the abovementioned factors, the market is expected to show growth over the forecast period.

## Bioprocess Validation Market Competitor Analysis

The pharmaceutical analytical testing market is fragmented in nature due to the presence of a number of companies globally. The studied market consists of several international and local companies that hold the majority of the market shares and are well known, including Laboratory Testing Inc., Eurofins Scientific, SGS SA, Toxikon Inc., Sartorius AG, Pall Corporation, Cobetter Filtration Equipments Co., Ltd, and DOC S.r.l.

### Additional Benefits:

- The market estimate (ME) sheet in Excel format
- 3 months of analyst support

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