

Global Biologics Regulatory Affairs Outsourcing Market Research Report 2026(Status and Outlook)

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Abstracts

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.

The global Biologics Regulatory Affairs Outsourcing market size was estimated at USD 2023.0 million in 2025 and is projected to grow at a compound annual growth rate (CAGR) of 9.10% during the forecast period.

This report offers a comprehensive and in-depth analysis of the global Biologics Regulatory Affairs Outsourcing market, covering all critical facets from a broad macroeconomic overview to detailed micro-level insights. It examines market size, competitive landscape, emerging development trends, niche segments, key drivers and challenges, as well as conducts SWOT and value chain analyses.

The insights provided enable readers to understand the competitive dynamics within the industry and formulate effective strategies to enhance profitability and market positioning. Additionally, the report presents a clear framework for evaluating the current status and future outlook of business organizations operating in this sector.

A significant focus of this report lies in the competitive landscape of the global Biologics

Regulatory Affairs Outsourcing market. It offers detailed profiles of major players, including their market shares, performance metrics, product portfolios, and operational status. This enables stakeholders to identify leading competitors and gain a nuanced understanding of market rivalry and structure.

In summary, this report serves as an essential resource for industry participants, investors, researchers, consultants, and business strategists, as well as anyone planning to enter or expand their presence in the Biologics Regulatory Affairs Outsourcing market.

Global Biologics Regulatory Affairs Outsourcing Market: Market Segmentation Analysis

This research report provides a detailed segmentation of the market by region (country), key manufacturers, product type, and application. Market segmentation divides the overall market into distinct subsets based on factors such as product categories, end-user industries, geographic locations, and other relevant criteria.

A clear understanding of these market segments enables decision-makers to tailor their product development, sales, and marketing strategies more effectively to meet the unique needs of each segment. Leveraging market segmentation insights can significantly enhance targeted approaches, optimize resource allocation, and accelerate product innovation cycles by aligning offerings with the specific demands of diverse customer groups.

Key Company

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 Segmentation (by Type)

Regulatory Consulting
Legal Representation
Regulatory Writing & Publishing
Product Registration
Regulatory Submissions
Regulatory Operations
Others

Market Segmentation (by Application)

Monoclonal Antibodies (mAbs)
Recombinant Proteins
Vaccines
Cell & Gene Therapies
Biosimilars
Others

Geographic Segmentation

North America (USA, Canada, Mexico)
Europe (Germany, UK, France, Russia, Italy, Rest of Europe)
Asia-Pacific (China, Japan, South Korea, India, Southeast Asia, Rest of Asia-Pacific)
South America (Brazil, Argentina, Columbia, Rest of South America)
The Middle East and Africa (Saudi Arabia, UAE, Egypt, Nigeria, South Africa, Rest of MEA)

Key Benefits of This Market Research:

Industry drivers, restraints, and opportunities covered in the study
Neutral perspective on the market performance
Recent industry trends and developments
Competitive landscape & strategies of key players

Potential & niche segments and regions exhibiting promising growth covered
Historical, current, and projected market size, in terms of value
In-depth analysis of the Biologics Regulatory Affairs Outsourcing Market
Overview of the regional outlook of the Biologics Regulatory Affairs Outsourcing Market:

Customization of the Report

In case of any queries or customization requirements, please connect with our sales team, who will ensure that your requirements are met.

Chapter Outline

Chapter 1 mainly introduces the statistical scope of the report, market division standards, and market research methods.

Chapter 2 is an executive summary of different market segments (by region, product type, application, etc), including the market size of each market segment, future development potential, and so on. It offers a high-level view of the current state of the Biologics Regulatory Affairs Outsourcing Market and its likely evolution in the short to mid-term, and long term.

Chapter 3 makes a detailed analysis of the market's competitive landscape of the market and provides the market share, capacity, output, price, latest development plan, merger, and acquisition information of the main manufacturers in the market.

Chapter 4 is the analysis of the whole market industrial chain, including the upstream and downstream of the industry, as well as Porter's five forces analysis.

