Medical Device Affairs Outsourcing Market Report 2026 Market Outlook Supported By A Forecast 6.9% CAGR

The Business Research Company's Medical Device Affairs Outsourcing Global Market Report 2026 – Market Size, Trends, And Forecast 2026-2035

The Business Research Company

LONDON, GREATER LONDON, UNITED KINGDOM, August 14, 2026 /EINPresswire.com/ -- The medical device affairs outsourcing market has been witnessing rapid growth driven by increasing regulatory demands and expanding global healthcare needs. As medical device companies face mounting compliance challenges, outsourcing regulatory and quality assurance tasks is becoming an essential strategy. This trend is expected to continue, with the market evolving alongside technological advancements and shifting industry priorities.

Market Size and Growth Outlook for the Medical Device Affairs Outsourcing Market
The size of the medical device affairs outsourcing market has expanded considerably in recent years. It is forecasted to increase from $5.45 billion in 2025 to $5.85 billion in 2026, representing a compound annual growth rate (CAGR) of 7.3%. This rise during the historical period is largely due to growing regulatory complexities, reliance on internal regulatory teams, a surge in medical device approvals, the broadening global medical device landscape, and heightened awareness about compliance risks.

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Looking ahead, the market is projected to maintain strong momentum, reaching $7.65 billion by 2030 with a CAGR of 6.9%. The expected growth stems from wider adoption of advanced regulatory software, expansion of outsourcing collaborations, greater emphasis on strategic regulatory planning, enhancement of post-market surveillance programs, and integration of artificial intelligence and analytics to boost regulatory efficiency. Key trends shaping this period include increased outsourcing by medical device firms, growing demand for cloud-based compliance tools, efforts to streamline clinical trial processes and regulatory submissions, expanded quality management system (QMS) support, and improved post-market risk assessment capabilities.

Understanding Medical Device Affairs Outsourcing and Its Importance
Medical device affairs outsourcing involves contracting external specialists or companies to handle regulatory compliance and quality assurance related to medical devices. This practice is increasingly popular among medical device manufacturers as it helps them navigate a complex and ever-changing regulatory environment. Outsourcing ensures adherence to international standards and regulations while enabling companies to focus on innovation and growth by delegating critical compliance functions to external experts.

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Key Drivers Fueling the Expansion of the Medical Device Affairs Outsourcing Market
One major factor propelling the medical device affairs outsourcing market is the rising demand for medical devices. These devices, which include instruments, apparatuses, machines, or implants used to diagnose, treat, or prevent medical conditions, are seeing increased consumption due to advancements in treatment efficacy, improved patient outcomes, and the growth of healthcare infrastructure worldwide. Outsourcing regulatory affairs helps companies streamline operations, enhance compliance, and accelerate market entry.

For example, in April 2024, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) reported a growth in the number of registered medical products—from approximately 2.25 million in 2022 to around 3.25 million in 2024—highlighting the expanding demand for medical devices and the subsequent need for outsourcing services in regulatory affairs.

Regional Leadership in the Medical Device Affairs Outsourcing Market by 2026
In 2025, Europe held the largest share of the medical device affairs outsourcing market. However, Asia-Pacific is expected to register the fastest growth rate over the forecast period. The market analysis includes regions such as Asia-Pacific, South East Asia, Western Europe, Eastern Europe, North America, South America, the Middle East, and Africa, providing a comprehensive view of global market trends and regional opportunities.

The 2026 edition of our market reports now delivers enhanced analytical coverage through market attractiveness scoring and analysis, total addressable market (TAM) analysis, company scoring matrix graphics and tables, Excel-based forecasting dashboards, market hotspots infographics, key technologies and future trend analysis, plus updated graphics and tables.

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