

# **Biological Safety Testing Products and Services Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2019-2029 Segmented By Product (Reagents & Kits, Services, Instruments), By Application (Vaccines & Therapeutics, Gene Therapy, Monoclonal Antibodies, Recombinant Protein, Blood & Blood-based Products, Tissue & Tissue-based Products, Stem Cells), By Test Type (Endotoxin Tests, Sterility Tests, Cell Line Authentication & Characterization Tests, Bioburden Tests, Adventitious Agent Detection Tests, Residual Host Contamination Detection Tests, Others), by region, and Competition**

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## **Abstracts**

Global Biological Safety Testing Products and Services Market has valued at USD 3.98 billion in 2023 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 9.10% through 2029. Biological Safety Testing Products and Services refer to a broad range of tools, methodologies, and services used to assess the safety, quality, and purity of biological products, pharmaceuticals, medical devices, and various other materials that meet living organisms. These products and services are critical for ensuring that biological substances, including vaccines, biologics, drugs, medical devices, and research materials, meet stringent safety and quality standards. Specialized equipment, such as automated liquid handling systems, microbiological incubators, and analytical instruments, is used for sample preparation and analysis in biological safety testing. Various consumable items, including culture media,

microplates, pipettes, and filtration membranes, are essential for conducting biological safety tests. Testing laboratories offer analytical services to assess the quality and safety of products, from pharmaceuticals to medical devices. These services may include potency testing, stability testing, and method validation. Custom method development and validation services are essential for creating and verifying testing protocols tailored to specific products and materials.

Increasing healthcare spending and a growing emphasis on patient safety worldwide drive demand for biological safety testing, particularly in the quality control of medical devices and pharmaceuticals. Advances in testing technologies, such as rapid microbiological methods, molecular biology techniques, and high-throughput screening, enhance the efficiency and accuracy of biological safety testing. As biopharmaceutical companies expand their global presence, they require reliable biological safety testing services and products in multiple regions. There's a growing emphasis on sustainable practices and reducing the environmental impact of laboratory testing, influencing the choice of testing products and services. The continuous development of new drugs and vaccines, including personalized medicine, drives demand for biological safety testing in research and clinical trials.

## Key Market Drivers

### Technological Advancements

Rapid Microbiological Methods (RMMs) have reduced the time required for traditional microbiological testing, such as sterility testing and microbial limit testing. Techniques like polymerase chain reaction (PCR), real-time PCR, and next-generation sequencing (NGS) enable faster and more accurate detection of microorganisms. Automation and robotics have streamlined high throughput screening processes, allowing for the testing of many samples simultaneously. This has increased the efficiency and throughput of biological safety testing. Advanced testing platforms permit the simultaneous measurement of multiple parameters, such as multiple analytes or different biological safety indicators, in a single assay. This reduces the time and resources required for testing. Label-free assays, such as surface plasmon resonance (SPR) and biolayer interferometry (BLI), enable real-time monitoring of binding interactions without the need for labeling molecules, making them valuable in affinity testing. Automated liquid handling, sample preparation, and data analysis systems have improved testing accuracy and reproducibility while reducing the risk of human error.

Mass spectrometry has become a powerful tool for high-throughput analysis of

biochemical activities and binding interactions. Innovations in MS technology have made it a versatile platform for various types of biological safety testing. High-resolution imaging and microscopy techniques provide detailed insights into the structure and behavior of microorganisms, cells, and other biological components, enhancing testing capabilities. AI and machine learning algorithms are being used to analyze large datasets, identify patterns, and predict outcomes in biological safety testing. They improve decision-making and data interpretation. Cloud-based platforms and remote monitoring tools allow for real-time access to testing data, enhancing collaboration, and enabling more efficient data analysis and reporting.

Biosensor technologies, including surface plasmon resonance sensors, optical sensors, and electrochemical sensors, offer real-time monitoring and quantitative measurement of biological interactions, making them valuable for safety testing. Techniques like nuclear magnetic resonance (NMR) and Fourier-transform infrared (FTIR) spectroscopy are used to analyze the chemical composition of samples, aiding in safety assessment. Microfluidics and lab-on-a-chip technologies have led to smaller, more portable testing devices, reducing the sample size required and allowing testing in a wider range of settings. Technology is advancing in the realm of data security and compliance management to meet regulatory requirements, ensuring data integrity and traceability. This factor will help in the development of the Global Biological Safety Testing Products and Services Market.