Chapter 5 introduces the latest developments of the market, the driving factors and restrictive factors of the market, the challenges and risks faced by manufacturers in the industry, and the analysis of relevant policies in the industry.

Chapter 6 provides the analysis of various market segments according to product types, covering the market size and development potential of each market segment, to help readers find the blue ocean market in different market segments.

Chapter 7 provides the analysis of various market segments according to application, covering the market size and development potential of each market segment, to help readers find the blue ocean market in different downstream markets.

Chapter 8 provides a quantitative analysis of the market size and development potential of each region and its main countries and introduces the market development, future development prospects, market space, and capacity of each country in the world.

Chapter 9 shares the main producing countries of Biologics Regulatory Affairs Outsourcing, their output value, profit level, regional supply, production capacity layout, etc. from the supply side.

Chapter 10 introduces the basic situation of the main companies in the market in detail, including product sales revenue, sales volume, price, gross profit margin, market share, product introduction, recent development, etc.

Chapter 11 provides a quantitative analysis of the market size and development potential of each region in the next five years.

Chapter 12 provides a quantitative analysis of the market size and development potential of each market segment in the next five years.

Chapter 13 is the main points and conclusions of the report.

Key Reasons to Buy this Report:

Access to date statistics compiled by our researchers. These provide you with historical and forecast data, which is analyzed to tell you why your market is set to change

This enables you to anticipate market changes to remain ahead of your competitors

You will be able to copy data from the Excel spreadsheet straight into your marketing plans, business presentations, or other strategic documents

The concise analysis, clear graph, and table format will enable you to pinpoint the information you require quickly

Provision of market value data for each segment and sub-segment

Indicates the region and segment that is expected to witness the fastest growth as well as to dominate the market

Analysis by geography highlighting the consumption of the product/service in the region as well as indicating the factors that are affecting the market within each region

Competitive landscape which incorporates the market ranking of the major players, along with new service/product launches, partnerships, business expansions, and acquisitions in the past five years of companies profiled

Extensive company profiles comprising of company overview, company insights,

product benchmarking, and SWOT analysis for the major market players

The current as well as the future market outlook of the industry concerning recent developments which involve growth opportunities and drivers as well as challenges and restraints of both emerging as well as developed regions

Includes in-depth analysis of the market from various perspectives through Porter's five forces analysis

Provides insight into the market through Value Chain

Market dynamics scenario, along with growth opportunities of the market in the years to come

6-month post-sales analyst support

Customization of the Report

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Contents

1 RESEARCH METHODOLOGY AND STATISTICAL SCOPE

- 1.1 Market Definition and Statistical Scope of Biologics Regulatory Affairs Outsourcing
- 1.2 Key Market Segments
 - 1.2.1 Biologics Regulatory Affairs Outsourcing Segment by Type
 - 1.2.2 Biologics Regulatory Affairs Outsourcing Segment by Application
- 1.3 Methodology & Sources of Information
 - 1.3.1 Research Methodology
 - 1.3.2 Research Process
 - 1.3.3 Market Breakdown and Data Triangulation
 - 1.3.4 Base Year
 - 1.3.5 Report Assumptions & Caveats

2 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET OVERVIEW

- 2.1 Global Market Overview
- 2.2 Market Segment Executive Summary
- 2.3 Global Market Size by Region

3 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET COMPETITIVE LANDSCAPE

- 3.1 Company Assessment Quadrant
- 3.2 Global Biologics Regulatory Affairs Outsourcing Product Life Cycle
- 3.3 Global Biologics Regulatory Affairs Outsourcing Revenue Market Share by Company (2020-2025)
- 3.4 Biologics Regulatory Affairs Outsourcing Market Share by Company Type (Tier 1, Tier 2, and Tier 3)
- 3.5 Headquarters, Areas Served, and Product Types of Major Players
- 3.6 Biologics Regulatory Affairs Outsourcing Market Competitive Situation and Trends
 - 3.6.1 Biologics Regulatory Affairs Outsourcing Market Concentration Rate
 - 3.6.2 Global 5 and 10 Largest Biologics Regulatory Affairs Outsourcing Players Market Share by Revenue
 - 3.6.3 Mergers & Acquisitions, Expansion

