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Global Medical Device Regulatory Affairs Market Size study, by Service (Regulatory Consulting, Legal Representation, Regulatory Writing & Publishing, Product Registration & Clinical Trial Applications, and Other Services) Type (Diagnostic, and Therapeutic) Service Provider (Outsource, and In-house) and Regional Forecasts 2021-2027

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Abstracts

The Global Medical Device Regulatory Affairs Market is valued approximately USD 4.5 billion in 2020 and is anticipated to grow with a healthy growth rate of more than 8.6% over the forecast period 2021-2027. The global medical device regulatory affairs market is gaining from the changing regulatory landscape and increased need for faster approval processes. The demand for the medical device regulatory affairs is being boosted by the rise of developing industries such as diagnostics and pharmaceuticals. The global market is progressing thanks to favorable government initiatives and the increasing complexity of medical equipment. Manufacturers of medical devices are adopting ways to safeguard their products in response to increased cybersecurity threats and the financial implications of data breaches. When it comes to data transfer to and from the device, the government is supporting these security enhancements to address these dangers and prevent unauthorized access. Market launch and recertification timescales are becoming more challenging due to increased regulatory issues such as medical device regulation and in vitro diagnostic device regulation, as well as regulatory cybersecurity monitoring. Due to the increased need for businesses to address regulatory challenges, the global medical device regulatory affairs market is expanding in demand. For instance, Emergo released 510(k) Builder in February 2020, a new subscription-based software tool that simplifies and streamlines the U.S. drug approval process. The FDA's submissions for medical device manufacturers allow for

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quicker market access. 510(k) Builder has comprehensive integration with FDA databases, assisting users in discovering required data such as product codes and predicate devices, as well as automating documentation formatting to FDA standards. Furthermore, expected modifications in the Medical Devices Regulation (MDR) and the In-vitro Diagnostic Devices Regulation (IVDR) from regulators will make meeting market launch and recertification timeframes much more challenging. As a result, the demand for regulatory outsourcing has grown in order to manage and improve current and ongoing regulatory requirements. As a result, the market is expected to grow.

The main regions of Asia Pacific, North America, Europe, Latin America, and the Rest of the World are included in the geographical analysis of the worldwide Medical Device Regulatory Affairs Market. Currently, the Asia Pacific region is predicted to lead the global medical device regulatory affairs market. The government's initiatives to simplify the regulatory system for foreign investigators, fast approval for innovative products, and simplified procurement restrictions are supporting the global market's growth. Due to the presence of two main international regulatory bodies in each area, the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), North America and Europe are expected to contribute considerably to the development of the global market. More than half of all medical devices are regulated by these authorities, and the US FDA publishes various guidelines for medical device producers to help with the process.

Major market player included in this report are:
Integer Holdings
ICON Plc
SGS SA
Emergo
Intertek Plc
Covance
IQVIA Holdings
Freyr
Medpace
Promedica International

The objective of the study is to define market sizes of different segments & countries in recent years and to forecast the values for 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 inRoute of Administration about the crucial aspects such as driving

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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 Type:
Diagnostic
Therapeutics
By Service:
Regulatory Consulting
Legal Representation
Regulatory Writing & Publishing
Product Registration & Clinical Trial Applications
Other Services
By Service Provider:
Outsource
In-house
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

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Mexico
Rest of the World

Furthermore, years considered for the study are as follows:

Historical year – 2018, 2019
Base year – 2020
Forecast period – 2021 to 2027

Target Audience of the Global Medical Device Regulatory Affairs Market in Market Study:

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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