

Regulatory Affairs Outsourcing Market Size, Share & Trends Analysis Report By Category (Biologics, Medical Devices), By Company Size (Medium, Large), By Indication, By Stage, By Services, By End Use, And Segment Forecasts, 2022 - 2030

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Abstracts

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Regulatory Affairs Outsourcing Market Growth & Trends

The global regulatory affairs outsourcing market size is expected to reach USD 13.9 billion by 2030, registering a CAGR of 8.9% over the forecast period, according to a new report by Grand View Research, Inc. Significant increase in the fixed costs of in-house resources for regulatory affairs & operation activities like training, technology, specialized knowledge, and facilities are driving outsourcing of regulatory affair functions. Addressing local regulatory challenges and constant changes in the regulations of the major markets, such as the U.S., Europe, and Asia, is creating demand for these services. Compliance with the current regulations has become an immense chore, leave alone trying to stay up to date with developments around the world. Amendments to current regulations are likely to simplify the regulatory pathway for the industry but in turn, complicate the operation for healthcare product manufacturing companies.

Thus, leading to the regulatory affairs outsourcing to service providers. The market witnessed a significant decline in 2020 due to the outbreak of the COVID-19 pandemic, as there was a halt in clinical trial activities including regulatory updates. Disruption in the supply chain and closure of R&D sites resulted in a significant loss of revenues in 2020 across the industry. However, due to the pandemic, various healthcare companies

are opting for more regulatory advice, as companies push to speed up the product development & approvals in therapies, vaccines, & devices for COVID-19. Owing to the urgent need for medical devices and therapies for COVID-19, regulatory authorities are providing emergency use authorization for the majority of products. Such actions have further promoted the demand for these services post 2020 and the positive rebound of sales across the industry can be witnessed from 2021.

Regulatory Affairs Outsourcing Market Report Highlights

The regulatory writing & publishing services segment dominated the market with the maximum revenue share in 2021 as they are offered from the early stages of development to the post-marketing authorization phase and are vital for the success of a product

The large companies segment is projected to witness the fastest CAGR during the forecast period. The availability of a wide variety of services and the presence of these providers in various geographies are the key factors driving the segment growth

The clinical studies stage segment accounted for the largest market share in 2021 due to the increasing demand for clinical trials in developing countries

The pharmaceutical companies end-use segment is anticipated to witness the fastest growth rate over the forecast period due to evolving areas, such as orphan drugs and personalized therapies

Asia Pacific held the maximum revenue share of the global market in 2021 owing to higher off shoring of such services into regions of economic benefits and the expansion of life sciences companies in countries, such as India & China

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