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# 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

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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.
Criterium, Inc.
PRA Health Sciences
Promedica International
Dr. Regenold GmbH
BioMapas
Zeincro Group

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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

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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:

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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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## CHAPTER 12. GLOBAL REGULATORY AFFAIRS OUTSOURCING MARKET, REGIONAL ANALYSIS



## CHAPTER 13. COMPETITIVE INTELLIGENCE

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## CHAPTER 14. RESEARCH PROCESS

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