4 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING VALUE CHAIN ANALYSIS

- 4.1 Biologics Regulatory Affairs Outsourcing Value Chain Analysis
- 4.2 Midstream Market Analysis
- 4.3 Downstream Customer Analysis

5 THE DEVELOPMENT AND DYNAMICS OF BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET

- 5.1 Key Development Trends
- 5.2 Driving Factors
- 5.3 Market Challenges
- 5.4 Industry News
 - 5.4.1 New Product Developments
 - 5.4.2 Mergers & Acquisitions
 - 5.4.3 Expansions
 - 5.4.4 Collaboration/Supply Contracts
- 5.5 PEST Analysis
 - 5.5.1 Industry Policies Analysis
 - 5.5.2 Economic Environment Analysis
 - 5.5.3 Social Environment Analysis
 - 5.5.4 Technological Environment Analysis
- 5.6 Global Biologics Regulatory Affairs Outsourcing Market Porter's Five Forces Analysis

6 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET SEGMENTATION BY TYPE

- 6.1 Evaluation Matrix of Segment Market Development Potential (Type)
- 6.2 Global Biologics Regulatory Affairs Outsourcing Market by Type (2020-2025)
- 6.3 Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Type (2021-2025)

7 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET SEGMENTATION BY APPLICATION

- 7.1 Evaluation Matrix of Segment Market Development Potential (Application)
- 7.2 Global Biologics Regulatory Affairs Outsourcing Market Size (M USD) by Application (2020-2025)
- 7.3 Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Application (2021-2025)

