

Regulatory Affairs Outsourcing Market will Grow at a Lucrative CAGR of 19% through 2021-2028

Regulatory Affairs Outsourcing Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2021-2028

WILMINGTON, DELAWARE, USA, June 22, 2022 /EINPresswire.com/ -- According to the report, the global <u>regulatory affairs outsourcing market</u> was valued at US\$ 4.5 Bn in 2020 and is projected to expand at a CAGR of 19.0% from 2021 to 2028. Regulatory affairs outsourcing refers to the hiring of third-party services by government bodies and private organizations to ensure public health and safety. The services include managing regulatory requirements for generic drugs, innovator drugs, biologics, biosimilars, etc.

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The outsourcing organizations control the safety and efficacy of the products and ensure that these are safe for consumption. These services are required for clinical trial and patent application, regulatory writing & publishing, product registration, and legal representation. Pharmaceutical organizations also opt for these services to seek speedy government approvals in various regions.

Increase in Pharmaceutical and Biotechnological Industries Globally

The growth of pharmaceutical and biotechnological industries across the globe is a key factor boosting the global regulatory affairs outsourcing market. Moreover, rise in focus of pharmaceutical organizations on expanding their operations and supplies in emerging economies propels the global market. Outsourcing regulatory affairs aids in minimizing the costs associated with managing in-house resources, such as facilities, training, technology, specialized knowledge, and geographic regulations.

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Regulatory affairs outsourcing services are also widely used for the development of biosimilars, orphan, and generic drugs. Life sciences organizations are increasingly outsourcing non-core

functions and regulatory services and improving their overall operational efficiencies. This, in turn, contributes to the growth of the global regulatory affairs outsourcing market.

Regulatory Writing & Publishing Segment to Dominate Market

In terms of service, the global regulatory affairs outsourcing market has been classified into regulatory affairs, clinical trial applications & product registrations, regulatory writing & publishing, regulatory consulting & legal representation, and others. The regulatory writing & publishing segment accounted for major share of the global market in 2020.

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North America to Dominate Global Market

In terms of region, the global regulatory affairs outsourcing market has been segmented into North America, Europe, Asia Pacific, Latin America, and Middle East & Africa. North America dominated the global market in 2020. Rise in the number of patent expirations and increase in cost of research & development activities are key factors driving the market in the region. However, the market in North America is likely to be hampered by high price fluctuations and hidden expenses in regulatory services provided by various clinical research organizations during the forecast period.

The U.S. is the largest market for healthcare regulatory affairs outsourcing in the world. Significant R&D in the field of drug discovery in the country can be attributed to the growth of the market in the country.

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Competition Landscape

The global regulatory affairs outsourcing market is fragmented in terms of number of players. Key players in the global market include Accell Clinical Research, LLC, Charles River Laboratories International, Inc., Clinilabs, Inc., Covance, Inc., Criterium, Inc., ICON plc, Medpace, Inc., PAREXEL International Corporation, Pharmaceutical Product Development, (PPD) LLC, Promedica International, Quintiles Transnational Corporation, and WuXi App Tec.

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