

Biosimilar Testing and Development 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

Global Biosimilar Testing and Development Services Market was valued at USD 3.68 Billion in 2024 and is expected to reach USD 7.41 Billion in the forecast period with a CAGR of 12.34% through 2030. The Global Biosimilar Testing and Development Services Market is experiencing significant expansion, driven by the increasing demand for cost-effective alternatives to biologic drugs. As patents for several blockbuster biologics continue to expire, pharmaceutical companies are focusing on the development of biosimilars to gain market share and offer affordable treatment options. This shift is fueling the demand for specialized testing and development services to ensure regulatory compliance, safety, and efficacy. Regulatory agencies such as the U.S. FDA and the EMA have established stringent guidelines for biosimilar approval, necessitating extensive analytical, non-clinical, and clinical testing. Contract research

organizations (CROs) and biopharmaceutical service providers are playing a crucial role in supporting biosimilar manufacturers with advanced characterization techniques, bioanalytical testing, and pharmacokinetic/pharmacodynamic studies. The growing acceptance of biosimilars among healthcare providers and patients is further accelerating market growth, reinforcing the need for robust testing frameworks.

The market is witnessing transformative trends that are shaping its evolution. Technological advancements in analytical methodologies, including mass spectrometry, next-generation sequencing, and chromatography, are improving the accuracy and efficiency of biosimilar characterization. The integration of artificial intelligence and machine learning in biosimilar testing is streamlining data analysis and enhancing predictive modeling capabilities. Strategic partnerships and collaborations between biosimilar manufacturers and testing service providers are becoming more prevalent, aimed at optimizing development timelines and reducing costs. The rise of digital biomanufacturing and automation is also enhancing process efficiency, minimizing variability, and ensuring compliance with regulatory requirements. Market participants are increasingly investing in expanding their service portfolios to include immunogenicity assessment, stability studies, and comparability exercises, aligning with the evolving regulatory landscape and industry needs.

Despite the promising outlook, the market faces several challenges that could impact growth. The high complexity and cost associated with biosimilar development and testing pose a significant barrier for small and mid-sized biopharmaceutical companies. Regulatory uncertainties and varying approval pathways across different regions add to the complexity of market entry. Establishing biosimilarity with reference biologics requires extensive analytical and clinical studies, prolonging development timelines and increasing investment risks. The need for highly skilled professionals in biosimilar testing and the limited availability of expertise in specialized analytical techniques further constrain market growth. Competition from innovator biologics, as well as the hesitancy among certain stakeholders regarding the interchangeability of biosimilars, continues to pose adoption challenges. However, continuous regulatory advancements, increasing investment in biosimilar R&D, and growing awareness among healthcare providers and patients about biosimilar efficacy and safety present substantial opportunities for market expansion.

Key Market Drivers

Rising Prevalence of Chronic and Autoimmune Diseases

The rising prevalence of chronic and autoimmune diseases is a significant driver of the Global Biosimilar Testing and Development Services Market, as it increases the demand for cost-effective biologic alternatives. Chronic diseases, also known as noncommunicable diseases (NCDs), are responsible for a substantial portion of global mortality. According to the World Health Organization (WHO), NCDs accounted for at least 43 million deaths in 2021, representing 75% of non-pandemic-related deaths globally. Cardiovascular diseases were the leading cause, responsible for at least 19 million deaths, followed by cancers (10 million), chronic respiratory diseases (4 million), and diabetes (over 2 million, including kidney disease deaths caused by diabetes).

Autoimmune diseases also contribute significantly to the global disease burden. For instance, in 2019, approximately 18 million people worldwide were living with rheumatoid arthritis, with about 70% of these individuals being women.

Musculoskeletal conditions, which include various autoimmune disorders, affect approximately 1.71 billion people globally and are the leading contributor to disability worldwide.

The increasing incidence of these chronic and autoimmune conditions necessitates long-term treatment, often involving biologic therapies. However, the high cost of these biologics poses a financial burden on healthcare systems and patients. Biosimilars offer a cost-effective alternative, providing similar efficacy and safety profiles at a lower price. The growing demand for biosimilars to manage chronic and autoimmune diseases is driving the need for comprehensive testing and development services to ensure their safety, efficacy, and regulatory compliance.

