

Biological Safety Testing Services Market Size, Share & Trends Analysis Report By Services (Sterility Testing Services, Endotoxin Testing Services), By Application, By End-use, By Region, And Segment Forecasts, 2025 - 2030

<https://marketpublishers.com/r/B3B145D6609DEN.html>

Date: February 2025

Pages: 150

Price: US\$ 5,950.00 (Single User License)

ID: B3B145D6609DEN

Abstracts

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Biological Safety Testing Services Market Growth & Trends

The global biological safety testing services market size is expected to reach USD 6.33 billion by 2030, growing at a CAGR of 11.78% during the forecast period, according to a new report by Grand View Research, Inc. The market can be attributed to the benefits offered by biological safety testing services, such as cost savings, an increased focus on sterility assurance, and the rising development of new pharmaceuticals, therapies, & medical devices. In addition, stringent regulatory requirements, a growing emphasis on patient safety, advancements in biotechnology, and the increasing prevalence of chronic and infectious diseases are some of the factors contributing to the market growth.

The biological safety testing services industry is experiencing rapid growth due to the increasing demand for biologics, cell & gene therapies, and vaccines. Some of the other key trends in the market include the expansion of biological safety testing services by contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs), as well as rising investments in biopharmaceutical research and development (R&D).

Moreover, stringent regulatory requirements from the FDA, EMA, and ICH have made biosafety testing essential for ensuring product safety, efficacy, and compliance. This has led to an increasing need for viral clearance, sterility, endotoxin, mycoplasma, and bioburden testing requirements which aims to improve efficiency and ethical

compliance. This has led most of the market players to increasingly outsourcing biosafety testing while are seeking cost-effective and specialized expertise with their emerging pipelines for biologic drugs. Furthermore, technological innovations such as automation, next-generation sequencing (NGS), real-time PCR, and AI-driven analytics are enhancing the accuracy, speed, and regulatory compliance of tests. Therefore, biological safety testing services are expected to evolve during the forecast period to meet the complex regulatory and quality control needs of the industry.

The strategic partnerships and accelerating product launches are also driving the market growth. For instance, in April 2024, Merck introduced the Aptegra CHO Genetic Stability Assay, the first all-in-one, validated genetic stability assay. Utilizing whole genome sequencing and bioinformatics, this innovation enhances biosafety testing efficiency, enabling faster transitions to commercial production.

Biological Safety Testing Services Market Report Highlights

The bioburden testing services segment dominated the market in 2024. Growth in the segment can be attributed to the increasing focus on sterility assurance of medical devices and pharmaceutical drugs and growing concern for product safety. These services are actively preferred to determine a test unit's microbial quality or cleanliness, thereby determining the sterilization process needed for effective decontamination.

Based on application, the vaccine & therapeutics segment held the largest market share in 2024, attributed to the stringent regulatory scenarios, growing demand for vaccines and biologic therapeutics, rapid adoption of automation, next-generation sequencing (NGS), and AI-driven analytics ensuring compliance and product safety drives the segment growth.

Based on end use, the biopharmaceutical companies segment dominated the market in 2024. This is attributable to increasing R&D investment, growing focus on product safety and testing, rising cost-efficiency service offerings, and increased biological production.

North America market accounted for the largest share of 33.15% in 2024 due to the rising number of medical device companies & pharmaceutical companies in countries like the U.S. and Canada, the North America is

anticipated to witness rapid growth over the estimated time. The presence of established market players within the region offering cost-efficient services in the U.S. is another factor anticipated to propel market growth.

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