

Healthcare Regulatory Affairs Outsourcing Market Size, Opportunities, Trends, Products, Revenue Analysis, For 2028

Market Size – USD 6.5 Billion in 2020, Market Growth - CAGR of 12.5%, Market Trends – Increasing healthcare R&D activities and increasing applications

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Rising demand for regulatory affairs outsourcing services in the healthcare industry is one of the key drivers for market growth

The global healthcare regulatory affairs outsourcing market size is expected to reach USD 16.67 billion in 2028 and register a revenue CAGR of 12.5% over the forecast period, according to the latest report by Reports and Data. Market revenue growth is significantly driven by increasing R&D activities across the pharmaceutical and biotechnology sectors, rising volumes of clinical trial applications, and growing need for timely product registration and approvals. Healthcare regulatory affairs outsourcing services predominantly include regulatory writing & publishing, regulatory submissions, clinical trial application, product registration, and regulatory consulting and legal services offered by highly experienced medical writers, publishers, and quality control (QC) auditors. These services are mostly utilized by large and mid-sized pharmaceutical companies, biotechnology companies, and medical device manufacturing companies. Regulatory affairs outsourcing ensures that these companies strictly comply with the product quality and safety standards and policies set by regulatory authorities.

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The report provides comprehensive assessment of the market covering key elements such as revenue estimations, cost analysis, import/export, production and consumption trends, CAGR, gross margin, and supply & demand patterns. It also sheds light on recent technological developments, product advancements, and research and development activities in the region.

The report examines the key players operating in the market along with their market position, market share, revenue, gross margin, and business strategies. SWOT analysis and Porter's Five Forces Analysis are used to examine and assess the market and its players. It also covers recent mergers and acquisitions, joint ventures, collaborations, agreements, partnerships, and product

launches and brand promotions.

Key companies profiled in the report include:

Covance Group Ltd., Parexel International Corporation, Accell Clinical Research LLC, Clinilabs Inc., Pharmaceutical Product Development, Medelis Inc., Freyr Solutions, Quintiles Transnational Holdings, Inc., Charles River Laboratories International, Inc., KAI Research, Inc., Medpace Inc., Criterium Inc., Cardinal Health, IQVIA, and ICON Plc.

Market Segmentation by Types:

Service Type Outlook (Revenue, USD Billion; 2018-2028)

Regulatory writing & publishing
Regulatory submissions
Clinical Trial Applications
Product Registrations
Regulatory Consulting and Legal Representation
Others

Stage Outlook (Revenue, USD Billion; 2018-2028)

Clinical

Preclinical

PMA (Post Market Authorization)

Category Outlook (Revenue, USD Billion; 2018-2028)

Drugs

Generics

Innovators

Biologics

Biotech

ATMPs

Biosimilars

Medical devices

Therapeutic

Diagnostic

End-use Outlook (Revenue, USD Billion; 2018-2028)

Pharmaceutical Companies

Biotechnology Companies

Medical Device Companies

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Regional analysis covers in-depth analysis of analysis of the revenue, market share, and growth rate of the global Healthcare Regulatory Affairs Outsourcing market in each region for the forecast period of 2021-2028. The report covers production and consumption rate, current and emerging trends, import/export, supply and demand, and presence of key players in each region.

North America

U.S.

Canada

Mexico

Europe

Germany

U.K.

Italy

France

BENELUX

Rest of Europe

Asia Pacific

China

India

Japan

South Korea

Rest of APAC

Latin America

Brazil

Rest of LATAM

Middle East & Africa

Saudi Arabia

U.A.E.

South Africa

Rest of MEA

Some Key Highlights from the Report:

Based on service type, the regulatory writing & publishing segment accounted for the highest revenue share of around 40% in 2020. Increasing need for high-quality, comprehensive and convincing regulatory filing documents and rising demand for regulatory writing & publishing services among healthcare companies including medical device and biopharmaceutical companies are key factors supporting the growth of this segment.

The clinical stage segment held the largest revenue share in 2020 and is expected to register the highest revenue CAGR over the forecast period. Growing number of clinical trial registrations and increasing development of biologics and personalized orphan drugs the major factors expected to fuel this segment's growth.

Based on end-use, the pharmaceutical companies segment is projected to register the highest

CAGR during the forecast period. Factors majorly contributing to this segment's growth are growing need for development of advanced pharmaceutical products, increasing number of clinical trials, and surging need for regulatory affairs outsourcing services.

Among regional markets, the North America market was the most dominant in terms of revenue share contribution in 2020. Increasing life sciences research & development programs, rise in drug discovery & development activities, growing number of clinical trials, and presence of leading pharmaceutical and biotechnology companies in the region are the most important factors accounting for the North America market growth.

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