

Biosimilar Testing Services Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Service Type (Analytical Testing, Clinical Testing), By Molecule Type (Monoclonal Antibodies, Recombinant Hormones, Insulin, Interferons, Enzymes, Others), By Therapeutic Area (Oncology, Autoimmune Diseases, Diabetes, Infectious Diseases, Neurology, Others), By End User (Pharmaceutical & Biotechnology Companies, Contract Research Organizations, Academic & Research Institutes, Others), By Region and Competition, 2020-2030F

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Abstracts

Market Overview

The Global Biosimilar Testing Services Market was valued at USD 1.53 Billion in 2024 and is projected to reach USD 3.03 Billion by 2030, growing at a CAGR of 12.04%. This growth is driven by rising demand for cost-effective alternatives to biologic drugs, particularly as patents for many high-revenue biologics expire. Pharmaceutical companies are increasingly investing in biosimilar development to gain competitive advantage and offer more affordable treatment options. This surge in biosimilar development has amplified the need for specialized testing services to ensure regulatory compliance, safety, and efficacy. Regulatory authorities such as the U.S. FDA and EMA require extensive analytical, non-clinical, and clinical testing for biosimilar

approval. As a result, contract research organizations (CROs) and biopharmaceutical service providers play a pivotal role in supporting biosimilar manufacturers with services such as characterization studies, bioanalytical testing, and pharmacokinetic/pharmacodynamic analysis.

Key Market Drivers

Rising Prevalence of Chronic and Autoimmune Diseases

The increasing incidence of chronic and autoimmune diseases is a key factor driving growth in the Global Biosimilar Testing Services Market, as it boosts demand for affordable biologic therapies. Chronic noncommunicable diseases (NCDs) continue to be a major global health concern. According to the World Health Organization (WHO), NCDs were responsible for approximately 43 million deaths in 2021—about 75% of all non-pandemic-related fatalities. Cardiovascular diseases led with 19 million deaths, followed by cancers (10 million), chronic respiratory illnesses (4 million), and diabetes-related complications (over 2 million). The high burden of these diseases has intensified the need for biosimilars as cost-effective alternatives, thereby increasing the demand for comprehensive testing services to ensure therapeutic equivalence and safety.

Key Market Challenges

High Complexity and Cost of Biosimilar Development and Testing

The intricate nature and high cost of biosimilar development and testing remain major challenges in the Global Biosimilar Testing Services Market. Unlike small-molecule generics, biosimilars are complex biologics produced using living systems, requiring advanced analytical and functional characterization to establish similarity with reference products. Technologies such as mass spectrometry, chromatography, capillary electrophoresis, and NMR spectroscopy are essential for detailed analysis, significantly raising development expenses. Biosimilar developers must also conduct robust comparability assessments, potency tests, immunogenicity evaluations, pharmacokinetic/pharmacodynamic studies, and clinical trials to comply with rigorous regulations set by bodies like the U.S. FDA, EMA, and PMDA. These multifaceted regulatory demands lead to prolonged development timelines and substantial financial investment, posing barriers especially for small and mid-sized firms.

Key Market Trends

Increasing Adoption of Advanced Analytical Techniques for Biosimilar Characterization

A prominent trend in the Global Biosimilar Testing Services Market is the growing reliance on advanced analytical tools for biosimilar characterization. To meet regulatory expectations set by agencies such as the U.S. FDA, EMA, and PMDA, biosimilar developers must demonstrate structural and functional equivalence to originator biologics. Traditional methods often lack the sensitivity to detect subtle molecular differences, prompting increased use of high-resolution mass spectrometry (HRMS), nuclear magnetic resonance (NMR) spectroscopy, capillary electrophoresis (CE), and surface plasmon resonance (SPR). These technologies enable comprehensive assessments of purity, potency, and immunogenicity.

With biologics like monoclonal antibodies, fusion proteins, and recombinant hormones growing more complex, the need for precise testing of attributes such as glycosylation patterns, post-translational modifications, and aggregation is intensifying. Complementary techniques like high-performance liquid chromatography (HPLC) and size-exclusion chromatography (SEC) are widely employed to analyze stability and degradation pathways. The integration of automation and high-throughput screening platforms is also enhancing reproducibility and reducing testing variability, ultimately improving testing efficiency and quality.

Key Market Players

Thermo Fisher Scientific Inc.

Charles River Laboratories, Inc.

SGS S.A.

Eurofins Scientific Limited

Intertek Group plc

Element Materials Technology

Pacific BioLabs, Inc.

Sartorius AG

WuXi AppTec

Syngene International Ltd.

Report Scope:

In this report, the Global Biosimilar Testing Services Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Biosimilar Testing Services Market, By Service Type:

Analytical Testing

Clinical Testing

Biosimilar Testing Services Market, By Molecule Type:

Monoclonal Antibodies

Recombinant Hormones

Insulin

Interferons

Enzymes

Others

Biosimilar Testing Services Market, By Therapeutic Area:

Oncology

Autoimmune Diseases

Diabetes

Infectious Diseases

Neurology

Others

Biosimilar Testing Services Market, By End User:

Pharmaceutical & Biotechnology Companies

Contract Research Organizations

Academic & Research Institutes

Others

Biosimilar Testing Services Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Biosimilar Testing Services Market.

Available Customizations:

Global Biosimilar Testing Services Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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