

Large Molecule Bioanalytical Technologies Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Products & Services (Product (Consumables & Accessories, Instruments, Reagents & Kits), Service), By Application (Biologics, Oligonucleotide Derived Drugs & Molecules, Viral Vector, Cell & Gene Therapy, Nanoparticles & Polymers, Others), By Region & Competition, 2021-2031F

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Abstracts

The global market for large molecule bioanalytical technologies is projected to expand significantly, from USD 9.73 billion in 2025 to USD 17.64 billion by 2031, demonstrating a compound annual growth rate (CAGR) of 10.42%. These technologies, including liquid chromatography-mass spectrometry and ligand binding assays, are crucial for quantifying and characterizing biologic therapeutics in biological samples. The market's growth is fundamentally propelled by the rising incidence of chronic diseases worldwide and the pharmaceutical industry's increasing focus on complex biologics, such as monoclonal antibodies, which necessitate thorough pharmacokinetic assessments.

A robust investment of approximately €55 billion in research and development by the European pharmaceutical industry in 2024 highlights the strong demand for accurate analytical tools essential for developing these novel therapies.

Market Driver

A key market driver is the swift expansion of the research and development pipeline for

biologics and biosimilars, which mandates comprehensive bioanalytical testing to ensure safety and efficacy. The growing number of therapeutic candidates, especially monoclonal antibodies and recombinant proteins, drives the need for high-throughput and sensitive platforms for immunogenicity and pharmacokinetic evaluations. For instance, the FDA approved a record 18 biosimilars in 2024, as reported by the Regulatory Affairs Professionals Society in January 2025, alongside the European Medicines Agency's recommendation for 114 new medicines for marketing authorization in 2024, many of which are innovative large molecules.

Furthermore, the market is significantly shaped by the increasing practice of outsourcing bioanalytical testing to Contract Research Organizations (CROs). Pharmaceutical firms engage CROs to reduce capital expenditures on advanced equipment and to leverage specialized expertise in complex large molecules, thereby optimizing development timelines and meeting regulatory demands. WuXi AppTec's TIDES business, focusing on oligonucleotide and peptide therapeutics, saw a 70.1% revenue increase year-over-year in 2024, emphasizing this reliance on outsourced specialized capabilities.

Market Challenge

A substantial hurdle for the market is the considerable capital investment required for high-sensitivity instrumentation, particularly for advanced platforms used in monoclonal antibody characterization. This financial burden disproportionately affects smaller laboratories and CROs, limiting their access to crucial analytical capabilities and hindering broader industry capacity.

This challenge is compounded by a stricter investment climate, which reduces the funding available for growth and technology procurement. For example, biotech startup funding fell sharply from \$2.6 billion in Q1 2025 to \$900 million in Q2, as reported by the Biotechnology Innovation Organization. This decline directly impedes new companies' ability to acquire essential bioanalytical tools and skilled personnel, thus slowing the adoption of high-performance technologies, creating capacity shortages, and delaying pharmacokinetic evaluations, ultimately retarding the overall growth of the biologic therapeutics market.

Market Trends

A notable market trend is the integration of artificial intelligence (AI) into bioanalytical workflows, transforming how laboratories manage intricate data and fine-tune assay parameters. Machine learning is increasingly employed to automate tasks like peak

integration in LC-MS and to predict immunogenicity risks for large molecules, thereby decreasing manual data review time and boosting reproducibility. This innovation addresses the need for efficient processing of extensive data from high-resolution mass spectrometry, allowing scientists to concentrate on more complex interpretive work. The Pistoia Alliance's 2025 'Lab of the Future Survey' indicated that 77% of life sciences laboratories plan to adopt AI within two years, marking it as a top investment for accelerating R&D.

Parallel to this, there is a significant shift towards developing specialized assays for cell and gene therapies. These advanced treatments, unlike conventional biologics, require unique bioanalytical approaches to quantify viral vectors, assess shedding, and monitor transgene expression. This demand is growing as regulatory frameworks for these therapies mature and approvals rise, with a record nine cell and gene therapies approved in 2024, according to the Alliance for Regenerative Medicine's 2025 briefing, fueling the need for novel, high-sensitivity testing methods.

Key Market Players

Intertek Group plc

F. Hoffmann-La Roche Ltd

Bio-Rad Laboratories, Inc.

Solvias AG

Bio-Techne Corp.

Waters Corporation

Verder Scientific GmbH & Co. KG

Charles River Laboratories

Merck KGaA

Cergentis B.V.

Report Scope

In this report, the Global Large Molecule Bioanalytical Technologies Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Large Molecule Bioanalytical Technologies Market, By Products & Services

Product

Service

Large Molecule Bioanalytical Technologies Market, By Application

Biologics

Oligonucleotide Derived Drugs & Molecules

Viral Vector

Cell & Gene Therapy

Nanoparticles & Polymers

Others

Large Molecule Bioanalytical Technologies 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

Large Molecule Bioanalytical Technologies Market - Global Industry Size, Share, Trends, Opportunity, and Forec...

Company Profiles: Detailed analysis of the major companies present in the Global Large Molecule Bioanalytical Technologies Market.

Available Customizations:

Global Large Molecule Bioanalytical Technologies 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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