### Rising Global Healthcare Expenditure

As healthcare spending increases, there is a growing emphasis on ensuring the safety, efficacy, and quality of medical products and treatments. Biological safety testing is essential for maintaining high standards and quality assurance in the healthcare sector. Patient safety is a top priority in healthcare. Ensuring that medical devices, pharmaceuticals, vaccines, and diagnostic tools are free from harmful contaminants and pathogens is essential to prevent harm to patients. Regulatory agencies, such as the FDA in the United States and equivalent bodies in other countries, enforce strict safety and quality standards for healthcare products. Compliance with these regulations necessitates extensive biological safety testing throughout the product development and manufacturing process. With increased healthcare expenditure, there is more investment in research and development for new medical products, including drugs, biologics, and medical devices. These products require rigorous biological safety testing to reach the market.

The demand for diagnostic tools and tests continues to rise as healthcare becomes

more personalized and precision oriented. These diagnostics must undergo rigorous testing to ensure accurate and reliable results. Healthcare spending drives the pharmaceutical and biotechnology industries, which depend on biological safety testing to ensure the safety and efficacy of drugs, biologics, and vaccines. The growing use of medical devices in healthcare, ranging from simple instruments to complex equipment, necessitates biological safety testing to meet regulatory and quality control standards. Preventing the spread of healthcare-associated infections is a key focus in healthcare. Biological safety testing is crucial in assessing the effectiveness of infection control measures and products used in healthcare facilities.

With the increasing interconnectedness of global healthcare, concerns over global health threats, such as pandemics or emerging infectious diseases, highlight the need for biological safety testing in diagnostics, treatment, and research. Expanding healthcare expenditure supports innovation in the development of new medical treatments, which, in turn, requires extensive research and testing, including biological safety testing. Growth in healthcare expenditure is not limited to one region, it's a global phenomenon. Therefore, biological safety testing products and services have a broad international market. Clinical trials, a crucial step in bringing new treatments and medical products to market, rely on rigorous biological safety testing to ensure the safety of study participants and the efficacy of interventions. This factor will pace up the demand of the Global Biological Safety Testing Products and Services Market.

### Global Expansion of Biopharmaceutical Companies

Biopharmaceutical companies conduct extensive research and development activities to develop new drugs, biologics, vaccines, and medical devices. As they expand globally, these companies require biological safety testing to ensure the safety and efficacy of their products, both in their home countries and in new international markets. Regulatory agencies in different countries have their own specific requirements for product safety and quality. Global biopharmaceutical companies must adhere to these diverse regulatory standards, which often involve thorough biological safety testing to obtain product approvals. The expansion of biopharmaceutical companies into new regions increases the demand for biological safety testing products and services. These companies need to meet the safety and quality standards of local markets where they operate or sell their products. Biopharmaceutical companies often have diverse product portfolios, ranging from pharmaceuticals to biologics, vaccines, and medical devices. Each of these product categories requires specific biological safety testing tailored to its characteristics. Many biopharmaceutical companies outsource aspects of their research, development, or manufacturing processes to contract research organizations

(CROs) or contract manufacturing organizations (CMOs). These service providers rely on biological safety testing to meet their clients' demands.

The biopharmaceutical industry is expanding rapidly in emerging markets such as Asia, Latin America, and the Middle East. These markets offer significant growth opportunities for global biopharmaceutical companies, further driving the need for biological safety testing in these regions. Global biopharmaceutical companies often collaborate with research institutions, academic centers, and biotech startups around the world.

Collaboration frequently involves biological safety testing for research and development projects. Biopharmaceutical companies lead in advanced research and innovation, such as the development of biologics, personalized medicine, and gene therapies. These cutting-edge products require sophisticated biological safety testing. Expanding globally necessitates launching and distributing products in different markets. Each market has specific requirements for biological safety testing before product distribution.