Increasing Patent Expirations of Blockbuster Biologics

The increasing patent expirations of blockbuster biologics are a significant driver of growth in the Global Biosimilar Testing and Development Services Market. Biologics, which are complex and highly effective treatments for conditions such as cancer, autoimmune diseases, and diabetes, have historically dominated the pharmaceutical industry. Many of these biologic drugs, including adalimumab (Humira), trastuzumab (Herceptin), bevacizumab (Avastin), and etanercept (Enbrel), have reached or are nearing the end of their patent exclusivity, opening the market for biosimilar competition. Patent expirations allow biosimilar manufacturers to develop lower-cost alternatives, driving the demand for comprehensive testing and development services to ensure regulatory approval.

Regulatory agencies such as the U.S. FDA, EMA, and PMDA have stringent guidelines requiring biosimilar developers to demonstrate comparability with reference biologics. This involves extensive analytical testing, pharmacokinetics and pharmacodynamics (PK/PD) studies, immunogenicity assessments, and clinical trials to confirm similarity in efficacy, safety, and quality. With multiple biologics losing patent protection, the number of biosimilar candidates entering development has surged, increasing the demand for specialized testing services. The complexity of biologics necessitates sophisticated analytical techniques, such as mass spectrometry, high-performance liquid chromatography (HPLC), and bioassays, to assess molecular structure, stability, and potency.

Governments and healthcare providers are actively promoting biosimilars to reduce treatment costs and improve patient access to biologic therapies. The growing number of biosimilar approvals has intensified competition, encouraging companies to invest in advanced testing methodologies to differentiate their products and ensure regulatory compliance. As of November 15, 2023, the U.S. Food and Drug Administration (FDA) has approved 44 biosimilars referencing 14 different biologic products, reflecting the accelerating pace of biosimilar entries into the market.

The rising pipeline of biosimilars, driven by continuous patent expirations, is expected to sustain long-term demand for biosimilar testing and development services, positioning this factor as a key driver of market growth.

Advancements in Analytical and Bioanalytical Testing Technologies

Advancements in analytical and bioanalytical testing technologies are a significant driver in the Global Biosimilar Testing and Development Services Market, enabling more precise characterization, quality assessment, and regulatory compliance for biosimilars. The complexity of biosimilar molecules necessitates comprehensive testing to ensure structural, functional, and immunogenic comparability with reference biologics. Sophisticated analytical techniques such as high-resolution mass spectrometry (HRMS), nuclear magnetic resonance (NMR) spectroscopy, capillary electrophoresis, and advanced chromatography methods are increasingly being employed to detect minor structural variations, post-translational modifications, and aggregation profiles. These technologies enhance the accuracy of biosimilarity assessments, reducing the likelihood of batch-to-batch variability and ensuring consistency in manufacturing.

Bioanalytical advancements are also playing a crucial role in pharmacokinetic (PK),

pharmacodynamic (PD), and immunogenicity evaluations. High-throughput screening methods, surface plasmon resonance (SPR), enzyme-linked immunosorbent assays (ELISA), and electrochemiluminescence-based immunoassays are improving the sensitivity and specificity of immunogenicity testing. These innovations facilitate early detection of anti-drug antibodies (ADAs) and potential adverse immune responses, which are critical for biosimilar approval and post-market surveillance. The integration of artificial intelligence (AI) and machine learning (ML) in data analysis is streamlining biosimilar testing by enhancing pattern recognition, optimizing large-scale data interpretation, and accelerating decision-making in biosimilar development.

Regulatory agencies such as the FDA, EMA, and ICH are setting stringent guidelines requiring high precision in analytical and bioanalytical testing. As regulatory expectations evolve, companies are adopting cutting-edge technologies to meet compliance standards while improving efficiency and reducing development timelines. The rising demand for automation in biosimilar testing workflows, real-time monitoring systems, and process analytical technology (PAT) is further transforming the market landscape. These advancements are significantly increasing the reliability and scalability of biosimilar testing, making them a key driving force in the growth of biosimilar development services worldwide.

According to the FDA's Biosimilars Action Plan, the agency has implemented an abbreviated pathway for the approval of biosimilar and interchangeable products, which relies on demonstrating biosimilarity through comprehensive analytical and bioanalytical testing. As of July 1, 2018, 68 programs were enrolled in the FDA's Biosimilar Product Development Program, reflecting the growing emphasis on advanced testing methodologies in biosimilar development.

