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Medical Device Regulatory Affairs Market Size, Share & Trends Analysis Report By Services (Regulatory Writing & Publishing, Legal Representation), By Type, By Service Provider, By Region, And Segment Forecasts, 2023 - 2030

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Abstracts

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Medical Device Regulatory Affairs Market Growth & Trends

The global medical device regulatory affairs market size is expected to reach USD 12.1 billion by 2030, according to a new report by Grand View Research, Inc. The market is expected to expand at a CAGR of 10.1% from 2023 to 2030. Technological advancements in medical devices, such as AI and machine learning, increasing trends toward portable and smaller devices, and strict government regulations for medical devices are driving the market.

Medical equipment regulation is a vast and rapidly changing field that is often complicated by legal challenges. Even within one regulatory framework, legal terms and their definitions are not always consistent. As technology expands, software, machine learning, and algorithms become essential component of an increasing number of digital health resources. This presents new challenges as an increasing number of instruments fall under the regulatory framework.

Medical device companies have to deal with continuous changes in regulatory requirements, which can differ based on business activities and geographies. Noncompliance with the changing regulatory requirements can result in penalties and delays, which may lead to a loss of revenue. According to a survey sponsored by

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Genpact, 72.0% of executives from the life sciences industry consider regulatory compliance to be one of the top three challenges they face. Such factors are expected to support the demand for these services further.

Public organizations worldwide are providing funding to improve healthcare R&D. For instance, in March 2022, over USD 188.0 million was funded by the U.K. government to support NHS-led health research pertaining to diagnostics and treatments. Such investments in the future are expected to increase the number of new medical device launches, thus creating opportunities for medical device regulatory services. Such activities are expected to support the market in the forecasted period.

Medical Device Regulatory Affairs Market Report Highlights

The regulatory writing and publishing segment dominated the market with the largest revenue share of 36.6% in 2022. This is due to a rise in the number of clinical trials, government support, and an increasing need to launch the product quickly

Based on type, the therapeutic segment accounted for the larger market share of 55.6% in 2022, due to increasing demand for equipment as a result of technological advancements in developed countries

There is a huge demand for outsourcing these services. Hence, the segment contributed to 57.0% of the global market in 2022. This is largely owing to the lack of in-house capabilities and ever-changing regulations for medical devices across the globe

Asia Pacific dominated the market and accounted for 37.5% of the revenue share in 2022. This is largely due to the expanding medical device market in India as a result of increased health awareness, a growing middle class, and government health initiatives.

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