Trusted Business Insights
&
Grand View Research

REPORT OVERVIEW: REGULATORY AFFAIRS OUTSOURCING MARKET

The global regulatory affairs outsourcing market size was estimated at USD 5.2 billion in 2020 and is anticipated to witness a CAGR of 10.8% over the forecast period 2021-2027. An increase in geographical expansion activities by companies that aim for speedy approvals in global markets is expected to contribute to the adoption of outsourcing models for healthcare regulatory affairs services. The outsourcing market for healthcare regulatory affairs is expanding rapidly due to the increase in the R&D activities, clinical trial applications, product registration, and drug pipeline. Companies are under constant pressure to procure timely clinical approvals from regulators in different regions.

Regulatory approval procedures are becoming more stringent and time-consuming, and market players aim to obtain approval for the product in the first attempt to gain higher market shares. Companies are required to have an in-house regulatory affairs department or they are outsourcing the regulatory affairs department due to stringent regulatory requirements in developed countries and changing regulations in developing countries. Establishing an in-house regulatory affairs department in offshore countries is not feasible. Hence, companies are adopting different outsourcing models based on the size and priority of the projects, thereby contributing to the market for healthcare regulatory affairs outsourcing.

Regulatory affairs outsourcing functions are challenging. The increasing demand to obtain approval for new products, maintain compliance, and doing more with less have increased during the last decade. Simultaneously, investments in the regulatory information systems have increased considerably to keep pace with the need to automate activities like regulatory publishing and operations. In this scenario, outsourcing is gradually becoming a integral part of the regulatory capability mix.

The pressure to reduce costs by life sciences companies is very high. The shift toward outcome-based model, increase in the use of generics, and demand for drugs and medical devices at a lesser price are expected to increase the need to reduce healthcare costs. An Increase in out-of-pocket expenses, uneven economic growth, and measures taken by various governments to maintain the cost of drugs are expected to contribute to the economic and competitive pressure.

Life science companies are now focusing on their core competencies and outsourcing noncore functions to increase their productivity and operational efficiency. These companies commonly outsource R&D functions to emerging markets, such as the Asia

Pacific and MEA, and have now started outsourcing regulatory affairs function to CROs or service providers for reducing cost and increasing focus on core functions.

SERVICE INSIGHTS: REGULATORY AFFAIRS OUTSOURCING MARKET

Based on services, the healthcare regulatory affairs outsourcing market is segmented into legal representation, product registration and clinical trial applications, regulatory writing and publishing, regulatory consulting, and other services. The regulatory writing and publishing segment led the market with the highest revenue in 2019. These services are offered from the early stages of product development to the premarket approval phase.

The legal representation segment is anticipated to witness the fastest growth over the forecast period due to the increasing demand for legal representatives across the globe caused by the globalization of medical device companies. For instance, companies not locally present in Europe require legal representatives to gain market authorization.

End-Use Insights

On the basis of end-use, the regulatory affairs outsourcing market is segmented into medical device companies, pharmaceutical companies, and biotechnology companies. The pharmaceutical companies segment was the largest in 2019 in terms of both the revenue and market share. This is due to the growth in evolving areas such as biosimilar, orphan drugs, personalized medicines, companion diagnostics, and adaptive trial designs, which is boosting market growth.

The shrinking pipeline of blockbuster drugs has led to efficient manufacturing and development of pharmaceutical products, which leads to the adoption of the full-time regulatory affairs outsourcing models by life sciences companies to reduce the overall cost of development. Small and mid-size companies hire consultants to manage their regulatory affairs outsourcing in the new territories. Thus, the demand for healthcare regulatory affairs consultants for outsourcing the services in small and mid-size life sciences companies is expected to increase owing to the expansion of these companies into new and emerging markets, which is expected to contribute to the growth of the market for healthcare regulatory affairs outsourcing.

REGIONAL INSIGHTS: REGULATORY AFFAIRS OUTSOURCING MARKET

The market was led by the Asia Pacific region in 2019, and the market in this region is expected to grow at the highest rate during the forecast. The growth of this market can be attributed to factors such as low costs of labor and increased availability of skilled workforce. In addition, increasing number of clinical trials and rising number of companies trying to enter markets in countries such as India and China, are expected to contribute to the market of the market for regulatory affairs outsourcing.

North America and Europe are also expected to be the key markets for regulatory affairs outsourcing owing to the presence of two major international agencies-the European Medicines Agency (EMA) and the U.S. FDA, respectively, which regulate more than half of the medical devices worldwide.

REGULATORY AFFAIRS OUTSOURCING MARKET SHARE INSIGHTS: REGULATORY AFFAIRS OUTSOURCING MARKET

Some of the players operating in the market are

- Accell Clinical Research, LLC.
- Genpact Ltd.
- Criterium, Inc.
- PRA Health Sciences
- Promedica International
- WuXi AppTec, Inc.
- Medpace
- Pharmaceutical Product Development, LLC (PPD)
- Charles River Laboratories International, Inc.
- ICON plc
- Covance, Parexel International Corporation; Inc.
- Freyr.

Mergers and acquisitions, collaborations, and expansion geographic presence and product portfolio are some of the key strategic initiatives undertaken by the market players. For instance, in December 2018, Freyr launched an advanced version of its existing publishing and submission tool, SUBMIT PRO. It is designed with an additional focus on regional submission templates of the U.S. FDA, Health Canada, EMA, and other major global health authorities, thereby increasing its product offerings.

This report forecasts revenue growth at global, regional, and country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2016 to 2027. For the purpose of this study, Trusted Business Insights has segmented the global regulatory affairs outsourcing market report on the basis of services, end use, and region:

SERVICE OUTLOOK (REVENUE, USD MILLION, 2016 - 2027)

- Regulatory Consulting

- Legal Representation
- Regulatory Writing & Publishing
- Product Registration & Clinical Trial Applications
- Other Services

END-USE OUTLOOK (REVENUE, USD MILLION, 2016 - 2027)

- Medical Device Companies
- Pharmaceutical Companies
- Biotechnology Companies