Collaborations with governments and healthcare organizations to address public health issues, such as vaccination campaigns or outbreak responses, require robust biological safety testing for diagnostics, vaccines, and treatments. This factor will accelerate the demand of the Global Biological Safety Testing Products and Services Market.

## Key Market Challenges

### Cost Pressures

Meeting the stringent regulatory requirements for biological safety testing can be costly. Companies must invest in staff training, quality control measures, and documentation to ensure compliance with various regulations, in addition to operational expenses. To stay competitive and meet evolving testing needs, companies in the industry must continually invest in cutting-edge laboratory equipment, instrumentation, and advanced technologies. These investments can be substantial and impact on the overall cost structure. Skilled professionals, such as microbiologists, biochemists, and quality control experts, are essential for biological safety testing. Attracting and retaining these experts can be costly due to the high demand for their specialized skills. Biological safety testing often requires the use of specialized reagents, consumables, and test materials, which can be expensive. Additionally, the labor-intensive nature of some testing procedures contributes to operational costs. Ensuring the accuracy and reliability of testing results necessitates comprehensive quality control and validation processes, which can be resource intensive.

### Complex Sample Types

Complex samples can be highly heterogeneous, with variations in composition, concentration, and physical properties. This heterogeneity complicates testing and may require more extensive testing procedures to account for potential variations. Complex samples may contain substances that interfere with the accuracy of testing methods. Interfering substances can lead to false positives or false negatives, making it essential to develop testing methods that can distinguish and quantify multiple components. Preparing complex samples for testing can be time-consuming and labor-intensive. Specialized sample preparation techniques may be necessary to extract, concentrate, or purify specific analytes or components of interest. Complex samples may carry a higher risk of cross-contamination during testing, which can compromise the integrity of results. Careful handling and containment measures are required to avoid contamination. Complex samples often necessitate multiplex testing, where multiple analytes or parameters are tested simultaneously. This requires advanced equipment and methodologies to ensure accurate and reliable results. The matrix of complex samples can influence the performance of analytical methods. Matrix effects can lead to biased or inaccurate results, and compensation strategies may be required.

## Key Market Trends

### Customization and Outsourcing

Customization involves tailoring biological safety testing services to the specific requirements of clients or projects. Businesses are increasingly seeking customized testing solutions that address their unique needs, whether related to the type of samples, the parameters being tested, or specific regulatory considerations. Customized services can range from assay development to adapting testing methodologies to accommodate complex or atypical sample types. Many companies are outsourcing their biological safety testing needs to specialized contract testing organizations (CROs). Outsourcing offers several advantages, including access to specialized expertise, state-of-the-art equipment, and cost-effectiveness. CROs often offer a range of testing services, from endotoxin testing to mycoplasma testing, sterility testing, and bioburden testing. This trend aligns with the growing emphasis on cost-efficiency, streamlined processes, and access to the latest testing technologies.

### Segmental Insights

### Product Insights



In 2023, the Global Biological Safety Testing Products and Services Market largest share was held by reagents and kits segment and is predicted to continue expanding over the coming years. Reagents and kits are fundamental components used in a wide range of biological safety testing procedures. They include materials for various tests, such as endotoxin testing, mycoplasma testing, and sterility testing. Their essential nature in the testing process contributes to their market dominance. Many biological safety tests, such as those required for pharmaceuticals, vaccines, and medical devices, are performed regularly as part of quality control and safety assurance in the manufacturing process. This leads to a consistent demand for reagents and kits. The pharmaceutical and biotechnology industries are highly regulated, with stringent requirements for product safety and quality. Compliance with these regulations often necessitates the use of standardized reagents and kits for testing. Reagents and kits are versatile and can be used across various types of biological safety testing, making them attractive to laboratories and manufacturers seeking a one-stop solution for different testing needs.

### Application Insights

In 2023, the Global Biological Safety Testing Products and Services Market largest share was held by vaccine and therapeutics segment and is predicted to continue expanding over the coming years. The occurrence of global health crises, such as pandemics or emerging infectious diseases, can drive significant demand for vaccines and therapeutics. The COVID-19 pandemic, for example, created a substantial need for vaccine development and testing, which may have influenced the segment's market share. Vaccines and therapeutic products are subject to rigorous regulatory scrutiny and testing to ensure their safety and efficacy. This involves a range of biological safety testing services to meet regulatory standards. Ongoing research and development efforts in the pharmaceutical and biotechnology industries continually drive the need for biological safety testing. New vaccines and therapeutic agents must undergo extensive testing during their development phases. Government-backed public health initiatives to combat infectious diseases, such as immunization programs, can lead to the production of large quantities of vaccines. Ensuring the safety of these vaccines is essential.

