

Global Regulatory Affairs Outsourcing Market Size study, by Services (Regulatory Consulting, Legal Representation, Regulatory Writing & Publishing, Product Registration & Clinical Trial Applications, Other Services) by Company Size (Small, Medium, Large) by Category (Drugs, Generics, Innovators, Biologics, Biotech, ATMPs, Biosimilars, Medical devices, Therapeutic, Diagnostic) by Indication (Oncology, Neurology, Cardiology, Immunology, Others) by Stage (Preclinical, Clinical, PMA (Post Market Authorization)) by End-use (Medical Device Companies, Pharmaceutical Companies, Biotechnology Companies) and Regional Forecasts 2022-2028

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Abstracts

Global Regulatory Affairs Outsourcing Market is valued approximately USD 5.72 billion in 2021 and is anticipated to grow with a healthy growth rate of more than 8.90 % over the forecast period 2022-2028. Regulatory affairs outsourcing is becoming more common in the healthcare industry. The adoption of regulatory outsourcing models is projected to be aided by an increase in geographical expansion activities by corporations seeking quick approvals in local markets. The regulatory affairs outsourcing market is quickly growing as a result of increased R&D activity, which is increasing the number of clinical trial applications and product registrations. Outsourcing

of regulatory affairs duties is being driven by a significant increase in the fixed expenses of in-house resources for regulatory affairs and operations activities such as training, technology, specialist knowledge, and facilities. For example, ProPharma Group bought iSafety Systems, an Indian pharmacovigilance service provider, in August 2021 to boost its pharmacovigilance market position. Similarly, in July 2021, ICON plc purchased PRA Health Sciences, contract research organization that specializes in medication development and regulatory consultation. The goal of this acquisition was to expand ICON plc's service portfolio. The demand for these services is being driven by local legal challenges and frequent changes in the rules of major markets such as the United States, Europe, and Asia.. Amendments to current regulations are likely to make the regulatory process easier for the business, but they will also make it more difficult for healthcare product manufacturers to operate. As a result, regulatory affairs are being outsourced to service providers. This is due to an increase in the number of clinical trial registrations in recent years. ClinicalTrials.gov reports that about 401,716 studies were registered in January 2022, up from around 325,834 by the end of 2019. Furthermore, an increase in the number of biologics, a high demand for innovative technologies, and a need for individualized orphan pharmaceuticals and medicine are all expected to drive segment growth throughout the projection period. However, over the projection period of 2022-2028, rigorous government regulations governing various medical items would stifle market growth.

The key regions considered for the global Regulatory Affairs Outsourcing Market study includes Asia Pacific, North America, Europe, Latin America, and Rest of the World. The Asia Pacific area had the largest share. Over the forecast period, the area is also expected to have the quickest CAGR. This can be linked to an increase in clinical trials as well as a rise in the number of enterprises attempting to penetrate developing markets such as India and China. Another element projected to drive regional market expansion is the availability of a competent labour in the region at cheaper costs than in the United States.

Major market player included in this report are:

Accell Clinical Research, LLC

GenPact Ltd.

Criterion, Inc.

PRA Health Sciences

Promedica International

Dr. Regenold GmbH

BioMapas

Zeincro Group

Parexel International Corp.
Charles River Laboratories International, Inc.

The objective of the study is to define market sizes of different segments & countries in recent years and to forecast the values to the coming eight years. The report is designed to incorporate both qualitative and quantitative aspects of the industry within each of the regions and countries involved in the study. Furthermore, the report also caters the detailed information about the crucial aspects such as driving factors & challenges which will define the future growth of the market. Additionally, the report shall also incorporate available opportunities in micro markets for stakeholders to invest along with the detailed analysis of competitive landscape and product offerings of key players. The detailed segments and sub-segment of the market are explained below:

By Services

Regulatory Consulting

Legal Representation

Regulatory Writing & Publishing

Product Registration & Clinical Trial Applications

Other Services

By Company Size

Small

Medium

Large

By Category

Drugs

Generics

Innovators

Biologics

Biotech

ATMPs

Biosimilars

Medical devices

Therapeutic

Diagnostic

By Indication

Oncology

Neurology

Cardiology

Immunology

Others

By Stage

Preclinical

Clinical

PMA (Post Market Authorization)

By End-use

Medical Device Companies

Pharmaceutical Companies

Biotechnology Companies

By Region:

North America

U.S.

Canada

Europe

UK

Germany

France

Spain

Italy

ROE

Asia Pacific

China

India

Japan

Australia

South Korea

RoAPAC

Latin America

Brazil

Mexico

Rest of the World

Furthermore, years considered for the study are as follows:

Historical year – 2018, 2019, 2020

Base year – 2021

Forecast period – 2022 to 2028

Target Audience of the Global Regulatory Affairs Outsourcing Market in Market Study:

Global Regulatory Affairs Outsourcing Market Size study, by Services (Regulatory Consulting, Legal Representat...

Key Consulting Companies & Advisors
Large, medium-sized, and small enterprises
Venture capitalists
Value-Added Resellers (VARs)
Third-party knowledge providers
Investment bankers
Investors

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