

Biological Safety Testing Market Report by Product and Services (Kits and Reagents, Instruments, Services), Test Type (Endotoxin Tests, Sterility Tests, Cell Line Authentication and Characterization Tests, Bioburden Tests, Residual Host Contaminant Detection Tests, Adventitious Agent Detection Tests, and Others), Application (Vaccine Development, Blood Products Testing, Cellular and Gene Therapy, Tissue and Tissue-related Products Testing, Stem Cell Research), and Region 2023-2028

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Abstracts

The global biological safety testing market size reached US\$ 4.0 Billion in 2022. Looking forward, IMARC Group expects the market to reach US\$ 8.0 Billion by 2028, exhibiting a growth rate (CAGR) of 12.25% during 2022-2028. The expansion of the pharmaceutical and biotechnology sectors, the impact of the COVID-19 pandemic, and the rising emphasis on regulatory compliance and safety standards are some of the major factors propelling the market.

Biological safety testing is the ongoing process of evaluating the safety and potential risks associated with biological products, substances, or materials, including pharmaceuticals, vaccines, and medical devices. This assessment encompasses a range of activities, such as assessing the potential for contamination by microorganisms, viruses, or other biological agents, as well as examining the toxicity and potential adverse effects of these products on humans, animals, or the environment. It is a critical aspect of ensuring that biologically derived products meet

regulatory standards and pose minimal risks to public health and safety. This continuous testing process involves rigorous analysis and monitoring to guarantee product safety throughout its lifecycle.

The global biological safety testing industry is experiencing robust growth driven by the expanding pharmaceutical and biotechnology sectors and the increasing demand for stringent safety assessments for their products. As these industries continue to innovate and develop new drugs, vaccines, and biologics, the need for comprehensive biological safety testing has intensified to ensure product efficacy and safety for consumers, creating a positive outlook for market expansion. Additionally, the COVID-19 pandemic has accentuated the importance of vaccines and therapeutic treatments, further fueling the demand for biological safety testing services. Moreover, regulatory bodies worldwide are increasingly emphasizing the need for rigorous safety evaluations, which is contributing to the market's growth. Furthermore, the growing awareness of product quality and safety among consumers combined with the emerging trend toward personalized medicine and the development of advanced therapies, such as gene and cell therapies, necessitates specialized safety testing protocols, thereby aiding in market expansion.

Biological Safety Testing Market Trends/Drivers:

Expanding pharmaceutical and biotechnology sectors

The pharmaceutical and biotechnology industries are expanding due to increased investments in research and development. These sectors lead in developing drugs, biologics, and vaccines for various healthcare needs, including complex diseases. Consequently, the demand for stringent safety assessments has risen, with biological safety testing being vital in ensuring patient safety. It involves thorough evaluations for contaminants such as viruses, microbes, and endotoxins, guaranteeing compliance with regulatory and safety standards. Concurrently, the evolving nature of diseases and the continuous innovation in products maintain a high demand for safety testing, including specialized assessments for emerging therapies including gene and cell therapies, contributing significantly to the market's growth.

Impact of the COVID-19 pandemic

The COVID-19 pandemic has significantly impacted the industry by accelerating the development and deployment of vaccines and treatments. This has emphasized the crucial role of rigorous safety testing. In addition to this, governments and regulatory authorities globally have intensified their scrutiny of these products, leading to a surge in

demand for various testing services, including vaccine safety assessments, virus detection assays, and quality control measures for COVID-19 diagnostics and treatments. Apart from this, the pandemic has reshaped the industry's focus, highlighting the need for preparedness in the face of future health crises, thereby sustaining the growth of the market.

Rising emphasis on regulatory compliance

Global regulatory bodies are tightening oversight of biopharmaceutical products, emphasizing patient safety and product quality. These regulations mandate comprehensive safety evaluations, making biological safety testing integral to drug approvals. Pharmaceutical and biotech companies must rigorously adhere to evolving standards to gain product approval and market access, fueling demand for testing services and reinforcing the importance of biological safety testing in compliance. Furthermore, increasingly complex regulatory requirements, especially for advanced therapies like gene and cell therapies, highlight the need for specialized testing. This sustains market growth as specialized assessments adapt to the unique characteristics of these therapies, ensuring their safety and efficacy and meeting evolving regulatory demands.

