Biologics Safety Testing Market Assessment, By Product and Services [Consumables, Instruments, Services], By Test Type [Residual Host Contamination Detection Tests, Adventitious Agent Detection Tests, Bioburden Tests, Cell Line Authentication and Characterization Tests, Sterility Tests, Endotoxin Tests, Others], By Application [Vaccines and Therapeutics, Blood and Blood Based Products, Gene Therapy, Tissue and Tissue Based Products, Stem Cell], By End-user [Pharmaceutical and Biotechnology Companies, Clinical Research Organizations and Contract Development and Manufacturing Organizations, Academic and Research Institutes], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global biologics safety testing market is projected to witness a CAGR of 11.80% during the forecast period 2024-2031, growing from USD 4.01 billion in 2023 to USD 9.79 billion in 2031. This market is an important part of the biotechnology market and is driven by factors such as the increasing prevalence of chronic diseases, technological advancements, and increased investments and funding.

Testing for biologics safety is crucial to guarantee the effectiveness and safety of therapeutic biologics. Modern molecular techniques have been around for a while, yet laboratories still mostly use protocols from the 1970s for animal testing. A recent

change to guidelines urges the biopharmaceutical sector to transition to new standards in biologics quality control (QC), such as next-generation sequencing (NGS)-based tests, and to stop using animals. Monoclonal antibodies, vaccines, recombinant proteins, viral vectors, and cell and gene therapies are just a few of the many modalities that fall under the broad category of therapeutic biologics. Animals are still extensively utilized in biologics quality control testing even after there was a global agreement to reduce the use of animals in medication development. This agreement is represented in the 3R (replace, reduce, refine) philosophy and directives put in place in the United States and European Union. Animal-based operations come with a price tag and need weeks or even months to complete, in addition to ethical concerns.

Leading science and technology organization Merck finished the second phase of its new USD 31.41 million Biologics Testing Center expansion in China in November 2023, adding 1,500 square meters to the lab. These are Merck's first biosafety labs in this market, giving customers local access to a wide variety of testing services and cell line characterization from pre-clinical research to commercialization.

Increasing Prevalence of Chronic Diseases

The need for biologics testing is driven mostly by the rising incidence of chronic illnesses. Advanced treatment alternatives, especially biologics like monoclonal antibodies and other targeted medicines, are needed as chronic illnesses like diabetes, cancer, and autoimmune disorders grow increasingly prevalent. Extensive testing is frequently necessary to guarantee the safety and effectiveness of biologics across a range of patient groups. The increasing number of patients related to chronic diseases calls for improved biological testing capacities in order to facilitate the development of customized medicine strategies that address individual patient demands and eventually lead to better treatment results.

According to the British Heart Foundation Report 2024, more than 200 million people globally are living with coronary heart disease. Out of 200 million coronary heart patients, 110 million are men, and 90 million are women. As per the World Health Organization (WHO), in 2022, there were 20 million new cancer patients, and close to 9.7 million patients died due to cancer.

Rising Adoption of Advanced Analytics Solutions in Biologics Safety Testing and Clinical Trials

Healthcare leaders see a wide range of opportunities to improve patient care by bringing data from disparate sources together in a meaningful way. Healthcare professionals believe data-driven insights could help optimize treatment plans and care pathways, identify evidence-based practices, and reduce waiting lists for diagnostic and elective procedures. However, to deliver on these possibilities, healthcare leaders recognize they first need to get the foundations right. The foundation of seamless data integration can be done by improving the accuracy of patient data, improving drug efficacy in biologics testing, enhancing interoperability among different platforms and healthcare settings, and strengthening data security and privacy. Healthcare executives see several chances to enhance patient care via the integration of data from various sources. Healthcare practitioners think data-driven insights might assist in finding evidence-based treatments, streamline treatment plans and care pathways, and shorten waiting lists for elective and diagnostic procedures. Healthcare executives understand that, in order to fully realize these opportunities, they must first lay the necessary groundwork. Improving patient data accuracy, boosting platform and healthcare setting interoperability, and fortifying data security and privacy are the cornerstones of a smooth data integration process.

