

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 Al-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

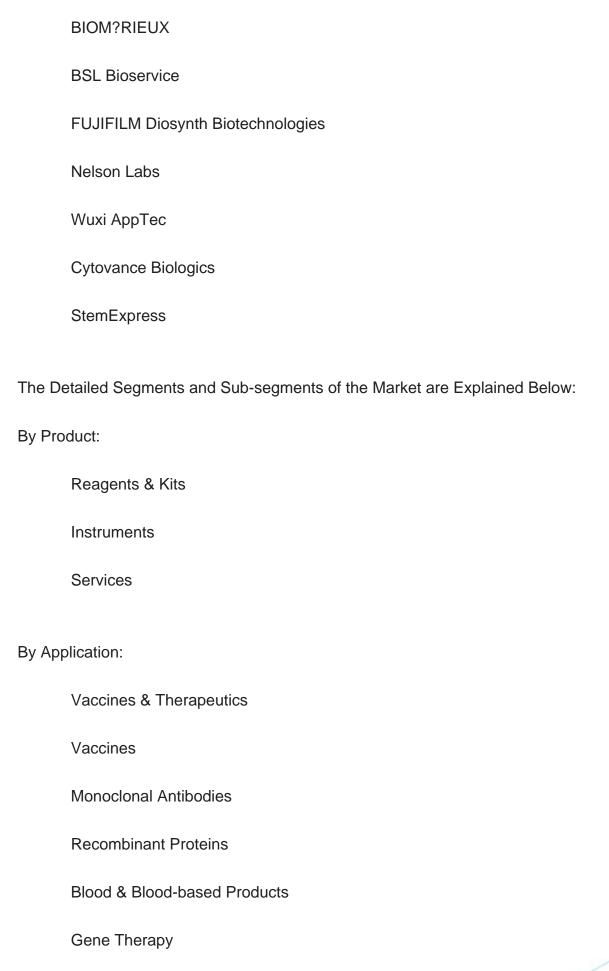
**Eurofins Scientific** 

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

Samsung Biologics

Sartorius AG







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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