

# Global Medical Device Affairs Outsourcing Market Set to Reach \$8.1 Billion by 2031, Driven by Regulatory Complexity

*growth of the medical device affairs outsourcing market size is driven by increase in number of on-going R&D activities, surge in number of clinical studies*

PORTLAND, OR, UNITED STATES, June 9, 2026 /EINPresswire.com/ -- A new market analysis indicates the global [medical device affairs outsourcing market](#) is poised for substantial expansion, with a new report projecting a valuation of \$8.1 billion by 2031. This significant growth represents a steady Compound Annual Growth Rate (CAGR) of 6% from 2022 to 2031, up from its 2021 valuation of \$4.6 billion. The findings underscore a clear industry trend: medical device companies are increasingly turning to external partners to manage the complex and ever-changing landscape of regulatory and clinical affairs.

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The primary driver of this market's growth is the rising complexity of the global regulatory environment. Medical device manufacturers face a labyrinth of rules and standards from bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Outsourcing these functions allows companies to tap into a network of specialized expertise without the overhead of building a large in-house team. This is particularly appealing for small and medium-sized enterprises (SMEs) that may not have the resources to navigate these challenges on their own.

In addition to regulatory hurdles, the market is also being fueled by the intense cost pressures faced by device manufacturers. Outsourcing regulatory affairs, quality assurance, and clinical trial management can significantly reduce operational costs, allowing companies to allocate resources to core competencies like research and development and product innovation. This strategic shift enables businesses to be more agile and responsive to market demands, accelerating the time-to-market for new and life-saving technologies.

The market's expansion is further supported by the growing number of new medical devices entering the market and the increasing demand for medical technology in emerging economies.

As more companies seek to launch products globally, the need for specialized guidance on a country-by-country basis becomes critical. Outsourcing firms are uniquely positioned to provide this expertise, offering services that ensure compliance across diverse jurisdictions and helping clients avoid costly delays or market access issues.

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Key Market Players -

Syneos Health, Inc.,  
Parexel International Corporation,  
Icon plc,  
Inizio,  
Thermo Fisher Scientific, Inc.,  
Indegene Private Limited,  
Wuxi AppTec,  
Excelya,  
Charles River,  
IQVIA Holdings Inc.,  
SGS SA

In essence, the medical device affairs outsourcing market is a direct response to the evolving needs of the industry. As companies grapple with complex regulations and the need for greater efficiency, external partners are becoming indispensable. The projected growth to \$8.1 billion by 2031 solidifies the market's role as a vital enabler of innovation, helping medical device companies bring new solutions to patients around the world.

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