

Biological Safety Testing Products and Services Market to Surge to USD 10.51 Billion by 2032, Growing at a 10.10% CAGR

Demand for Biologics and Advanced Testing Methods Drives Market Growth; North America Leads, Asia Pacific Emerges as Fastest Growing Region

AUSTIN, TX, UNITED STATES, November 22, 2024 /EINPresswire.com/ -- The [Biological Safety Testing Products and Services Market](#), valued at USD 4.42 billion in 2023, is projected to reach USD 10.51 billion by 2032 at a CAGR of 10.10% during the forecast period of 2024-2032.



Ensuring Biologics Safety: The Driving Forces Behind Market Expansion

Biological safety testing products and services play a critical role in ensuring the safety and efficacy of biologics, vaccines, and gene therapies by assessing microbial contamination, toxicity, and other safety parameters. The market is witnessing substantial growth, fueled by the increasing prevalence of chronic and infectious diseases, which has amplified the demand for innovative biologics. The expanding biopharmaceutical market further drives this growth, with companies investing heavily in next-generation therapies such as gene and cell treatments, vaccines, and monoclonal antibodies. Biocon Biologics launched a cost-effective Humira biosimilar in July 2023, improving accessibility for biological safety. Leading market players, including Lonza Group and Charles River Laboratories, are strengthening their testing capabilities through strategic expansions and acquisitions, such as Lonza's new facilities in the U.S. and Europe and Charles River's acquisition of Cognate BioServices. Additionally, government initiatives like the US FDA's 2023 "BioRationality" guideline are fostering streamlined and cost-effective safety testing processes, ensuring compliance with stringent safety standards. These combined efforts underscore the pivotal role of biological safety testing in advancing global healthcare while supporting the rapid evolution of the biopharmaceutical industry.

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Key Biological Safety Testing Products and Services Market Players:

- Lonza
- BIOMÉRIEUX
- Thermo Fisher Scientific Inc.
- SGS Société Générale de Surveillance SA
- Eurofins Scientific
- Sartorius AG
- Samsung Biologics
- Merck KGaA
- BSL Bioservice
- Charles River Laboratories and Other Players

Segment analysis

By Product:

The widespread use in clinical and research laboratories, the reagents and kits segment dominated more than 40.54% of the market share in 2023. These critical products, such as antibiotics, biological buffers, and matrix factors, play a crucial role in different tests like toxicology and bioburden assessments. The increasing popularity of high-throughput testing for complex biological samples has greatly increased the need for advanced reagents and kits.

The instruments segment is expected to experience the fastest growth throughout the forecast period, driven by the rising use of sophisticated testing equipment in labs across the globe. Tools like flow cytometers, electrochemiluminescence analyzers, and automated bioburden testing systems are necessary for conducting specific tests. The increasing focus on adherence to strict safety regulations mandated by international bodies is also fueling the need for precise instruments.

By Application:

The vaccines and therapeutics segment dominated the market share in 2023. This leadership is due to the creation of new treatments and vaccines that must undergo thorough safety checks to comply with regulations. Comprehensive guidelines like those issued by the U.S. FDA uphold the safety of materials used in vaccine production and their therapeutic value.

Moreover, the gene and cell therapy segment is projected to experience the fastest growth, fueled by progress in regenerative medicine and the rising participation of therapies in clinical trials. Thorough testing procedures for these intricate biologics guarantee their safety and efficacy, with safety testing playing a key role in their development.

Key Market Segments

By Product

- Reagents & Kits
- Instruments
- Services

By Application

- Vaccines & Therapeutics
- Vaccines
- Monoclonal Antibodies
- Recombinant Protein
- Blood & Blood-based Products
- Gene Therapy
- Tissue & Tissue-based Products
- Stem Cell

By Test Type

- Endotoxin Tests
- Sterility Tests
- Cell Line Authentication & Characterization Tests
- Bioburden Tests
- Adventitious Agent Detection Tests
- Residual Host Contamination Detection Tests
- Others

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Regional Insights

In 2023, North America dominated the market with a share of 37.22%. The region's large market share is due to the biotechnology industry's significant investments, rising use in cancer research, and the creation of new biologics, vaccines, and drugs. Additionally, companies guarantee market growth through increased investments in research and development. Furthermore, the market is influenced by the extensive growth initiatives undertaken by the top market competitors. Expansion is also helped by the increasing number of chronic diseases in the area, which is projected to boost the use of advanced technologies by researchers and healthcare professionals.

In the North American market in 2023, the U.S. also dominated with the largest portion. The nation continues to lead as the main market in North America because of its robust and well-established biopharmaceutical sector and strong emphasis on research and development. Moreover, numerous pharmaceutical and biotech firms, along with academic and research organizations, result in a consistent need for thorough safety testing, ultimately solidifying the

country's position as a leader in the field.

Recent Market Developments

- In May 2023, Merck KGaA disclosed a USD37.7 million investment in its biosafety testing facilities in Glasgow and Stirling, Scotland. This action is intended to increase global testing capabilities, demonstrating its dedication to improving safety measures.
- In 2023, Thermo Fisher Scientific released the Gibco CTS TrueCut Cas9 Protein, aiming to enhance the precision and productivity of gene editing. This new technology meets the increasing need for safety testing in gene therapy and biologics.

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