

# Biological Safety Testing Market to Reach \$12.98 Billion by 2032, Driven by Rising Demand for Biologics and Biosimilars

*The global biological safety testing market size was USD 4.32 billion in 2022 and is expected to reach USD 12.98 billion in 2032, and register a CAGR of 13%.*

NEW YORK CITY, NY, UNITED STATES, May 5, 2023 /EINPresswire.com/ -- The [Biological Safety Testing Market](#) size was USD 4.32 billion in 2022 and is

expected to reach USD 12.98 billion by 2032, with a CAGR of 13%. The growth in the pharmaceutical and biotechnology sectors, especially biologics and biosimilars, is the primary driving factor behind the increase in revenue. The increasing prevalence of chronic diseases and cancer is also contributing to the demand for biological safety testing. To guarantee the safety and effectiveness of biologics and biosimilars, biological safety testing is a crucial part of the medication development process.

The market's expansion is further supported by the rising need for innovative technologies for biological safety testing. Manufacturers are continuously developing new technologies to increase the sensitivity and accuracy of biological safety testing while also saving time and money. Strict regulatory requirements for biological safety testing established by agencies such as the FDA, EMA, and PMDA are also driving the demand for biological safety testing at all stages of drug development.

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Moreover, the market's growth is being fueled by increasing demand for cell and gene therapies as potential treatment options for various diseases. However, the high cost of biological safety testing due to the use of innovative technologies and strict regulatory requirements could impede revenue growth. Furthermore, a scarcity of qualified individuals in the field of biological safety testing could limit the market's growth to some extent.



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## Segments Covered in the Report –

The biological safety testing market offers a range of products and services, including instruments, kits and reagents, and services. Instruments and equipment are widely used for conducting biological safety tests in laboratories. Kits and reagents are used to measure the presence of contaminants, toxins, and other agents in samples. Services include testing, validation, and consulting services for companies in the pharmaceutical, biotechnology, and medical device industries.

The market for biological safety testing is also segmented by test type, including endotoxin tests, sterility tests, cell line authentication and characterization tests, bioburden tests, adventitious agent detection tests, and others. Endotoxin tests are used to detect and quantify bacterial endotoxins, which can cause fever and sepsis in humans. Sterility tests are used to determine if a product or sample is free of microorganisms. Cell line authentication and characterization tests are used to ensure that cell lines used in research are accurate and free of contamination. Bioburden tests are used to measure the total number of viable microorganisms in a sample, and adventitious agent detection tests are used to detect the presence of viruses, bacteria, fungi, and other contaminants.

The biological safety testing market is also segmented by application, including blood and blood products, vaccines and therapeutics, gene therapy, tissue and tissue products, stem cell products, and others. Blood and blood products are tested to ensure that they are free of contaminants and diseases before being used for transfusions. Vaccines and therapeutics are tested to ensure that they are safe and effective before being approved for use in humans. Gene therapy products are tested to ensure that they are safe and effective and to monitor any adverse reactions. Tissue and tissue products are tested to ensure that they are free of diseases and contaminants before being used in transplantation procedures. Stem cell products are tested to ensure that they are safe and effective before being used in regenerative medicine.

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### Strategic development:

Thermo Fisher Scientific announced in 2021 that it acquired PPD, Inc., a global contract research organization (CRO) that offers a wide range of drug development services, including biological safety testing. The acquisition aimed to enhance Thermo Fisher's offerings in the CRO market and strengthen its position in the biological safety testing market.

In the same year, Charles River Laboratories International, Inc. expanded its biologics testing capabilities by establishing a new laboratory in Shanghai, China. The new facility offers a complete range of biologics testing services, which includes biological safety testing.

In 2020, Merck KGaA disclosed the addition of a new laboratory in Carlsbad, California, which expanded its global BioReliance® viral and gene therapy testing capabilities. The laboratory provides a comprehensive range of biological safety testing services for viral and gene therapy products.

#### Competitive Landscape:

The global biological safety testing market is projected to see substantial growth in the coming years as the demand for biologics and biosimilars continues to rise. The development of these complex molecules in the pharmaceutical and biotechnology sectors has created a pressing need for effective safety testing to ensure their efficacy and safety before they are released to the market. The biological safety testing market is relatively concentrated, with a few major players holding a significant share of the market.

Merck KGaA, Thermo Fisher Scientific Inc., Charles River Laboratories International, Inc., Lonza Group AG, SGS SA, WuXi AppTec, Eurofins Scientific SE, Cytiva, bioMérieux SA, and Sartorius AG are among the key players included in the global biological safety testing market report. These companies offer a wide range of services in the biological safety testing market, including endotoxin tests, sterility tests, cell line authentication and characterization tests, bioburden tests, adventitious agent detection tests, and others.

To expand their offerings and strengthen their positions in the market, many of these companies have pursued mergers and acquisitions, as well as the opening of new testing facilities. For example, Thermo Fisher Scientific Inc. recently acquired PPD, Inc., a contract research organization that offers biological safety testing services, while Charles River Laboratories International, Inc. expanded its biologics testing capabilities with the opening of a new laboratory in Shanghai, China.

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Overall, the biological safety testing market plays a crucial role in ensuring the safety and efficacy of pharmaceuticals, biologics, and medical devices. The demand for biological safety testing is driven by the growing need for advanced healthcare products and services, rising incidences of chronic diseases, and increasing investments in research and development.

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