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Global Biologics Regulatory Affairs Outsourcing Market Growth (Status and Outlook) 2025-2031

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Abstracts

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The global Biologics Regulatory Affairs Outsourcing market size is predicted to grow from US$ 2269 million in 2025 to US$ 3889 million in 2031; it is expected to grow at a CAGR of 9.4% from 2025 to 2031.

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.

United States market for Biologics Regulatory Affairs Outsourcing is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

China market for Biologics Regulatory Affairs Outsourcing is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

Europe market for Biologics Regulatory Affairs Outsourcing is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

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Global key Biologics Regulatory Affairs Outsourcing players cover Lonza AG, Wuxi AppTec Inc., Thermo Fisher Scientific Inc., Eurofins Scientific SE, Freyr solutions, etc. In terms of revenue, the global two largest companies occupied for a share nearly % in 2024.

LPI (LP Information)' newest research report, the “Biologics Regulatory Affairs Outsourcing Industry Forecast” looks at past sales and reviews total world Biologics Regulatory Affairs Outsourcing sales in 2024, providing a comprehensive analysis by region and market sector of projected Biologics Regulatory Affairs Outsourcing sales for 2025 through 2031. With Biologics Regulatory Affairs Outsourcing sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world Biologics Regulatory Affairs Outsourcing industry.

This Insight Report provides a comprehensive analysis of the global Biologics Regulatory Affairs Outsourcing landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Biologics Regulatory Affairs Outsourcing portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms’ unique position in an accelerating global Biologics Regulatory Affairs Outsourcing market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Biologics Regulatory Affairs Outsourcing and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Biologics Regulatory Affairs Outsourcing.

This report presents a comprehensive overview, market shares, and growth opportunities of Biologics Regulatory Affairs Outsourcing market by product type, application, key players and key regions and countries.

Segmentation by Type:

Regulatory Consulting

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Legal Representation

Regulatory Writing & Publishing

Product Registration

Regulatory Submissions

Regulatory Operations

Others

Segmentation by Application:

Monoclonal Antibodies (mAbs)

Recombinant Proteins

Vaccines

Cell & Gene Therapies

Biosimilars

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

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- APAC
  - China
  - Japan
  - Korea
  - Southeast Asia
  - India
  - Australia
- Europe
  - Germany
  - France
  - UK
  - Italy
  - Russia
- Middle East & Africa
  - Egypt
  - South Africa
  - Israel
  - Turkey
  - GCC Countries

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The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

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)

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