8 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET SEGMENTATION BY REGION

8.1 Global Biologics Regulatory Affairs Outsourcing Market Size by Region

8.1.1 Global Biologics Regulatory Affairs Outsourcing Market Size by Region

8.1.2 Global Biologics Regulatory Affairs Outsourcing Market Size Market Share by Region

8.2 North America

8.2.1 North America Biologics Regulatory Affairs Outsourcing Market Size by Country

8.2.2 U.S.

8.2.3 Canada

8.2.4 Mexico

8.3 Europe

8.3.1 Europe Biologics Regulatory Affairs Outsourcing Market Size by Country

8.3.2 Germany

8.3.3 France

8.3.4 U.K.

8.3.5 Italy

8.3.6 Spain

8.4 Asia Pacific

8.4.1 Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size by Region

8.4.2 China

8.4.3 Japan

8.4.4 South Korea

8.4.5 India

8.4.6 Southeast Asia

8.5 South America

8.5.1 South America Biologics Regulatory Affairs Outsourcing Market Size by Country

8.5.2 Brazil

8.5.3 Argentina

8.5.4 Columbia

8.6 Middle East and Africa

8.6.1 Middle East and Africa Biologics Regulatory Affairs Outsourcing Market Size by Region

8.6.2 Saudi Arabia

8.6.3 UAE

8.6.4 Egypt

8.6.5 Nigeria

8.6.6 South Africa

9 KEY COMPANIES PROFILE

9.1 Lonza AG

9.1.1 Lonza AG Basic Information

9.1.2 Lonza AG Biologics Regulatory Affairs Outsourcing Product Overview

9.1.3 Lonza AG Biologics Regulatory Affairs Outsourcing Product Market Performance

9.1.4 Lonza AG SWOT Analysis

9.1.5 Lonza AG Business Overview

9.1.6 Lonza AG Recent Developments

9.2 Wuxi AppTec Inc.

9.2.1 Wuxi AppTec Inc. Basic Information

9.2.2 Wuxi AppTec Inc. Biologics Regulatory Affairs Outsourcing Product Overview

9.2.3 Wuxi AppTec Inc. Biologics Regulatory Affairs Outsourcing Product Market

Performance

9.2.4 Wuxi AppTec Inc. SWOT Analysis

9.2.5 Wuxi AppTec Inc. Business Overview

9.2.6 Wuxi AppTec Inc. Recent Developments

9.3 Thermo Fisher Scientific Inc.

9.3.1 Thermo Fisher Scientific Inc. Basic Information

9.3.2 Thermo Fisher Scientific Inc. Biologics Regulatory Affairs Outsourcing Product Overview

9.3.3 Thermo Fisher Scientific Inc. Biologics Regulatory Affairs Outsourcing Product Market Performance

9.3.4 Thermo Fisher Scientific Inc. SWOT Analysis

9.3.5 Thermo Fisher Scientific Inc. Business Overview

9.3.6 Thermo Fisher Scientific Inc. Recent Developments

9.4 Eurofins Scientific SE

9.4.1 Eurofins Scientific SE Basic Information

9.4.2 Eurofins Scientific SE Biologics Regulatory Affairs Outsourcing Product Overview

9.4.3 Eurofins Scientific SE Biologics Regulatory Affairs Outsourcing Product Market

Performance

9.4.4 Eurofins Scientific SE Business Overview

9.4.5 Eurofins Scientific SE Recent Developments

9.5 Freyr solutions

9.5.1 Freyr solutions Basic Information

9.5.2 Freyr solutions Biologics Regulatory Affairs Outsourcing Product Overview

9.5.3 Freyr solutions Biologics Regulatory Affairs Outsourcing Product Market

Performance

- 9.5.4 Freyr solutions Business Overview
- 9.5.5 Freyr solutions Recent Developments

9.6 Catalent Inc.

- 9.6.1 Catalent Inc. Basic Information
- 9.6.2 Catalent Inc. Biologics Regulatory Affairs Outsourcing Product Overview
- 9.6.3 Catalent Inc. Biologics Regulatory Affairs Outsourcing Product Market

Performance

- 9.6.4 Catalent Inc. Business Overview
- 9.6.5 Catalent Inc. Recent Developments

9.7 Piramal Group

- 9.7.1 Piramal Group Basic Information
- 9.7.2 Piramal Group Biologics Regulatory Affairs Outsourcing Product Overview
- 9.7.3 Piramal Group Biologics Regulatory Affairs Outsourcing Product Market

Performance

- 9.7.4 Piramal Group Business Overview
- 9.7.5 Piramal Group Recent Developments

9.8 AGC Biologics

- 9.8.1 AGC Biologics Basic Information
- 9.8.2 AGC Biologics Biologics Regulatory Affairs Outsourcing Product Overview
- 9.8.3 AGC Biologics Biologics Regulatory Affairs Outsourcing Product Market

Performance

- 9.8.4 AGC Biologics Business Overview
- 9.8.5 AGC Biologics Recent Developments

9.9 ICON Plc.

- 9.9.1 ICON Plc. Basic Information
- 9.9.2 ICON Plc. Biologics Regulatory Affairs Outsourcing Product Overview
- 9.9.3 ICON Plc. Biologics Regulatory Affairs Outsourcing Product Market Performance
- 9.9.4 ICON Plc. Business Overview
- 9.9.5 ICON Plc. Recent Developments

9.10 Charles River Laboratories International, Inc.

- 9.10.1 Charles River Laboratories International, Inc. Basic Information
- 9.10.2 Charles River Laboratories International, Inc. Biologics Regulatory Affairs Outsourcing Product Overview
- 9.10.3 Charles River Laboratories International, Inc. Biologics Regulatory Affairs Outsourcing Product Market Performance
- 9.10.4 Charles River Laboratories International, Inc. Business Overview
- 9.10.5 Charles River Laboratories International, Inc. Recent Developments

