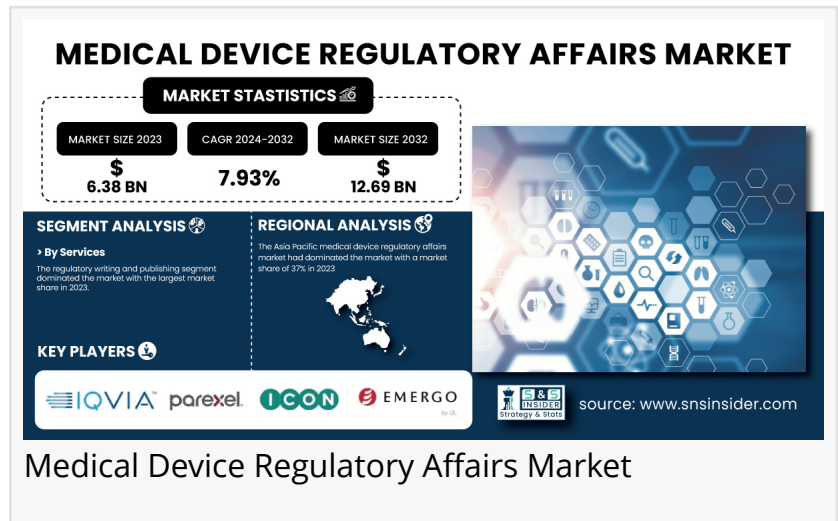


# Medical Device Regulatory Affairs Market Set for Rapid Growth: USD 6.38B to USD 12.96B by 2032

*Technological advances and evolving global regulations drive surge in demand for regulatory services and in-house capabilities across regions.*

AUSTIN, TX, UNITED STATES, February 20, 2025 /EINPresswire.com/ -- According to Research by SNS Insider, The [Medical Device Regulatory Affairs Market](#), valued at USD 6.38 billion in 2023, is on track to nearly double to USD 12.96 billion by 2032, registering a CAGR of 7.93% during 2024-2032.



Medical Device Regulatory Affairs Market

The medical device regulatory affairs market is growing rapidly because of technological advancements and changing global regulations. The growing complexity of medical devices, especially with AI incorporation, is generating demand for regulatory services to comply and remain safe. Firms are outsourcing regulatory activities to maximize efficiency, and emerging markets are contributing significantly. Increased globalization, strict regulations such as the EU MDR, and an increasing need for specialist advice are driving market growth.

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## Key Players in Medical Device Regulatory Affairs Market

- Emergo by UL (Regulatory Pathway Planning, Device Registration Services)
- ICON plc (Clinical Trial Submissions, Regulatory Consulting)
- Parexel International (Regulatory Submission Management, Global Compliance Support)
- IQVIA (Regulatory Strategy Development, Post-Market Surveillance Support)
- TÜV SÜD (CE Marking Assistance, Technical Documentation Review)
- Intertek Group plc (Pre-Market Approval (PMA) Support, Quality Management System Audits)
- NAMSA (Biocompatibility Testing Submissions, FDA 510(k) Filing Services)
- Medistri SA (EU MDR Compliance Services, Product Testing and Validation)
- SGS SA (Notified Body Services, Risk Assessment Support)

- Wuxi AppTec (Regulatory Submission Writing, Preclinical and Clinical Study Management)
- Eurofins Scientific (Risk Analysis and Usability Testing, Product Registration Services)
- Covance Inc. (Labcorp Drug Development) (Global Regulatory Consulting, Post-Approval Monitoring)
- ProPharma Group (Regulatory Affairs Outsourcing, FDA Meeting Preparation)
- NSF International (Gap Analysis for Regulatory Compliance, QMS Implementation Support)
- MCRA (Medical Device Regulatory Advisors) (Pre-Submission Services, FDA Clearance Submissions)
- Qserve Group (Clinical Evaluation Reports (CER), EU MDR Readiness Programs)
- RQM+ (ISO 13485 Compliance Services, Regulatory Due Diligence)
- Certara (Model-Based Regulatory Submissions, Health Authority Interaction Support)
- Greenlight Guru (Quality Management Software for Compliance, Regulatory File Submission Tracking)
- PharmaLex GmbH (Post-Market Compliance Services, Global Registration Dossier Preparation)

