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Regulatory Affairs Outsourcing Market Size, Share & Trends Analysis Report By Service, By Company Size, By Category, By Indication, By Stage, By End-user, By Region, And Segment Forecasts, 2021 - 2028

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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 14.9 billion by 2028, according to a new report by Grand View Research, Inc. It is expected to expand at a CAGR of 11.9% from 2021 to 2028. A significant increase in the fixed costs of in-house resources for regulatory affairs and operation activities, like training, technology, specialized knowledge, and facilities, is driving the outsourcing of regulatory affairs functions.

Addressing local regulatory challenges and constant changes in the regulations of the major markets, such as the U.S., Europe, and Asia, are creating demand for the 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.

Moreover, due to the COVID-19, various healthcare companies are likely to opt for more regulatory advice in the recovery phase – on remote monitoring, telemedicine, data privacy, and more. Furthermore, as companies push to speed up the product development and approvals in therapies, vaccines, and devices for COVID-19, they are

likely to engage even more intensively with the regulatory agencies.

Regulatory Affairs Outsourcing Market Report Highlights

The regulatory writing and publishing services dominated the market with a share of 36.7% in 2020 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

In terms of company size, the large size companies are projected to expand at the fastest CAGR of 12.3% during the forecast period. Goodwill and resource abundance are the two key factors promoting their selection by end users

By stage, the clinical segment accounted for the largest share of 46.7% in 2020 due to the increasing demand for clinical trials in developing countries

Based on end user, the pharmaceutical companies are anticipated to register the fastest growth rate over the forecast period. This may be due to evolving areas such as orphan drugs and adaptive trial designs

The Asia Pacific held the largest share of 37.9% in 2020 owing to higher offshoring of such services into regions of economic benefits and the expansion of life sciences companies in countries, such as India and China

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