### Test Type Insights

In 2023, the Global Biological Safety Testing Products and Services Market largest share was held by Endotoxin segment in the forecast period and is predicted to continue expanding over the coming years. Endotoxin testing is a critical component of quality control and safety assessment in the biopharmaceutical and medical device

industries. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) mandate rigorous testing for endotoxins to ensure the safety of pharmaceutical products, medical devices, and vaccines. This regulatory requirement drives significant demand for endotoxin testing services and products. Endotoxins, which are components of the cell walls of Gram-negative bacteria, can be harmful when introduced into the human body. They are known to cause severe adverse reactions, including fever, sepsis, and even death. Consequently, ensuring that endotoxin levels are within safe limits is vital to product safety and patient well-being. Endotoxin testing is used in a wide range of applications, including testing of drugs, vaccines, medical devices, and biotechnology products. As these industries continue to expand and develop new products, the demand for endotoxin testing remains consistently high. The pharmaceutical industry relies on endotoxin testing to validate the quality of drugs and pharmaceutical products. Any failure to meet endotoxin limits can lead to product recalls and regulatory issues, making it a top priority for pharmaceutical companies. With a growing emphasis on patient safety, pharmaceutical manufacturers and healthcare providers place a significant focus on ensuring that endotoxin levels are within safe limits to prevent harm to patients who use these products.

## Regional Insights

The North America region dominates the Global Biological Safety Testing Products and Services Market in 2023. North America, particularly the United States, is home to a robust and highly developed biopharmaceutical industry. This industry encompasses pharmaceuticals, biotechnology, and medical device companies that require extensive biological safety testing to ensure product safety and compliance. The presence of numerous biopharmaceutical firms creates a significant demand for biological safety testing products and services. The region is known for its cutting-edge research and development activities in the life sciences sector. This research includes drug discovery, vaccine development, and biotechnology advancements, all of which necessitate rigorous biological safety testing. The United States has a stringent regulatory environment governed by agencies like the U.S. Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). These agencies enforce strict safety and quality standards, which require extensive testing of biopharmaceutical products, contributing to the demand for testing services. North American companies and research institutions often lead in the development and adoption of innovative testing technologies. This emphasis on innovation and continuous improvement helps maintain the region's leadership in biological safety testing. The region has access to a highly skilled and educated workforce with expertise in biotechnology, biochemistry,



microbiology, and related fields, which is crucial for conducting complex biological safety tests.

### Key Market Players

Charles River Laboratories

BSL Bioservice

Merck KGaA (MilliporeSigma)

Samsung Biologics

Sartorius AG

Eurofins Scientific

SGS Soci?t? G?n?rale de Surveillance SA

Thermo Fisher Scientific Inc.

BIOM?RIEUX

Lonza Group AG

### Report Scope:

In this report, the Global Biological Safety Testing Products and Services Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Biological Safety Testing Products and Services Market, By Product:

Reagents & Kits

Services

Instruments

## Biological Safety Testing Products and Services Market, By Application:

Vaccines & Therapeutics

Gene Therapy

Monoclonal Antibodies

Recombinant Protein

Blood & Blood-based Products

Tissue & Tissue-based Products

Stem Cells

## Biological Safety Testing Products and Services Market, By Test Type:

Endotoxin Tests

Sterility Tests

Cell Line Authentication & Characterization Tests

Bioburden Tests

Adventitious Agent Detection Tests

Residual Host Contamination Detection Tests

Others

## Biological Safety Testing Products and Services Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

### Competitive Landscape

**Company Profiles:** Detailed analysis of the major companies present in the Global Biological Safety Testing Products And Services Market.

### Available Customizations:

Global Biological Safety Testing Products and Services Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

### Company Information

Detailed analysis and profiling of additional market players (up to five).

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