

Medical Device Outsourcing Market Insights: Contract Manufacturing, Regulatory Services & Growth | DataM Intelligence

The medical device outsourcing market was \$127 Billion in 2023, projected to reach \$340 Billion by 2031 at a CAGR of 13.1%.

AUSTIN, TX, UNITED STATES, October 3, 2025 /EINPresswire.com/ -- According to DataM Intelligence, the [medical device outsourcing market](#) was valued at USD 127,048.5 million in 2023 and is projected to reach USD 340,743.1 million by 2031, growing at a CAGR of 13.1% during the forecast period (2024-2031). North America holds the largest market share due to advanced

healthcare infrastructure, high prevalence of chronic diseases, and the presence of key medical device manufacturers. Conversely, the Asia Pacific region is the fastest-growing market, attributed to rising investments in manufacturing facilities, growing healthcare awareness, and favorable government initiatives that promote medical device production and outsourcing.

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Contract manufacturing, regulatory support, and prototype services dominate the rapidly expanding \$340B medical device outsourcing market globally.”

DataM Intelligence

The Medical Device Outsourcing Market has been witnessing remarkable growth, driven by the increasing demand for cost-effective and efficient production of medical devices. Outsourcing in the medical device sector involves delegating manufacturing, assembly, testing, or regulatory services to third-party providers, allowing companies to focus on core competencies such as research, design, and marketing. This trend has gained momentum as manufacturers aim to reduce operational

costs, accelerate product time-to-market, and navigate stringent regulatory requirements effectively. With rising incidences of chronic diseases, the demand for innovative medical devices is surging, thereby propelling the outsourcing market to new heights.



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Key Highlights from the Report:

- The global market is projected to grow at a CAGR of 13.1% from 2024 to 2031.
- North America holds the largest market share due to advanced healthcare infrastructure and high chronic disease prevalence.
- Asia Pacific is the fastest-growing region, driven by increasing manufacturing investments and healthcare demand.
- The services segment, including contract manufacturing and regulatory support, dominates the market.
- Rising chronic disease incidence and demand for high-quality healthcare devices are key growth drivers.
- Technological advancements and strategic collaborations are fueling market expansion globally.

Recent Developments:

United States: Recent Industry Developments

1. In August 2025, Flex Ltd. expanded its medical device outsourcing services for U.S. clients, focusing on design, prototyping, and full-scale manufacturing.
2. In July 2025, Jabil Healthcare launched turnkey manufacturing solutions for medical devices, including assembly, testing, and regulatory support.
3. In June 2025, Integer Holdings Corporation partnered with hospitals and medtech startups to provide custom device manufacturing and contract services, enhancing production efficiency.

Europe: Recent Industry Developments:

1. In July 2025, Phillips-Medisize Europe introduced advanced outsourcing solutions, offering end-to-end development for diagnostic and therapeutic devices.
2. In June 2025, Creganna Medical expanded device manufacturing services, including design, assembly, and packaging for European clients.
3. In May 2025, Sierra Circuits Europe partnered with medtech companies to implement full-service contract manufacturing solutions, reducing time-to-market.

Japan: Recent Industry Developments:

1. In July 2025, Fujifilm Healthcare Japan launched medical device outsourcing services, targeting diagnostics and surgical devices.
2. In June 2025, Terumo Corporation expanded contract manufacturing capabilities for precision medical instruments.
3. In May 2025, Nipro Corporation partnered with hospitals and startups to provide end-to-end device outsourcing solutions, improving production efficiency and regulatory compliance.

Company Insights

Key players operating in the medical device outsourcing market include:

- Integer Holdings Corporation
- Thermo Fisher Scientific
- Nortech Systems, Inc.
- Plexus Corp.
- West Pharmaceutical Services, Inc.
- Celestica, Inc.
- Intertek Group
- WuXi Apptec
- IQVIA Holdings
- Benchmark Electronic Inc.

