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Biologics Regulatory Affairs Outsourcing Market Size, Share & Trends Analysis Report By Service (Regulatory Consulting), By Phase (Preclinical), By Modality, Phase by Service, Phase by Modality, Modality by Service, By Region, And Segment Forecasts, 2024 - 2030

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Abstracts

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Biologics Regulatory Affairs Outsourcing Market Growth & Trends

The global biologics regulatory affairs outsourcing market size is expected t%li%reach USD 3.69 billion by 2030, registering a CAGR of 8.87% from 2024 t%li%2030, according t%li%a new report by Grand View Research, Inc. Globalization of biopharmaceutical companies is one of the major growth drivers boosting overall market demand. Emerging markets of Asia Pacific, Latin America, and MEA regions offer low product development & manufacturing costs, tax benefits, and availability of skilled labor at relatively low costs with supportive regulations. The abovementioned factors have made the regional markets attractive prospects in terms of outsourcing and expansion for biopharmaceutical companies, thereby stimulating the demand for regulatory services. Furthermore, the presence of EMA- and/or FDA-approved facilities in emerging economies is anticipated t%li%increase foreign investments in the country and the demand for regulatory services, such as legal representation and regulatory consulting services.

A significant increase has been witnessed in the number of clinical trials conducted in emerging economies. This can be attributed t%li%the availability of skilled labor,

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advanced technologies, and infrastructure facilities at relatively lower costs than developed economies such as the U.S., which is expected t%li%stimulate the demand for regulatory services such as clinical trial applications & product registrations in these regions. Emerging economies contribute t%li%more than 30.0% of total clinical trial applications submitted across the globe, and the share is expected t%li%increase over the coming years, contributing t%li%market growth.

Several biopharmaceutical companies are focusing on their core competencies and outsourcing noncore functions t%li%increase their productivity & operational efficiency. These companies face several challenges with regard t%li%complying with global regulations, which can be a lengthy and tedious process. Thus, the race t%li%launch a novel molecule in the market in a feasible timeline and at a reasonable cost will likely propel the demand for service providers. Furthermore, many small- and medium-scale biopharma companies lacking in-house capabilities are inclined towards outsourcing regulatory affairs, which is estimated t%li%positively influence the industry's progression.

Growth in markets for biosimilars, orphan drugs, personalized medicines, adaptive trial designs, and others is projected t%li%boost the demand for regulatory specialization in these areas. As several companies expand int%li%new avenues, the increasing need for skilled service providers with experience in regulations leads t%li%the necessity t%li%comply with regulations. Government support, especially in developed economies, has significantly increased the development of orphan drugs. Patent expiration of biologics, such as Simulect, Vectibix, Mircera, and Kineret, is increasing the demand and development of biosimilars, thereby contributing t%li%the demand for regulatory services in this segment.

Biologics Regulatory Affairs Outsourcing Market Report Highlights

The regulatory writing & publishing segment held the largest market share in 2023. The high segment growth is owing t%li%the increasing complexity of biologics requiring precise and comprehensive documentation, stringent global regulatory requirements demanding thorough submissions, and the need for specialized expertise t%li%ensure compliance. The rapid pace of innovation in biologics, such as gene therapies and biosimilars, necessitates up-to-date knowledge of evolving regulations is anticipated overall market growth

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The pharmaceutical companies segment accounted for the largest revenue share of over 76.23% in 2023. The segmental growth is owing t%li%a high number of clinical trials for biologics, a growing product pipeline for ATMPs, stringent regulatory guidelines for advanced therapeutics, and growing outsourcing trends for non-core activities such as clinical trials, data management, regulatory compliance etc., are few factors further boosting segment growth

The monoclonal antibodies (mAbs) segment accounted for the largest revenue share in 2023. The segmental growth is owing t%li%rapid advancements in mAb technology, including novel delivery methods and therapeutic targets, which require updated and precise regulatory strategies leading t%li%overall market growth potential

North America dominated the market with a share of 30.54% in 2023. The regional market growth is owing t%li%high R&D activities and government initiatives for clinical trials. Moreover, the strong presence of biopharmaceutical companies and outsourcing service providers is another major factor expected t%li%propel market growth. For instance, in October 2021, the U.S. FDA approved 11 novel clinical trial research, resulting in over USD 25 million in funding over the next four years t%li%support the development of innovative drugs t%li%treat rare diseases

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