9.11 Labcorp

- 9.11.1 Labcorp Basic Information
- 9.11.2 Labcorp Biologics Regulatory Affairs Outsourcing Product Overview
- 9.11.3 Labcorp Biologics Regulatory Affairs Outsourcing Product Market Performance
- 9.11.4 Labcorp Business Overview
- 9.11.5 Labcorp Recent Developments
- 9.12 Parexel International
 - 9.12.1 Parexel International Basic Information
 - 9.12.2 Parexel International Biologics Regulatory Affairs Outsourcing Product Overview
 - 9.12.3 Parexel International Biologics Regulatory Affairs Outsourcing Product Market Performance
 - 9.12.4 Parexel International Business Overview
 - 9.12.5 Parexel International Recent Developments
- 9.13 Medpace Holdings, Inc.
 - 9.13.1 Medpace Holdings, Inc. Basic Information
 - 9.13.2 Medpace Holdings, Inc. Biologics Regulatory Affairs Outsourcing Product Overview
 - 9.13.3 Medpace Holdings, Inc. Biologics Regulatory Affairs Outsourcing Product Market Performance
 - 9.13.4 Medpace Holdings, Inc. Business Overview
 - 9.13.5 Medpace Holdings, Inc. Recent Developments
- 9.14 IQVIA
 - 9.14.1 IQVIA Basic Information
 - 9.14.2 IQVIA Biologics Regulatory Affairs Outsourcing Product Overview
 - 9.14.3 IQVIA Biologics Regulatory Affairs Outsourcing Product Market Performance
 - 9.14.4 IQVIA Business Overview
 - 9.14.5 IQVIA Recent Developments
- 9.15 Syneos Health
 - 9.15.1 Syneos Health Basic Information
 - 9.15.2 Syneos Health Biologics Regulatory Affairs Outsourcing Product Overview
 - 9.15.3 Syneos Health Biologics Regulatory Affairs Outsourcing Product Market Performance
 - 9.15.4 Syneos Health Business Overview
 - 9.15.5 Syneos Health Recent Developments
- 9.16 SGS SA (SGS)
 - 9.16.1 SGS SA (SGS) Basic Information
 - 9.16.2 SGS SA (SGS) Biologics Regulatory Affairs Outsourcing Product Overview
 - 9.16.3 SGS SA (SGS) Biologics Regulatory Affairs Outsourcing Product Market Performance

- 9.16.4 SGS SA (SGS) Business Overview
- 9.16.5 SGS SA (SGS) Recent Developments

10 BIOLOGICS REGULATORY AFFAIRS OUTSOURCING MARKET FORECAST BY REGION

- 10.1 Global Biologics Regulatory Affairs Outsourcing Market Size Forecast
- 10.2 Global Biologics Regulatory Affairs Outsourcing Market Forecast by Region
 - 10.2.1 North America Market Size Forecast by Country
 - 10.2.2 Europe Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country
 - 10.2.3 Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size Forecast by Region
 - 10.2.4 South America Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country
 - 10.2.5 Middle East and Africa Forecasted Sales of Biologics Regulatory Affairs Outsourcing by Country

11 FORECAST MARKET BY TYPE AND BY APPLICATION (2026-2035)

- 11.1 Global Biologics Regulatory Affairs Outsourcing Market Forecast by Type (2026-2035)
 - 11.1.1 Global Biologics Regulatory Affairs Outsourcing Market Size Forecast by Type (2026-2035)
- 11.2 Global Biologics Regulatory Affairs Outsourcing Market Forecast by Application (2026-2035)
 - 11.2.1 Global Biologics Regulatory Affairs Outsourcing Market Size (M USD) Forecast by Application (2026-2035)

12 CONCLUSION AND KEY FINDINGS

List Of Tables

LIST OF TABLES

Table 1. Introduction of the Type

Table 2. Introduction of the Application

Table 3. Global Biologics Regulatory Affairs Outsourcing Market Size by Type (M USD)

Table 4. Global Biologics Regulatory Affairs Outsourcing Market Size by Application

Table 5. Biologics Regulatory Affairs Outsourcing Market Size Comparison by Region (M USD)

Table 6. Global Biologics Regulatory Affairs Outsourcing Revenue (M USD) by Company (2020-2025)

Table 7. Global Biologics Regulatory Affairs Outsourcing Revenue Share by Company (2020-2025)

Table 8. Company Type (Tier 1, Tier 2, and Tier 3) & (based on the Revenue in Biologics Regulatory Affairs Outsourcing as of 2025)

Table 9. Headquarters, Areas Served, and Product Types of Major Players

Table 10. Product Type of Major Players

Table 11. Global Biologics Regulatory Affairs Outsourcing Company Market Concentration Ratio (CR5 and HHI)