In the European Union, the EMA has established a solid framework for the approval of biosimilar medicines, emphasizing the importance of robust analytical and bioanalytical testing to ensure comparability with reference products. The EU approved its first biosimilar in 2006 and has since pioneered the regulation of biosimilar medicines by shaping biosimilar development globally. These regulatory frameworks underscore the critical role of advancements in analytical and bioanalytical testing technologies in facilitating the development, approval, and market acceptance of biosimilars.

Key Market Challenges

High Complexity and Cost of Biosimilar Development and Testing

High complexity and cost associated with biosimilar development and testing present a significant challenge in the Global Biosimilar Testing and Development Services Market. Unlike small-molecule generics, biosimilars are large, structurally complex molecules derived from living cells, requiring extensive characterization to ensure similarity with reference biologics. This complexity necessitates sophisticated analytical techniques such as mass spectrometry, chromatography, nuclear magnetic resonance (NMR) spectroscopy, and capillary electrophoresis, significantly increasing development costs. Biosimilar manufacturers must conduct comparability studies, potency assays, immunogenicity testing, pharmacokinetic (PK) and pharmacodynamic (PD) evaluations, as well as clinical trials to meet stringent regulatory requirements set by agencies such as the U.S. FDA, EMA, and PMDA. These regulatory expectations mandate extensive data generation, prolonging development timelines and increasing financial burdens.

High costs are further compounded by the need for state-of-the-art biomanufacturing infrastructure and advanced bioanalytical testing facilities. Establishing and maintaining Good Manufacturing Practice (GMP)-compliant production and testing laboratories require significant capital investment. Scaling up biosimilar production while maintaining batch-to-batch consistency presents another challenge, demanding continuous quality control measures and sophisticated process analytical technology (PAT) systems. The longer development timelines, coupled with the risk of regulatory rejections or demands for additional data, contribute to financial uncertainties. Smaller biopharmaceutical firms and emerging biosimilar developers face difficulties in sustaining the required investments, leading to dependency on partnerships, mergers, or outsourcing to contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs).

Biosimilar testing complexity is further heightened by immunogenicity concerns, as slight structural variations can trigger adverse immune responses. Extensive in vitro and in vivo testing is required to assess immunogenic potential, increasing both time and cost burdens. The need for large-scale clinical trials, real-world evidence studies, and post-marketing surveillance programs adds to financial constraints. Navigating diverse global regulatory landscapes and achieving approval in multiple markets pose additional hurdles, making biosimilar development and testing a costly and resource-intensive process.

Stringent and Evolving Regulatory Requirements

Stringent and evolving regulatory requirements present a major challenge in the Global Biosimilar Testing and Development Services Market. Regulatory agencies such as the

U.S. FDA, European Medicines Agency (EMA), and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan impose rigorous guidelines to ensure biosimilars meet the same safety, efficacy, and quality standards as their reference biologics. Unlike small-molecule generics, biosimilars require comprehensive analytical characterization, comparability studies, non-clinical evaluations, pharmacokinetic (PK) and pharmacodynamic (PD) assessments, and clinical trials to demonstrate similarity. Meeting these extensive requirements increases the complexity of biosimilar development and prolongs approval timelines.

Regulatory expectations are continuously evolving, requiring biosimilar developers to adapt to new analytical standards, testing methodologies, and clinical trial designs. Agencies frequently update guidelines on interchangeability, immunogenicity assessments, and real-world evidence requirements, creating uncertainty for manufacturers. Differences in regulatory frameworks across regions add another layer of complexity. Biosimilar developers must navigate diverse approval pathways, leading to additional costs and extended testing durations.

Demonstrating biosimilarity at a molecular, functional, and clinical level requires highly sophisticated testing methodologies, which must comply with evolving Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) standards. Regulatory agencies often demand additional data or post-marketing surveillance studies to monitor long-term safety, further increasing development costs and delaying commercialization. Small and mid-sized biosimilar manufacturers face difficulties keeping up with changing regulations, leading to reliance on regulatory consultants and contract research organizations (CROs). The uncertainty surrounding future regulatory changes, combined with the need for continuous compliance updates, poses significant financial and operational challenges for companies developing biosimilars, impacting market growth and innovation in biosimilar testing and development services.