In 2024, Yotta Data Services Pvt Ltd. announced a partnership with Partex NV to improve healthcare services in drug discovery and patient care. The partnership will leverage Yotta's Shakti-Cloud platform, backed by Nvidia H100 GPU processing infrastructure, to enable Partex's AI-driven healthcare solutions. The collaboration intends to create AI-based solutions that will improve healthcare services' efficacy and efficiency, especially in the areas of patient care and drug development.

Residual Host Contamination Detection Tests Dominate the Market

Biologics safety testing can be divided into the following categories - residual host contamination detection tests, adventitious agent detection tests, bioburden tests, cell line authentication & characterization tests, sterility tests, endotoxin tests, and many others. Assays for detecting residual host contamination are crucial to the biopharmaceutical industry and testing for residual host cell DNA (HCDNA) is one area of particular importance. These tests aim to locate and quantify any host cell DNA that is still needed to produce biologics, such as therapeutic proteins and vaccines. These tests usually employ sensitive techniques, such as Polymerase Chain Reaction (PCR), to identify and measure any leftover DNA remains. Modern technologies enable the identification of even minute amounts, which is crucial for ensuring the safety of products. Tests for residual host contamination provide strong regulatory compliance, enhanced safety, and quality assurance, among other clinical benefits.

Pharmaceutical and Biotechnology Companies Dominate the Market

To guarantee the effectiveness and safety of biologics such as therapeutic proteins and vaccines, pharmaceutical and biotechnology businesses are essential to the safety testing process of biologics. Throughout the development process, these businesses oversee carrying out thorough evaluations that involve testing for toxins, leftover host cell proteins, and viral safety. Advanced testing procedures are necessary to address specific safety issues related to various biologics products because of the complexity and variety of biologics. For instance, Skan AG, a leader in cleanroom technology, decontamination procedures, and isolators for the aseptic manufacturing of biopharmaceuticals launched Claire Neo in June 2024. Claire Neo is a new line of safety cabinets designed to suit future laboratory standards in the pharmaceutical, medical, and biological sectors. Users may be as flexible as possible with the new safety cabinets. The manufacture in metric increments of 30 cm is the main emphasis of this new flexibility.

Future Market Scenario (2024-2031F)

- Integration of Bioinformatics and Data Analytics: Bioinformatics will enable the integration and analysis of large datasets generated during biologics safety testing. This will help identify trends, understand complex interactions, and ensure compliance with regulatory standards, ultimately enhancing the overall safety profile of biologic therapies.
- Introduction of Rapid Microbiological Methods: The development and implementation of rapid microbiological testing techniques will facilitate quicker detection of microbial contamination in biologics. These methods can provide results in real-time, which is crucial for maintaining the safety and quality of biologic products during manufacturing.
- NGS Will Become an Important Part of Biologics Testing: The adoption of NGS in safety testing will allow for comprehensive analysis of genetic material in biologics, enabling the detection of contaminants and residual host cell DNA with greater precision. This technology can significantly improve the reliability of safety assessments.

Key Player Landscape and Outlook

Key players in this sector, including Charles River Laboratories International, Inc., BSL BIOSERVICE Scientific Laboratories Munich GmbH, Merck KGaA, Thermo Fisher Scientific Inc., Sartorious AG, F.Hoffman-La Roche Ltd, Biomerieux SA, Eurofins Scientific SE, Lonza Group AG, Maravai LifeSciences Holdings, Inc. are actively enhancing their service offerings and expanding their technological capabilities to meet stringent regulatory standards and ensure the safety of biologics. Companies are also engaging in strategic acquisitions and partnerships to bolster their market positions and improve testing methodologies, thereby addressing the increasing demand for comprehensive safety evaluations in the biopharmaceutical industry.

SAMDI Tech, Inc., a provider of high-throughput screening (HTS) technologies, was acquired by Charles River Laboratories, Inc. in January 2023. By utilizing SAMDI Tech's technology to speed up the identification of viable drug candidates, this acquisition seeks to improve drug discovery procedures.

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