Table 12. Mergers & Acquisitions, Expansion Plans

Table 13. Midstream Market Analysis

Table 14. Downstream Customer Analysis

Table 15. Key Development Trends

Table 16. Driving Factors

Table 17. Biologics Regulatory Affairs Outsourcing Market Challenges

Table 18. Goldman Sachs' forecast real GDP growth rate for 2024-2026

Table 19. S&P Global ' Forecast Real GDP Growth Rate For 2024-2027

Table 20. World Bank ' Forecast Real GDP Growth Rate For 2024-2026

Table 21. Global Biologics Regulatory Affairs Outsourcing Market Size by Type (M USD)

Table 22. Global Biologics Regulatory Affairs Outsourcing Market Size (M USD) by Type (2020-2025)

Table 23. Global Biologics Regulatory Affairs Outsourcing Market Share by Type (2020-2025)

Table 24. Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Type (2021-2025)

Table 25. Global Biologics Regulatory Affairs Outsourcing Market Size by Application

Table 26. Global Biologics Regulatory Affairs Outsourcing Market Size by Application

(2020-2025) & (M USD)

Table 27. Global Biologics Regulatory Affairs Outsourcing Market Share by Application (2020-2025)

Table 28. Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Application (2021-2025)

Table 29. Global Biologics Regulatory Affairs Outsourcing Market Size by Region (2020-2025) & (M USD)

Table 30. Global Biologics Regulatory Affairs Outsourcing Market Size Market Share by Region (2020-2025)

Table 31. North America Biologics Regulatory Affairs Outsourcing Market Size by Country (2020-2025) & (M USD)

Table 32. Europe Biologics Regulatory Affairs Outsourcing Market Size by Country (2020-2025) & (M USD)

Table 33. Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size by Region (2020-2025) & (M USD)

Table 34. South America Biologics Regulatory Affairs Outsourcing Market Size by Country (2020-2025) & (M USD)

Table 35. Middle East and Africa Biologics Regulatory Affairs Outsourcing Market Size by Region (2020-2025) & (M USD)

Table 36. Lonza AG Basic Information

Table 37. Lonza AG Biologics Regulatory Affairs Outsourcing Product Overview

Table 38. Lonza AG Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 39. Lonza AG SWOT Analysis

Table 40. Lonza AG Business Overview

Table 41. Lonza AG Recent Developments

Table 42. Wuxi AppTec Inc. Basic Information

Table 43. Wuxi AppTec Inc. Biologics Regulatory Affairs Outsourcing Product Overview

Table 44. Wuxi AppTec Inc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 45. Wuxi AppTec Inc. SWOT Analysis

Table 46. Wuxi AppTec Inc. Business Overview

Table 47. Wuxi AppTec Inc. Recent Developments

Table 48. Thermo Fisher Scientific Inc. Basic Information

Table 49. Thermo Fisher Scientific Inc. Biologics Regulatory Affairs Outsourcing Product Overview

Table 50. Thermo Fisher Scientific Inc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 51. Thermo Fisher Scientific Inc. SWOT Analysis

Table 52. Thermo Fisher Scientific Inc. Business Overview

Table 53. Thermo Fisher Scientific Inc. Recent Developments

Table 54. Eurofins Scientific SE Basic Information

Table 55. Eurofins Scientific SE Biologics Regulatory Affairs Outsourcing Product Overview

Table 56. Eurofins Scientific SE Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 57. Eurofins Scientific SE Business Overview

Table 58. Eurofins Scientific SE Recent Developments

Table 59. Freyr solutions Basic Information

Table 60. Freyr solutions Biologics Regulatory Affairs Outsourcing Product Overview

Table 61. Freyr solutions Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 62. Freyr solutions Business Overview

Table 63. Freyr solutions Recent Developments

Table 64. Catalent Inc. Basic Information

Table 65. Catalent Inc. Biologics Regulatory Affairs Outsourcing Product Overview

Table 66. Catalent Inc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 67. Catalent Inc. Business Overview