Key Market Trends

Increasing Adoption of Advanced Analytical Techniques for Biosimilar Characterization

Increasing adoption of advanced analytical techniques for biosimilar characterization is a significant trend shaping the Global Biosimilar Testing and Development Services Market. Regulatory agencies such as the U.S. FDA, EMA, and PMDA require biosimilar developers to demonstrate high similarity with reference biologics in terms of structure, purity, potency, and immunogenicity. Traditional analytical methods often fall short in detecting minor variations, leading to the growing use of sophisticated techniques such

as high-resolution mass spectrometry (HRMS), nuclear magnetic resonance (NMR) spectroscopy, capillary electrophoresis (CE), and surface plasmon resonance (SPR). These techniques provide highly detailed molecular characterization, ensuring biosimilars meet stringent regulatory standards.

The complexity of biologics, particularly monoclonal antibodies (mAbs), fusion proteins, and recombinant hormones, has necessitated advancements in analytical testing methodologies. Mass spectrometry enables precise assessment of post-translational modifications, glycosylation patterns, and aggregation profiles, which are critical for biosimilar comparability studies. Chromatographic techniques, including high-performance liquid chromatography (HPLC) and size-exclusion chromatography (SEC), are widely used to evaluate purity, stability, and degradation pathways. Adoption of high-throughput screening methods and automation-driven bioassays has improved testing efficiency, reducing variability and increasing reproducibility.

Artificial intelligence (AI) and machine learning (ML) are being integrated into biosimilar analytical workflows to enhance data interpretation and predictive modeling. AI-driven platforms analyze vast datasets, improving structural similarity assessments and accelerating decision-making in biosimilar development. Regulatory agencies are emphasizing multi-attribute method (MAM) approaches, which use advanced mass spectrometry to provide a more comprehensive biosimilar characterization than conventional methods. Biopharmaceutical companies and contract research organizations (CROs) are investing in state-of-the-art bioanalytical laboratories to keep pace with evolving regulatory expectations and industry demands. The increasing reliance on advanced analytical techniques is streamlining biosimilar development, ensuring higher quality standards, and reducing approval timelines, driving significant growth in the biosimilar testing and development services market.

Expansion of Outsourced Biosimilar Testing Services

Expansion of outsourced biosimilar testing services for biosimilar characterization is a key trend in the Global Biosimilar Testing and Development Services Market. Biopharmaceutical companies are increasingly outsourcing analytical testing, comparability studies, and bioassay development to contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) to reduce costs and accelerate time to market. Biosimilar development requires extensive structural, functional, and biological characterization, involving sophisticated techniques such as mass spectrometry, chromatography, capillary electrophoresis, and cell-based potency assays. Establishing in-house testing capabilities demands significant

investment in infrastructure, skilled personnel, and regulatory compliance, prompting companies to seek specialized outsourced services.

Regulatory agencies such as the U.S. FDA, EMA, and PMDA mandate rigorous analytical and functional testing for biosimilars, increasing the complexity of development programs. CROs and CDMOs offer end-to-end biosimilar testing solutions, including physicochemical characterization, immunogenicity assessment, pharmacokinetics, and stability studies, ensuring compliance with evolving regulatory requirements. The growing pipeline of biosimilar candidates across multiple therapeutic areas, including oncology, autoimmune diseases, and endocrinology, is driving demand for specialized testing expertise. Emerging markets such as India, China, and South Korea are becoming hubs for outsourced biosimilar testing due to their cost-effective services and regulatory advancements.

Advancements in analytical technologies, automation, and artificial intelligence (AI)-driven data analytics have enhanced the efficiency and accuracy of biosimilar testing. Outsourcing partners provide Good Laboratory Practice (GLP)-compliant and Good Manufacturing Practice (GMP)-certified services, enabling biopharmaceutical companies to meet stringent regulatory expectations while focusing on core research and commercialization efforts. Strategic collaborations between biosimilar developers and CROs/CDMOs are expanding, ensuring access to cutting-edge analytical platforms and expertise. The shift toward outsourced biosimilar testing services is streamlining development timelines, optimizing resource allocation, and supporting the rapid expansion of the global biosimilar market.

