

Bioprocess Validation Market Size, Share & Trends Analysis Report By Testing Type (Extractables & Leachables Testing, Bioprocess Residuals Testing), By Stage, By Mode (In house, Outsourced) By Region And Segment Forecasts, 2023 - 2030

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Abstracts

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Bioprocess validation Market Growth & Trends

The global bioprocess validation market size is projected to reach USD 842.5 million by 2030, at a CAGR of 9.10% from 2023 to 2030, according to a new report by Grand View Research, Inc. Bioprocess validation is the process of documentation of all the stages, activities and procedures of the bioproduct formation. This documentation complied with the EMEA and US FDA guidelines of cGMP. It aims to deliver standard, quality, and safe manufacturing of bioproducts. The process has a wide range of applications in drug discovery, therapeutics development, and biosimilar development. Precise analysis of active pharmaceutical ingredients and the removal of contaminants such as endotoxins and, bacteria during drug development are the most crucial step of bioprocess validations.

There is a surge in demand for the in-house as well as outsourcing of the validation process, which drives the global market. Trace contaminants are formed during the production and manufacturing process of bio-products. This is due to the presence of extractable and leachables, which can cause potential hazards to consumers. This can be a major restraining factor, which can hamper the market growth. Moreover, biopharmaceutical and biotechnology industries focusing on low manufacturing costs with higher yields of the products create lucrative opportunities for market growth. The

major challenge faced by the key players and bio manufacturers is the approval of novel therapies to validate drug and therapeutics development by the government and regulatory agencies.

COVID-19 has had a positive impact on the global market as the R&D sector and the development of vaccines and therapeutics have flourished. Moreover, increasing demand for the safety and quality cGMP-approved vaccines to treat the COVID-19 virus has led to an increase in the mergers and, partnerships among the market key players for enhancing the upstream and downstream process for delivering efficient bioproducts. An effective validation process not just ensures the quality and safety but also the efficacy of the product. Moreover, during the post-COVID era, most of the biopharmaceutical industries, suppliers, and service providers have increased their pandemic-related research, development, and manufacturing of biosimilars, thus propelling the market.

The increasing CDMOs, bioprocess outsourcing services, stringent government regulations, and guidelines for developing safe and quality products propel the global bioprocess validation industry. Moreover, an increase in the number of clinical trials to deliver impurity-free biosimilars and drugs for the treatment of chronic diseases such as cancer, diabetes, and arthritis boosts the market. In addition to these leading advancements in the life sciences tools and automated systems for the bioprocess, methods boost industry growth.

Bioprocess Validation Market Report Highlights

The bioprocess residuals testing segment dominated the market with the largest market share of 28.65% in 2022. The increases in the demand for impurity-free bio-products by pharmaceutical, biopharmaceutical, and biotechnology industries and enhancing drug discovery and therapeutics development process will drive the segment to grow in the upcoming forecast.

By stage segment, the continued process verification segment held the largest share of 42.3% in 2022. This is due to the increasing use and availability of automation facilities for continued process verification, which drives the segment to account for the largest share.

By mode segment, the outsourced segment dominated the market in 2022. The presence of increased bioprocess validation outsourcing testing services by the majority of the critical players propels the market to account for a large share of

this segment.

North America held the largest share of 38.93% in 2022, due to the presence of an established healthcare sector and key players such as Thermo Fisher Scientific, Inc.; Danaher Corporation; and others in the region.

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