

Global Sterility Testing Service Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global Sterility Testing Service market size is predicted to grow from US\$ 344 million in 2025 to US\$ 558 million in 2032; it is expected to grow at a CAGR of 7.0% from 2026 to 2032.

Sterility Testing Service refers to outsourced testing services provided by third-party laboratories or quality control organizations. These services involve testing for microbial contamination and verifying the sterility of sterile pharmaceuticals, medical devices, biological products, and cell and gene therapy products, based on pharmacopoeias and regulatory guidelines (such as sterility testing methods, culture medium methods, and rapid microbiological methods). The core objective is to confirm that the product is free of viable microorganisms after manufacturing and packaging, thereby meeting regulatory requirements for market approval, batch release, and ongoing quality monitoring.

With the rapid growth of biopharmaceuticals, cell and gene therapy (CGT), vaccines, and sterile injectables, the demand for sterility testing is continuously increasing. In particular, the extremely high release speed requirements for small-batch, high-value products (such as CAR-T and mRNA vaccines) are driving the industry to upgrade from the traditional 14-day culture method to rapid microbial detection (RMM) and automated systems. To reduce CAPEX and compliance risks, pharmaceutical companies are increasingly outsourcing sterility testing to GMP-certified professional laboratories.

Simultaneously, stricter regulations and the increasing complexity of global supply chains are strengthening the importance of third-party testing. Regulatory agencies such as the FDA and EMA are imposing higher requirements on sterility assurance levels (SAL), environmental monitoring, and batch release, prompting companies to

establish continuous quality and global multi-site testing networks. This is driving the accelerated expansion of large CROs/CDMOs and specialized microbial testing institutions, resulting in a trend of increasing industry concentration and technological upgrades.

LPI (LP Information)' newest research report, the 'Sterility Testing Service Industry Forecast' looks at past sales and reviews total world Sterility Testing Service sales in 2025, providing a comprehensive analysis by region and market sector of projected Sterility Testing Service sales for 2026 through 2032. With Sterility Testing Service sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Sterility Testing Service industry.

This Insight Report provides a comprehensive analysis of the global Sterility Testing Service landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Sterility Testing Service portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Sterility Testing Service market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Sterility Testing Service and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Sterility Testing Service.

This report presents a comprehensive overview, market shares, and growth opportunities of Sterility Testing Service market by product type, application, key players and key regions and countries.

Segmentation by Type:

Direct Inoculation

Membrane Filtration

Others

Segmentation by Stage:

Preclinical / Process Development Testing

Clinical Trial Batch Testing

Commercial Batch Release Testing

Post-Market Surveillance Testing

Segmentation by Product:

Sterile Pharmaceuticals & Injectables

Biologics & Vaccines

Cell & Gene Therapy Products

Others

Segmentation by Application:

Medical

Pharmaceutical

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Sigma-Aldrich

Charles River Laboratories

Nova Biologicals

Eurofins

SGS

Nelson Labs

Sartorius

Lucideon

Pacific BioLabs

Gillson Sciences

Viroxy

Contract Pharma

CPT Labs

Sartorius

IDEXX BioAnalytics

Lucideon

Pacific BioLabs

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