Segmental Insights

Service Type Insights

Based on the Service Type, Analytical Testing emerged as the dominant segment in the Global Biosimilar Testing and Development Services Market in 2024. This is due to its critical role in demonstrating biosimilarity between biosimilars and reference biologics. Biosimilars, unlike small-molecule generics, require extensive analytical characterization to confirm structural, functional, and physicochemical similarities while ensuring batch-to-batch consistency. Regulatory agencies such as the U.S. FDA and EMA mandate rigorous analytical testing before biosimilar candidates proceed to preclinical and clinical evaluations. Advanced techniques such as mass spectrometry, chromatography, nuclear magnetic resonance (NMR) spectroscopy, and capillary electrophoresis are widely employed to assess molecular attributes, post-translational modifications,

aggregation profiles, and impurity levels. The rising adoption of high-throughput screening methods, artificial intelligence-driven analytical tools, and automation in bioassays has further strengthened the demand for analytical testing services. Additionally, biosimilars for highly complex biologics, including monoclonal antibodies (mAbs), require extensive comparability studies, potency assays, immunogenicity assessments, and forced degradation studies, increasing reliance on analytical testing solutions. The growing number of biosimilars entering clinical pipelines, coupled with stringent regulatory requirements and the push for accelerated biosimilar approvals, has solidified analytical testing as the most essential and widely utilized service in biosimilar development, driving its dominance in the market.

Molecule Type Insights

Based on the Molecule Type, Monoclonal Antibodies emerged as the dominant segment in the Global Biosimilar Testing and Development Services Market in 2024. This is due to their widespread clinical applications, high market value, and increasing biosimilar competition. mAbs are among the most complex biologics, requiring extensive analytical characterization, structural comparability assessments, and rigorous immunogenicity testing to establish biosimilarity. These molecules are widely used in treating oncology, autoimmune diseases, and infectious diseases, which are key therapeutic areas driving biosimilar development. Blockbuster biologics such as rituximab (Rituxan/MabThera), trastuzumab (Herceptin), bevacizumab (Avastin), and adalimumab (Humira) have witnessed patent expirations, leading to a surge in biosimilar approvals and market entries. Due to their intricate structure and post-translational modifications, mAbs demand comprehensive testing services, including mass spectrometry, glycosylation profiling, functional bioassays, and immunogenicity assessments, further fueling the dominance of this segment. Regulatory agencies require robust comparability studies, stability testing, and pharmacokinetic/pharmacodynamic (PK/PD) evaluations for mAb biosimilars, intensifying the demand for specialized testing services. Moreover, advancements in AI-driven analytical methods, automation in bioassays, and high-throughput screening technologies are enhancing testing efficiency and accuracy. As the demand for cost-effective biologic alternatives continues to rise, monoclonal antibodies remain at the forefront of biosimilar development, driving their dominance in biosimilar testing and development services.

Regional Insights

North America emerged as the dominant region in the Global Biosimilar Testing and

Development Services Market in 2024. This is due to its well-established regulatory framework, strong presence of biopharmaceutical companies, and increasing adoption of biosimilars. The U.S. Food and Drug Administration (FDA) has implemented a structured biosimilar approval pathway under the Biologics Price Competition and Innovation Act (BPCIA), fostering a favorable environment for biosimilar development and testing. The region hosts leading biotechnology and pharmaceutical firms investing heavily in biosimilar research, along with a strong network of contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) providing specialized biosimilar testing services. The high cost of biologic therapies has driven payer incentives, government initiatives, and hospital formularies to encourage biosimilar adoption, further fueling demand for rigorous testing to ensure regulatory compliance and market acceptance. The presence of advanced analytical laboratories, cutting-edge biomanufacturing technologies, and AI-driven bioanalytical platforms has strengthened North America's leadership in biosimilar characterization, comparability studies, and clinical trials. Additionally, major biosimilar approvals, especially in oncology and autoimmune diseases, have accelerated the need for robust pharmacovigilance and immunogenicity testing. With continued regulatory support and increasing biosimilar penetration, North America remains the dominant hub for biosimilar testing and development services.

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 and Development Services Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Biosimilar Testing and Development Services Market, By Service Type:

Analytical Testing

Clinical Testing

Biosimilar Testing and Development Services Market, By Molecule Type:

Monoclonal Antibodies

Recombinant Hormones

Insulin

Interferons

Enzymes

Others

Biosimilar Testing and Development Services Market, By Therapeutic Area:

Oncology

Autoimmune Diseases

Diabetes

Infectious Diseases

Neurology

Others

Biosimilar Testing and Development Services Market, By End User:

Pharmaceutical & Biotechnology Companies

Contract Research Organizations

Academic & Research Institutes

Others

Biosimilar Testing and Development 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 and Development Services Market.

Available Customizations:

Global Biosimilar Testing and Development 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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