

# **Global Biological Safety Testing Products and Services Market Size Study, By Product (Reagents & Kits, Instruments, Services), By Application (Vaccines & Therapeutics, Gene Therapy, Blood & Blood-based Products, Tissue & Tissue-based Products, Stem Cells), By Test Type (Endotoxin Tests, Sterility Tests, Cell Line Authentication, Bioburden Tests, Adventitious Agent Detection), and Regional Forecasts 2022-2032**

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## **Abstracts**

The global biological safety testing products and services market was valued at approximately USD 4.57 billion in 2023 and is anticipated to expand at a CAGR of 10.7% over the forecast period 2024-2032. Increasing demand for biologics, vaccines, and gene therapy products has propelled the need for stringent safety evaluations, fostering the adoption of biological safety testing solutions. As regulatory authorities impose rigorous safety standards for pharmaceutical and biopharmaceutical products, the demand for innovative testing methodologies is increasing.

Biological safety testing ensures that pharmaceutical and biologics manufacturing processes remain free from contamination. Rising government funding and private investments in drug development, coupled with the expansion of biotechnology and pharmaceutical industries, have further boosted the adoption of advanced biological safety testing methods. Companies are prioritizing regulatory compliance to mitigate risks associated with microbial contamination, residual host-cell proteins, and endotoxin levels. For instance, in 2023, Charles River Laboratories expanded its safety testing capabilities with enhanced in vitro testing solutions, catering to the evolving needs of

biopharmaceutical developers.

Furthermore, the growing focus on personalized medicine and gene therapies has necessitated advanced biological safety testing protocols. The rise in cell-based therapies and monoclonal antibodies (mAbs) has heightened concerns regarding product integrity, sterility, and safety. Regulatory bodies such as the FDA, EMA, and WHO have implemented stringent guidelines requiring robust biological safety testing at various stages of development and manufacturing. Technological advancements, including CRISPR-based testing methods and next-generation sequencing (NGS), have further enhanced testing accuracy and efficiency.

Despite these positive trends, high costs associated with biological safety testing instruments and services remain a challenge for small and mid-sized biopharmaceutical firms. However, ongoing technological advancements, the emergence of AI-driven biosafety solutions, and the increasing integration of automated testing platforms are expected to reduce operational costs over time. Additionally, market players are focusing on expanding their service portfolios through acquisitions and strategic partnerships. In January 2023, Thermo Fisher Scientific acquired a major stake in a biosafety testing service provider to enhance its global presence and strengthen its regulatory compliance capabilities.

Major Market Players Included in this Report Are:

Charles River Laboratories

Thermo Fisher Scientific Inc.

Merck KGaA (MilliporeSigma)

Lonza

Eurofins Scientific

SGS Société Générale de Surveillance SA

Samsung Biologics

Sartorius AG

BIOM?RIEUX

BSL Bioservice

FUJIFILM Diosynth Biotechnologies

Nelson Labs

Wuxi AppTec

Cytovance Biologics

StemExpress

The Detailed Segments and Sub-segments of the Market are Explained Below:

By Product:

Reagents & Kits

Instruments

Services

By Application:

Vaccines & Therapeutics

Vaccines

Monoclonal Antibodies

Recombinant Proteins

Blood & Blood-based Products

Gene Therapy

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:

North America

U.S.

Canada

Europe

UK

Germany

France

Italy

Spain

Denmark

Sweden

Norway

#### Asia Pacific

Japan

China

India

South Korea

Australia

Thailand

#### Latin America

Brazil

Mexico

Argentina

#### Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

Years considered for the study are as follows:

Historical Year – 2022

Base Year – 2023

Forecast Period – 2024 to 2032

Key Takeaways:

Market Estimates & Forecast for 10 years (2022-2032)

Annualized revenues & regional-level analysis for each market segment

Geographical landscape analysis with country-level market insights

Competitive landscape with information on major market players

Key business strategies & investment recommendations

Competitive structure & demand-supply analysis

Comprehensive regulatory framework overview impacting market growth

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