

Global Biologics Regulatory Affairs Outsourcing Market 2025 by Company, Regions, Type and Application, Forecast to 2031

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Abstracts

According to our (Global Info Research) latest study, the global Biologics Regulatory Affairs Outsourcing market size was valued at US\$ 2082 million in 2024 and is forecast to a readjusted size of USD 3968 million by 2031 with a CAGR of 8.8% during review period.

Biologics regulatory affairs outsourcing is a commercial service in which biologics companies entrust regulatory affairs-related work to external professional organizations. Biologics include complex pharmaceutical products such as vaccines, blood products, recombinant proteins, monoclonal antibodies, etc., and the research and development, production, sales and use of these products are subject to strict regulatory supervision. Regulatory affairs outsourcing involves ensuring that these biologics comply with relevant domestic and international regulatory requirements at all stages, including but not limited to clinical trial applications, drug registrations, license applications, quality standard formulation and maintenance, regulatory compliance supervision, etc.

This report is a detailed and comprehensive analysis for global Biologics Regulatory Affairs Outsourcing market. Both quantitative and qualitative analyses are presented by company, by region & country, by Type and by Application. As the market is constantly changing, this report explores the competition, supply and demand trends, as well as key factors that contribute to its changing demands across many markets. Company profiles and product examples of selected competitors, along with market share estimates of some of the selected leaders for the year 2025, are provided.

Key Features:

Global Biologics Regulatory Affairs Outsourcing market size and forecasts, in consumption value (\$ Million), 2020-2031

Global Biologics Regulatory Affairs Outsourcing market size and forecasts by region and country, in consumption value (\$ Million), 2020-2031

Global Biologics Regulatory Affairs Outsourcing market size and forecasts, by Type and by Application, in consumption value (\$ Million), 2020-2031

Global Biologics Regulatory Affairs Outsourcing market shares of main players, in revenue (\$ Million), 2020-2025

The Primary Objectives in This Report Are:

- To determine the size of the total market opportunity of global and key countries
- To assess the growth potential for Biologics Regulatory Affairs Outsourcing
- To forecast future growth in each product and end-use market
- To assess competitive factors affecting the marketplace

This report profiles key players in the global Biologics Regulatory Affairs Outsourcing market based on the following parameters - company overview, revenue, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include Lonza AG, Wuxi AppTec Inc., Thermo Fisher Scientific Inc., Eurofins Scientific SE, Freyr solutions, Catalent Inc., Piramal Group, AGC Biologics, ICON Plc., Charles River Laboratories International, Inc., etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Market segmentation

Biologics Regulatory Affairs Outsourcing market is split by Type and by Application. For the period 2020-2031, the growth among segments provides accurate calculations and forecasts for Consumption Value by Type and by Application. This analysis can help you expand your business by targeting qualified niche markets.

Market segment by Type

Regulatory Consulting

Legal Representation

Regulatory Writing & Publishing

Product Registration

Regulatory Submissions

Regulatory Operations

Others

Market segment by Application

Monoclonal Antibodies (mAbs)

Recombinant Proteins

Vaccines

Cell & Gene Therapies

Biosimilars

Others

Market segment by players, this report covers

Lonza AG

Wuxi AppTec Inc.

Thermo Fisher Scientific Inc.

Eurofins Scientific SE

Freyr solutions

Catalent Inc.

Piramal Group

AGC Biologics

ICON Plc.

Charles River Laboratories International, Inc.

Labcorp

Parexel International

Medpace Holdings, Inc.

IQVIA

Syneos Health

SGS SA (SGS)

Market segment by regions, regional analysis covers

North America (United States, Canada and Mexico)

Europe (Germany, France, UK, Russia, Italy and Rest of Europe)

Asia-Pacific (China, Japan, South Korea, India, Southeast Asia and Rest of Asia-Pacific)

South America (Brazil, Rest of South America)

Middle East & Africa (Turkey, Saudi Arabia, UAE, Rest of Middle East & Africa)

The content of the study subjects, includes a total of 13 chapters:

Chapter 1, to describe Biologics Regulatory Affairs Outsourcing product scope, market overview, market estimation caveats and base year.

Chapter 2, to profile the top players of Biologics Regulatory Affairs Outsourcing, with revenue, gross margin, and global market share of Biologics Regulatory Affairs

Outsourcing from 2020 to 2025.

Chapter 3, the Biologics Regulatory Affairs Outsourcing competitive situation, revenue, and global market share of top players are analyzed emphatically by landscape contrast.

Chapter 4 and 5, to segment the market size by Type and by Application, with consumption value and growth rate by Type, by Application, from 2020 to 2031

Chapter 6, 7, 8, 9, and 10, to break the market size data at the country level, with revenue and market share for key countries in the world, from 2020 to 2025. and Biologics Regulatory Affairs Outsourcing market forecast, by regions, by Type and by Application, with consumption value, from 2026 to 2031.

Chapter 11, market dynamics, drivers, restraints, trends, Porters Five Forces analysis.

Chapter 12, the key raw materials and key suppliers, and industry chain of Biologics Regulatory Affairs Outsourcing.

Chapter 13, to describe Biologics Regulatory Affairs Outsourcing research findings and conclusion.

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