Biological Safety Testing Industry Segmentation:

IMARC Group provides an analysis of the key trends in each segment of the market report, along with forecasts at the global, regional and country levels from 2023-2028. Our report has categorized the market based on product and services, test type and application.

Breakup by Product and Services:

Kits and Reagents

Instruments

Services

Kits and reagents account for the majority of the market share

The report has provided a detailed breakup and analysis of the market based on the product and services. This includes kits and reagents, instruments, and services. According to the report, kits and reagents represented the largest segment.

The increasing trend towards decentralized testing and point-of-care (POC) diagnostics

driving the need for user-friendly and portable testing kits represents one of the prime factors fueling the demand for biological safety testing. These kits enable healthcare professionals to perform safety assessments quickly and efficiently, especially in resource-limited settings. In confluence with this, the expansion of research and development activities in the life sciences, including genomics, proteomics, and cell culture, necessitates a continuous supply of high-quality testing reagents and kits for various applications, spurring market growth. Furthermore, the growing focus on ensuring product quality and safety in the food and beverage (F&B) industry, where biological contaminants can pose significant risks, is boosting demand for testing kits and reagents for microbiological analysis, thereby aiding in market expansion.

Breakup by Test Type:

Endotoxin Tests

Sterility Tests

Cell Line Authentication and Characterization Tests

Bioburden Tests

Residual Host Contaminant Detection Tests

Adventitious Agent Detection Tests

Others

Endotoxin tests hold the largest share in the market

A detailed breakup and analysis of the market based on the test type have also been provided in the report. This includes endotoxin, sterility, cell line authentication and characterization, bioburden, residual host and contaminant detection, adventitious agent detection tests, and others. According to the report, endotoxin tests accounted for the largest market share.

The rising demand for endotoxin tests primarily propelled by the critical need to ensure the safety and efficacy of medical devices and pharmaceutical products is strengthening the global biological safety testing market. Endotoxins, which are toxic substances present in the cell walls of Gram-negative bacteria, can lead to severe health complications when introduced into the human body. The increasing complexity and diversity of medical devices, including implants and drug delivery systems, necessitate stringent testing for endotoxins to mitigate potential risks to patients. Furthermore, the rising focus on personalized medicine and biopharmaceuticals, such as gene therapies and monoclonal antibodies, requires meticulous endotoxin testing to guarantee the purity and safety of these advanced therapies, strengthening the market. Besides this,

regulatory agencies worldwide mandate compliance with strict endotoxin limits, reinforcing the demand for accurate and reliable endotoxin tests in pharmaceutical manufacturing and healthcare settings, thereby bolstering the market growth.

Breakup by Application:

- Vaccine Development
- Blood Products Testing
- Cellular and Gene Therapy
- Tissue and Tissue-related Products Testing
- Stem Cell Research

Vaccine development dominates the market

The report has provided a detailed breakup and analysis of the market based on the application. This includes vaccine development, blood product testing, cellular and gene therapy, tissue and tissue-related product testing, and stem cell research. According to the report, vaccine development represented the largest segment.

The demand for biological safety testing in vaccine development is primarily propelled by the urgent global need for safe and effective vaccines. As the world faces various infectious diseases and viral outbreaks, including the COVID-19 pandemic, there is an unprecedented focus on vaccine development. Regulatory authorities require comprehensive safety assessments to ensure that vaccines are not only effective but also free from harmful contaminants. Biological safety testing plays a critical role in this process, involving the evaluation of vaccine candidates for potential viral and microbial contaminants, ensuring the absence of endotoxins, and assessing their overall safety for human use. Moreover, the emergence of novel vaccine technologies, such as mRNA-based vaccines, necessitates specialized safety evaluations, contributing to the growing demand for biological safety testing services. This heightened emphasis on vaccine safety underscores the crucial role played by such testing in safeguarding public health on a global scale.