Table 68. Catalent Inc. Recent Developments

Table 69. Piramal Group Basic Information

Table 70. Piramal Group Biologics Regulatory Affairs Outsourcing Product Overview

Table 71. Piramal Group Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 72. Piramal Group Business Overview

Table 73. Piramal Group Recent Developments

Table 74. AGC Biologics Basic Information

Table 75. AGC Biologics Biologics Regulatory Affairs Outsourcing Product Overview

Table 76. AGC Biologics Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 77. AGC Biologics Business Overview

Table 78. AGC Biologics Recent Developments

Table 79. ICON Plc. Basic Information

Table 80. ICON Plc. Biologics Regulatory Affairs Outsourcing Product Overview

Table 81. ICON Plc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 82. ICON Plc. Business Overview

Table 83. ICON Plc. Recent Developments

- Table 84. Charles River Laboratories International, Inc. Basic Information
- Table 85. Charles River Laboratories International, Inc. Biologics Regulatory Affairs Outsourcing Product Overview
- Table 86. Charles River Laboratories International, Inc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 87. Charles River Laboratories International, Inc. Business Overview
- Table 88. Charles River Laboratories International, Inc. Recent Developments
- Table 89. Labcorp Basic Information
- Table 90. Labcorp Biologics Regulatory Affairs Outsourcing Product Overview
- Table 91. Labcorp Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 92. Labcorp Business Overview
- Table 93. Labcorp Recent Developments
- Table 94. Parexel International Basic Information
- Table 95. Parexel International Biologics Regulatory Affairs Outsourcing Product Overview
- Table 96. Parexel International Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 97. Parexel International Business Overview
- Table 98. Parexel International Recent Developments
- Table 99. Medpace Holdings, Inc. Basic Information
- Table 100. Medpace Holdings, Inc. Biologics Regulatory Affairs Outsourcing Product Overview
- Table 101. Medpace Holdings, Inc. Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 102. Medpace Holdings, Inc. Business Overview
- Table 103. Medpace Holdings, Inc. Recent Developments
- Table 104. IQVIA Basic Information
- Table 105. IQVIA Biologics Regulatory Affairs Outsourcing Product Overview
- Table 106. IQVIA Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 107. IQVIA Business Overview
- Table 108. IQVIA Recent Developments
- Table 109. Syneos Health Basic Information
- Table 110. Syneos Health Biologics Regulatory Affairs Outsourcing Product Overview
- Table 111. Syneos Health Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)
- Table 112. Syneos Health Business Overview
- Table 113. Syneos Health Recent Developments

Table 114. SGS SA (SGS) Basic Information

Table 115. SGS SA (SGS) Biologics Regulatory Affairs Outsourcing Product Overview

Table 116. SGS SA (SGS) Biologics Regulatory Affairs Outsourcing Revenue (M USD) and Gross Margin (2020-2025)

Table 117. SGS SA (SGS) Business Overview

Table 118. SGS SA (SGS) Recent Developments

Table 119. Global Biologics Regulatory Affairs Outsourcing Market Size Forecast by Region (2026-2035) & (M USD)

Table 120. North America Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country (2026-2035) & (M USD)

Table 121. Europe Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country (2026-2035) & (M USD)

Table 122. Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size Forecast by Region (2026-2035) & (M USD)

Table 123. South America Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country (2026-2035) & (M USD)

Table 124. Middle East and Africa Biologics Regulatory Affairs Outsourcing Market Size Forecast by Country (2026-2035) & (M USD)

Table 125. Global Biologics Regulatory Affairs Outsourcing Market Size Forecast by Type (2026-2035) & (M USD)

Table 126. Global Biologics Regulatory Affairs Outsourcing Market Size Forecast by Application (2026-2035) & (M USD)

