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Pharmaceutical Sterility Testing Market Research Report—Global Forecast till 2032

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Description:

Global Pharmaceutical Sterility Testing Market Overview

Pharmaceutical Sterility Testing Market Size was valued at USD 0.6 billion in 2022. The pharmaceutical sterility testing market industry is projected to grow from USD 0.636 Billion in 2023 to USD 1.0223 billion by 2032, exhibiting a compound annual growth rate (CAGR) of 6.10% during the forecast period (2023 - 2032). Government investments in the healthcare sector, expanding R&D activity, an increase in new drugs being introduced, and a growing emphasis on quality and sterility are major market drivers anticipated to propel the market.

Pharmaceutical Sterility Testing Market Overview

Source: Secondary Research, Primary Research, MRFR Database and Analyst Review

Pharmaceutical Sterility Testing Market Trends

- **Growing Pharmaceutical Companies & the Launch of More Drugs Will Accelerate Market Growth**

The development of pharmaceutical companies, the launch of more drugs, the rising prevalence of chronic diseases, and government support for the pharmaceutical industry are the main drivers of market CAGR for pharmaceutical sterility testing. For instance, in September 2016, Merck KGaA unveiled Steritest Symbio Pump system accessories. The attachments enable quicker and safer sterility verification in any environment. The Centers for Disease Control and Prevention (CDC) estimate that in 2012, 117 million Americans had one or more chronic illnesses. The growth of the market is being aided by factors such as rising healthcare spending, an increase in pharmaceutical outsourcing, and technological advancements in direct immunization, membrane filtration, and quick sterility testing such as bacterial endotoxin testing.

Over time, there have been more approvals and launches of novel medications. Around 53 innovative medications were authorized as new molecular entities under New Drug Applications (NDAs) by the US Food and Drug Administration (USFDA) Centre for Drug Evaluation and Research in 2020. The Pharma and Annual Review 2021 study states that 1,324 new medications were introduced to the market worldwide in 2020. The use of pharmaceutical sterility testing is increasing as a result of these new product launches, and growth in the market for pharmaceutical sterility testing is anticipated over the coming years. Additionally, pharmaceutical sterility testing is carried out at every stage of production in the pharmaceutical and biopharmaceutical industries to lessen the likelihood of product contamination. The growth of the biotechnology and pharmaceutical industries will consequently lead to a sharp rise in the overall need for pharmaceutical sterility testing in the coming years.

The pharmaceutical sterility testing industry expanded as a result of more drugs being introduced to the market and increased R&D expenditures. In order to prevent product contamination and ensure that the pharmaceuticals are free of any live microorganisms, sterility is a crucial step in the manufacturing process. The market is being driven by a greater emphasis on quality and sterility, increased production and launch of drugs and medical devices, rising R&D activities in the pharmaceutical industry, and all of these factors together. Thus, driving the pharmaceutical sterility testing market revenue.

Pharmaceutical Sterility Testing Market Segment Insights

Pharmaceutical Sterility Testing Sample Insights

The pharmaceutical sterility testing market segmentation, based on sample includes Sterile Drugs, Medical Devices, and Biologics. The sterile drugs segment dominated the market. All sorts of bacteria should be eliminated from sterile medications, and they should also be isotonic. Parenteral

preparations and ophthalmic preparations are examples of sterile dosage forms.

Pharmaceutical Sterility Testing Product Type Insights

The pharmaceutical sterility testing market segmentation, based on product type, includes Instruments, Kits & Reagents, and Services. The kits & reagents category generated the most income. This increase is attributable to the accessibility of several items that aid in reducing the possibility of false negative and false positive outcomes. Another one of them is sterility testing pumps, which can be easily integrated into any testing environment and aid in maximizing safety and streamlining productivity. Over the anticipated period, segmental growth will be aided by the rising demand for comparable products.

Pharmaceutical Sterility Testing Type Insights

The pharmaceutical sterility testing market segmentation, based on type, includes In-house and Outsourcing. The outsourcing category generated the most income. An appealing option is to outsource sterility testing. Since they do not have the resources to conduct reliable sterility testing in-house, small and medium-sized pharmaceutical and medical device firms would rather contract out these services to comply with FDA regulations. Additionally, outsourcing helps pharmaceutical and medical device businesses save money and time because they don't have to spend money on new equipment or hire and train personnel.

Figure 1: Pharmaceutical Sterility Testing Market, by Type, 2022 & 2032 (USD billion)

Pharmaceutical Sterility Testing Market, by Type, 2022 & 2032

Source: Secondary Research, Primary Research, MRFR Database and Analyst Review

Pharmaceutical Sterility Testing Test Type Insights

The pharmaceutical sterility testing market segmentation, based on test type, includes Sterility Testing, Bioburden Testing, and Bacterial Endotoxin Testing. The bacterial endotoxin testing category generated the most income. For all medications delivered parenterally, bacterial endotoxin testing is necessary. Medical items like implants are also tested using these procedures. The sector market is expanding due to the rising demand for parenteral medications and implants.

Pharmaceutical Sterility Testing End User Insights

The pharmaceutical sterility testing market segmentation, based on end user, includes Compounding Pharmacies, Medical Devices Companies, and Pharmaceutical Companies. The pharmaceutical companies category generated the most income. Since most of these medications are taken orally by patients, pharmaceutical companies must perform sterility testing to ensure product safety, particularly for oral dosage forms. The needed sterility tests for a particular drug are detailed in each country's pharmacopeia according to established norms.

Pharmaceutical Sterility Testing Regional Insights

By Region, the study provides the market insights into North America, Europe, Asia-Pacific and Rest of the World. The North American pharmaceutical sterility testing market area will dominate this market. The expansion of the pharmaceutical businesses in the United States and Canada might explain this. The presence of numerous prominent market players in this area is anticipated to substantially impact the market's expansion. The region's market is expanding as a result of strict regulatory requirements for the sterility testing of medicines and medical equipment.