Breakup by Region:

- North America
- United States
- Canada
- Asia-Pacific

China
Japan
India
South Korea
Australia
Indonesia
Others
Europe
Germany
France
United Kingdom
Italy
Spain
Russia
Others
Latin America
Brazil
Mexico
Others
Middle East and Africa

North America exhibits a clear dominance, accounting for the largest biological safety testing market share

The market research report has also provided a comprehensive analysis of all the major regional markets, which include North America (the United States and Canada); Asia Pacific (China, Japan, India, South Korea, Australia, Indonesia, and others); Europe (Germany, France, the United Kingdom, Italy, Spain, Russia, and others); Latin America (Brazil, Mexico, and others); and the Middle East and Africa. According to the report, North America accounted for the largest market share.

North America boasts a robust pharmaceutical and biotechnology industry, with a strong emphasis on research and development. The constant innovation and introduction of new drugs, biologics, and medical devices necessitate rigorous safety evaluations, driving the demand for biological safety testing services. In addition to this, the region's proactive regulatory environment, governed by stringent standards set by the FDA and other regulatory bodies, mandates comprehensive safety assessments, further propelling market growth. Moreover, the ongoing efforts to combat public health threats, such as the COVID-19 pandemic, have heightened the demand for vaccine

development and testing, particularly in North America, where numerous pharmaceutical companies and research institutions are actively involved in vaccine research and production. These factors, combined with the region's advanced healthcare infrastructure and the increasing awareness of product quality and safety, continue to fuel the expansion of the North America biological safety testing market.

Competitive Landscape:

The global biological safety testing market is characterized by intense competition among key players, driven by the industry's critical role in ensuring the safety and quality of pharmaceuticals, biologics, and medical devices. Prominent companies in this landscape engage in various strategies to maintain their market positions, such as mergers, acquisitions, and collaborations to expand their service portfolios and geographic reach. Furthermore, investments in research and development to introduce innovative testing technologies and methodologies are common strategies, allowing companies to stay at the forefront of industry trends. The increasing focus on personalized medicine and advanced therapies, such as gene and cell therapies, presents growth opportunities for firms specializing in specialized safety testing services. Overall, the competitive landscape of the global biological safety testing market is marked by a dynamic interplay of established players.

The market research report has provided a comprehensive analysis of the competitive landscape. Detailed profiles of all major companies have also been provided. Some of the key players in the market include:

Avance Biosciences
Charles River Laboratories
Creative Biogene
Eurofins Scientific
Lonza Group AG
Maravai LifeSciences
Pace Analytical Services Inc.
Pacific BioLabs
Sartorius AG
SGS SA
Virusure GmbH (Asahi Kasei Corporation)
WuXi Biologics

(Please note that this is only a partial list of the key players, and the complete list is provided in the report.)

Recent Developments:

In May 2022, Charles River Laboratories collaborated with a drug discovery technology firm on Logica which is an artificial intelligence (AI) tool specially designed to boost the development of new treatments.

In May 2022, Avance Biosciences announced the completion of their newly acquired 26,000 square feet of laboratory space. This expansion will allow Avance to offer a wider range of protein and cell-based assay services to their biopharma and CDMO clients. The new facilities will focus on protein analysis services, including ELISA assays, protein characterization, and immunoassays.

In September 2023, Pace® Analytical Services announced a new PFAS test method that provides reliable results faster and at a lower cost. The method, ASTM D8421/EPA 8327, uses isotope dilution and LC/MS/MS to analyze for up to 44 PFAS compounds in aqueous and solid samples. This method offers advantages such as faster delivery of results, reduced sample size, and reliable quantification.

Key Questions Answered in This Report:

How has the global biological safety testing market performed so far, and how will it perform in the coming years?

What are the drivers, restraints, and opportunities in the global biological safety testing market?

What is the impact of each driver, restraint, and opportunity on the global biological safety testing market?

What are the key regional markets?

Which countries represent the most attractive biological safety testing market?

What is the breakup of the market based on the product and services?

Which is the most attractive product and services in the biological safety testing market?

What is the breakup of the market based on the test type?

Which is the most attractive test type in the biological safety testing market?

What is the breakup of the market based on the application?

Which is the most attractive application in the biological safety testing market?

What is the competitive structure of the global biological safety testing market?

Who are the key players/companies in the global biological safety testing market?

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