List Of Figures

LIST OF FIGURES

- Figure 1. Industry Chain of Biologics Regulatory Affairs Outsourcing
- Figure 2. Data Triangulation
- Figure 3. Key Caveats
- Figure 4. Global Biologics Regulatory Affairs Outsourcing Market Size (M USD), 2025-2035
- Figure 5. Global Biologics Regulatory Affairs Outsourcing Market Size (M USD) (2020-2035)
- Figure 6. Evaluation Matrix of Segment Market Development Potential (Type)
- Figure 7. Evaluation Matrix of Segment Market Development Potential (Application)
- Figure 8. Evaluation Matrix of Regional Market Development Potential
- Figure 9. Biologics Regulatory Affairs Outsourcing Market Size by Country (M USD)
- Figure 10. Company Assessment Quadrant
- Figure 11. Global Biologics Regulatory Affairs Outsourcing Product Life Cycle
- Figure 12. Global Biologics Regulatory Affairs Outsourcing Revenue Share by Company in 2025
- Figure 13. Biologics Regulatory Affairs Outsourcing Market Share by Company Type (Tier 1, Tier 2 and Tier 3): 2025
- Figure 14. The Global 5 and 10 Largest Players: Market Share by Biologics Regulatory Affairs Outsourcing Revenue in 2025
- Figure 15. Value Chain Map of Biologics Regulatory Affairs Outsourcing
- Figure 16. Global Biologics Regulatory Affairs Outsourcing Market PEST Analysis
- Figure 17. Global Biologics Regulatory Affairs Outsourcing Market Porter's Five Forces Analysis
- Figure 18. Evaluation Matrix of Segment Market Development Potential (Type)
- Figure 19. Global Biologics Regulatory Affairs Outsourcing Market Share by Type
- Figure 20. Market Share of Biologics Regulatory Affairs Outsourcing by Type (2020-2025)
- Figure 21. Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Type (2021-2025)
- Figure 22. Evaluation Matrix of Segment Market Development Potential (Application)
- Figure 23. Global Biologics Regulatory Affairs Outsourcing Market Share by Application
- Figure 24. Global Biologics Regulatory Affairs Outsourcing Market Share by Application (2020-2025)
- Figure 25. Global Biologics Regulatory Affairs Outsourcing Market Share by Application in 2024

Figure 26. Global Biologics Regulatory Affairs Outsourcing Market Size Growth Rate by Application (2021-2025)

Figure 27. Global Biologics Regulatory Affairs Outsourcing Market Size Market Share by Region (2020-2025)

Figure 28. North America Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 29. North America Biologics Regulatory Affairs Outsourcing Market Size Market Share by Country in 2024

Figure 30. U.S. Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 31. Canada Biologics Regulatory Affairs Outsourcing Market Size (M USD) and Growth Rate (2020-2025)

Figure 32. Mexico Biologics Regulatory Affairs Outsourcing Market Size (M USD) and Growth Rate (2020-2025)

Figure 33. Europe Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 34. Europe Biologics Regulatory Affairs Outsourcing Market Share by Country in 2024

Figure 35. Germany Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 36. France Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 37. U.K. Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 38. Italy Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 39. Spain Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 40. Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (M USD)

Figure 41. Asia Pacific Biologics Regulatory Affairs Outsourcing Market Size Market Share by Region in 2024

Figure 42. China Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 43. Japan Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 44. South Korea Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 45. India Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate

(2020-2025) & (M USD)

Figure 46. Southeast Asia Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 47. South America Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (M USD)

Figure 48. South America Biologics Regulatory Affairs Outsourcing Market Size Market Share by Country in 2024

Figure 49. Brazil Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 50. Argentina Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 51. Columbia Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 52. Middle East and Africa Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (M USD)

Figure 53. Middle East and Africa Biologics Regulatory Affairs Outsourcing Market Size Market Share by Region in 2024

Figure 54. Saudi Arabia Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 55. UAE Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 56. Egypt Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 57. Nigeria Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 58. South Africa Biologics Regulatory Affairs Outsourcing Market Size and Growth Rate (2020-2025) & (M USD)

Figure 59. Global Biologics Regulatory Affairs Outsourcing Market Size Forecast by Value (2020-2035) & (M USD)

Figure 60. Global Biologics Regulatory Affairs Outsourcing Market Share Forecast by Type (2026-2035)

Figure 61. Global Biologics Regulatory Affairs Outsourcing Market Share Forecast by Application (2026-2035)

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