Further, the major countries studied in the market report are The U.S., Canada, Germany, France, the UK, Italy, Spain, China, Japan, India, Australia, South Korea, and Brazil.

Figure 2: PHARMACEUTICAL STERILITY TESTING MARKET SHARE BY REGION 2022 (%)

PHARMACEUTICAL STERILITY TESTING MARKET SHARE BY REGION 2022

Source: Secondary Research, Primary Research, MRFR Database and Analyst Review

Europe pharmaceutical sterility testing market accounts for the second-largest market share due to elements including strict sterilization laws in the pharmaceutical and medical sectors, the rise in chronic disease prevalence, and the rising biotechnology and healthcare sectors. Further, the German pharmaceutical sterility testing market held the largest market share, and the UK pharmaceutical sterility testing market was the fastest growing market in the European region.

The Asia-Pacific Pharmaceutical sterility testing Market is expected to grow at the fastest CAGR from 2023 to 2032. This is a result of emerging countries increasingly harmonizing their regulatory norms with ICH standards. Additionally, several of the region's growing nations are adopting various steps to expand the domestic pharmaceutical industry and are enticing corporations to establish operations there (collaborations that promote outsourcing activities). Such efforts are probably going to help with regional development. Moreover, China's pharmaceutical sterility testing market held the largest market share, and the Indian pharmaceutical sterility testing market was the fastest growing market in the Asia-Pacific region.

Pharmaceutical sterility testing Key Market Players & Competitive Insights

Leading market players are investing heavily in research and development in order to expand their

product lines, which will help the pharmaceutical sterility testing market, grow even more. Market participants are also undertaking a variety of strategic activities to expand their footprint, with important market developments including new product launches, contractual agreements, mergers and acquisitions, higher investments, and collaboration with other organizations. To expand and survive in a more competitive and rising market climate, pharmaceutical sterility testing industry must offer cost-effective items.

Manufacturing locally to minimize operational costs is one of the key business tactics used by manufacturers in the pharmaceutical sterility testing industry to benefit clients and increase the market sector. In recent years, the pharmaceutical sterility testing industry has offered some of the most significant advantages to medicine. Major players in the pharmaceutical sterility testing market attempting to increase market demand by investing in research and development operations include Merck KGaA (Germany), Rapid Micro Biosystems (US), Sartorius AG (Germany), Solvias AG (Switzerland), SGS SA (Switzerland), Boston Analytical (US), bioMérieux Inc. (France), Charles River Laboratories International Inc. (US), Thermo Fisher Scientific Inc. (US), Pace Analytical Services LLC (US) and Toxikon Inc. (US).

Charles River Laboratories, Inc offers services for clinical trials and drug development. The business provides testing and development services for vaccines, biosimilars, and medications for cancer, heart disease, bone conditions, endocrine disorders, and other diseases. Charles River Laboratories offers its services throughout the world. In September 2019, in order to test for endotoxins, Charles River Laboratories introduced the EndoScan-V software platform and the Celsis automated detection system.

The Merck Group, also known as Merck, is a multinational science and technology firm with its headquarters in Darmstadt with operations in 66 different countries. Around 250 businesses make up the group, with Merck KGaA in Germany serving as its centerpiece. Three business segments make up the company: healthcare, life sciences, and electronics. As one of the biggest pharmaceutical corporations in the world and the oldest continuously operational chemical and pharmaceutical company, Merck was established in 1668.

Key Companies in the pharmaceutical sterility testing market include

- Merck KGaA (Germany)
- Rapid Micro Biosystems (US)
- Sartorius AG (Germany)
- Solvias AG (Switzerland)
- SGS SA (Switzerland)
- Boston Analytical (US)
- bioMérieux Inc. (France)
- Charles River Laboratories International Inc. (US)
- Thermo Fisher Scientific Inc. (US)
- Pace Analytical Services LLC (US)
- Toxikon Inc. (US)

Pharmaceutical Sterility Testing Industry Developments

June 2022:*In order to conduct on-site sterility testing for its GMP batches, Berkshire Sterile Manufacturing opened a sterility testing isolator. The business provides sterile filling of injectable medications, the majority of which are undergoing clinical studies or have a little commercial demand.*

August 2020:*Emerson Resources Inc. was purchased by Pace Analytical Services, LLC. Emerson Resources Inc. is a contract production and manufacturing organization (CDMO) that specializes in producing clinical trial materials and developing drug forms for pharmaceutical companies. This purchase benefits pharmaceutical and biopharmaceutical clients by processing materials for phase 2 clinical trial research and development.*

Pharmaceutical Sterility Testing Market Segmentation

Pharmaceutical Sterility Testing Sample Outlook

- Sterile Drugs
- Medical Devices
- Biologics

Pharmaceutical Sterility Testing Product Type Outlook

- Instruments
- Kits & Reagents
- Services

Pharmaceutical Sterility Testing Type Outlook

- In-house
- Outsourcing

Pharmaceutical Sterility Testing Test Type Outlook

- Sterility Testing
- Bioburden Testing
- Bacterial Endotoxin Testing

Pharmaceutical Sterility Testing End User Outlook

- Compounding Pharmacies
- Medical Devices Companies
- Pharmaceutical Companies

Pharmaceutical sterility testing Regional Outlook

- North America
- US
- Canada
- Europe
- Germany
- France
- UK
- Italy
- Spain
- Rest of Europe
- Asia-Pacific
 - China
 - Japan
 - India
 - Australia
 - South Korea
 - Australia
 - Rest of Asia-Pacific
- Rest of the World
 - Middle East
 - Africa

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