Biologics Development and Manufacturing Testing: Technologies and Global Markets

Market Research Report | 2023-02-17 | 123 pages | BCC Research

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Report description:

Description

Report Scope:

This report aims to provide a comprehensive study of the global market for biologics safety testing, both in terms of quantitative and qualitative data, to help develop business/growth strategies, assess the market landscape, analyze their position in the current marketplace, and make informed business decisions regarding biologics safety testing products and services. Biologics safety testing includes biosafety testing & characterization of raw materials, cell bank & virus seeds, unprocessed bulks/viral harvests, and drug substance/product.

This report segments the global biologics safety testing market by application, test application, testing technology, and region of operations. BCC Research analyses each market and its applications, regulatory environments, technology, market projections, and market share. Industry growth drivers, restraints, trends, and opportunities in the biological safety testing market are also discussed in detail. The report also provides information on the competitive landscape, elaborate company profiles, and the impact of COVID-19 on the biologics safety testing market.

Report Includes:

- 13 data tables and 16 additional tables
- An up-to-date review and analysis of the global markets for biological safety testing and related technologies
- Analyses of the global market trends, with market revenue data for 2019-2022, estimates for 2023, and projections of compound annual growth rates (CAGRs) through 2027
- Discussion of market dynamics that impact the growth for biologics development and manufacturing testing, clinical applications, safety regulations, industry structure, and penetration of technologies within the biotech industry

- Coverage of the technological, economic, and business considerations of global biological safety testing market, with analyses and growth forecasts through 2027
- Estimation of the actual market size and revenue forecast for global biological safety testing market in USD million values, and corresponding market share analysis based on test type, application, technology, and region
- Identification of the companies best positioned to meet the increasing demand for biological safety testing owing to their proprietary technologies, product launches, mergers and acquisitions, and other strategic advantages
- Review of recent industry structure for biomarkers, R&D activities, and analysis of the competitive landscape based on recent developments and segmental revenues
- Descriptive company profiles of the market leading players, including Catalent, Eurofins Scientific, Lonza, Merck, Thermo Fisher Scientific and WuXi AppTec

Executive Summary

Summary:

Biologics are the fastest growing sector of the pharmaceutical industry. This shift towards commercialization of more biological drugs is mostly due to their high specificity, enhanced efficacy, affinity, solubility, and low toxicity. Biological therapeutic drugs or biologics are inherently variable and difficult to control and measure to assure product safety, identity, quality, purity, and strength. Due to their unique nature, biological products present significant challenges for quality control. Biologics safety testing is a major step in the drug discovery, development, and manufacturing process to ensure sterility, purity, stability, and overall quality of biological agents and processes to produce noncontaminated products. Safety testing reduces risks, shortens time to market, and tests the quality, safety, and performance of products against relevant health, safety, and regulatory standards. Health authorities, including the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the International Council for Harmonisation (ICH) require biological products (or biologics) to undergo stringent safety testing throughout development and manufacturing to ensure the final product is effective, safe, and free of contaminants.

The growth in biologics sales and pipeline drive the overall need for biologics clinical development and manufacturing services across the whole spectrum from pre-clinical services to commercial manufacturing. Moreover, the biopharmaceutical industry is experiencing a global shift towards new molecular formats and more complex molecules, including bi- and multispecific antibodies, fusion proteins, and various types of bioconjugates. As these therapies gain complexity in their applications and properties, unique challenges related to their bioavailability and handling arise. Simultaneously, the product landscape is changing rapidly and is becoming more challenging from a regulatory perspective with increased pressure for speed to market, alongside accelerated development pathways and timelines. As the biopharmaceutical industry's drug research and development needs continue to increase, this in turn drives enhanced opportunities for the biologics safety testing market. The continued expansion of pharmaceutical R&D outsourcing market and stringent regulatory requirements will continue supporting growth in the biologics testing market in coming years.

The global market for biologics safety testing was valued at $REDACTED billion in 2021. The market is projected to reach $REDACTED billion in 2027, growing at a CAGR of REDACTED% during the forecast period. The predicted increases in the use of biologics worldwide, as well as the increasing number of new biologics entering the market are the two main drivers of growth in the biological safety testing market. Moreover,increasing government support for the pharmaceutical and biotechnology industries will further boostthe demand for biologics safety testing. Increasingly, the trend among large biopharmaceuticalcompanies is to outsource the majority of their biologics safety testing needs to smaller, independentlaboratories for final analysis and verification. with increased global demand for biologics and withmultiple developers targeting the same molecules, there is a clear race to be the first to submission forany biologic molecule. This is driving the need for advanced biologics testing to accelerate and shortentheir development and releas e to market timelines.

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