By Services, the regulatory writing and publishing segment dominated the market with a 35% market share in 2023

Because of the growing demand for properly documented submissions that adhere to high global compliance standards, medical device companies need to develop lengthy technical files, clinical evaluations, and risk assessment reports to adhere to changing regulations like the EU Medical Device Regulation (MDR) and the U.S. FDA's 510(k) process. The technicality of regulatory documentation calls for scientific writing skills, necessitating outsourcing as a favored solution to efficiency and precision. Further, constant updates in regulations and the rising implementation of AI-driven medical devices have elevated the demand for thorough, high-quality documentation, solidifying this segment's market dominance.

The product registration and clinical trial application segment is likely to witness the fastest growth rate during the forecast period, with increased numbers of new medical device innovations that need to obtain regulatory approvals in different regions. More demand for AI-driven, wearable, and minimally invasive medical devices is forcing businesses to traverse complex approval processes, including clinical trial submissions. Stricter regulatory reforms, including the EU MDR and IVDR, mandate manufacturers to perform more intense clinical assessments before entering the market. In addition, new markets in the Asia Pacific and Latin America are seeing rising adoption of medical devices, compelling manufacturers to rationalize registration procedures across the world, thus propelling the high growth of this segment.

By Type, the therapeutics segment dominated the medical device regulatory affairs market in 2023

As a result of increased demand for sophisticated medical devices utilized in the management of chronic conditions, such as cardiovascular diseases, diabetes, and orthopedic disorders, with the

increasing stringency of the regulatory framework for therapeutic devices, manufacturers have to maneuver complicated approval procedures, including the U.S. FDA's 510(k) and PMA routes, and the EU Medical Device Regulation (MDR). The growing use of AI-based and implantable therapeutic devices has also increased regulatory scrutiny, propelling the need for expert regulatory affairs services. As there is ongoing innovation in therapeutic medical devices, regulatory compliance continues to be a priority, establishing this segment's leadership in the market.

By Service Provider, the in-house segment is experiencing the fastest growth with the highest CAGR in the forecast period

Large medical device firms invest in internal regulatory resources to maximize compliance effectiveness and reduce long-term reliance on third-party service providers. With increased regulations globally, firms believe there is a strategic benefit in holding onto in-house regulatory capabilities to handle approvals, post-market monitoring, and compliance changes in an anticipatory manner. Furthermore, constant regulatory updates require ongoing monitoring, rendering in-house teams more economical for big companies with wide product lines. The integration of AI-driven compliance software and digital regulatory management platforms also boosts the trend towards in-house regulatory services, propelling the segment's growth during the forecast period.

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Asia Pacific dominated the medical device regulatory affairs market with a 37% market share in 2023

Owing to the growing medical device manufacturing industry in the region, low production prices, and developing regulatory environment. Nations such as China, Japan, and India have put up rigorous regulatory guidelines, including China's NMPA and India's CDSCO, fueling demand for compliance services. Besides, the region's expanding healthcare infrastructure, rising foreign investments, and a growing number of clinical trials have driven the region's dominance of the regulatory affairs market.

The medical device regulatory affairs market is anticipated to see the fastest growth, with 10.23% CAGR, in North America because of the high density of medical device companies in the region and ongoing regulatory developments. The changing guidelines of the U.S. FDA, such as tighter premarket approval procedures and post-market surveillance regulations, are boosting demand for regulatory affairs services. Also, the quick uptake of AI-based and digital health technologies, coupled with rising outsourcing of regulatory activities, is driving market growth in North America during the forecast period.

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