Market Segmentation:

The medical device outsourcing market is segmented to provide a detailed understanding of the competitive landscape and growth opportunities:

By Product Type:

The market is categorized into raw materials, electronics, and finished goods. Raw materials outsourcing allows companies to secure high-quality components efficiently, while finished goods outsourcing enables faster production cycles and market entry. Electronics outsourcing has become critical with the rising complexity of medical devices, especially in diagnostic and monitoring equipment.

By Device Type:

Devices are classified as Class I, II, and III, based on regulatory standards. Class III devices, including implantables and life-support systems, are highly complex and often require specialized manufacturing capabilities, making outsourcing a practical solution for many companies. The demand for Class II and III devices is driving the need for precision manufacturing and high-quality assurance.

By Application:

The market encompasses orthopedic & spine, cardiovascular, radiology, and general medical devices. Cardiovascular and orthopedic segments are experiencing significant growth due to the rising prevalence of cardiac disorders, bone injuries, and aging populations globally. Outsourcing enables manufacturers to leverage specialized expertise for developing high-precision devices in these therapeutic areas.

By Service:

Outsourcing services include prototype development, finished device manufacturing, assembly & packaging, and testing & regulatory support services. Contract manufacturing dominates the service segment, offering cost efficiency, compliance with global regulatory standards, and accelerated production timelines. Companies increasingly rely on these services to reduce overhead costs and focus on innovation.

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Regional Insights

North America dominates the global market, supported by a well-established medical device industry, advanced healthcare systems, and high consumer awareness. Countries like the United States and Canada host numerous medical device manufacturers and outsourcing service providers, making the region a hub for product innovation and regulatory compliance. Strategic acquisitions and partnerships further strengthen market leadership in this region.

Europe shows steady growth due to stringent regulatory frameworks and a strong emphasis on healthcare quality. Nations like Germany, France, and the UK are key contributors, driven by a robust manufacturing ecosystem and high adoption of advanced technologies. Outsourcing partnerships in Europe focus on achieving compliance, enhancing device quality, and reducing production costs.

Asia Pacific is emerging as the fastest-growing region, thanks to increasing healthcare infrastructure investments, cost advantages, and favorable government policies supporting manufacturing and outsourcing. Countries like China, India, and Japan are witnessing rapid expansion in contract manufacturing services for medical devices, fueling regional growth and attracting global players.

Latin America, the Middle East, and Africa are gradually developing as promising markets. Growth is driven by increasing healthcare awareness, expanding medical infrastructure, and rising demand for cost-effective medical devices in these regions.

Market Dynamics:

Market Drivers:

The medical device outsourcing market is propelled by rising incidences of chronic diseases such as cardiovascular, neurological, and orthopedic disorders. The need to reduce operational costs, accelerate product development, and access specialized manufacturing capabilities encourages outsourcing. Technological advancements and the growing trend of offshoring further contribute to market expansion, enabling manufacturers to deliver high-quality devices efficiently.

Market Restraints:

Despite the promising growth, the market faces challenges such as the risk of losing confidential information when outsourcing production and services. Companies must ensure data security, intellectual property protection, and compliance with regulatory standards. Additionally, differences in global regulatory frameworks can create complexities, affecting seamless outsourcing operations.

Market Opportunities:

Significant opportunities exist in emerging markets, where increasing healthcare investments and demand for advanced medical devices present lucrative prospects for outsourcing service providers. Strategic partnerships, technological innovations, and novel product launches create avenues for growth, allowing manufacturers to expand capabilities while minimizing risks and costs.

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Reasons to Buy the Report:

- Comprehensive analysis of market size, share, and growth prospects.
- Detailed segmentation insights by product, device type, application, and service.
- Regional analysis highlighting key trends and growth opportunities.
- Competitive landscape and company profiling for strategic decision-making.
- Insights into market drivers, restraints, and emerging opportunities.

Frequently Asked Questions (FAQs):

- How big is the medical device outsourcing market in 2024?
- Who are the key players in the global medical device outsourcing market?
- What is the projected CAGR of the medical device outsourcing market?
- What is the market forecast for 2031?
- Which region is estimated to dominate the industry through the forecast period?

Conclusion:

The global medical device outsourcing market is poised for substantial growth, driven by rising chronic disease prevalence, technological advancements, and the need for cost-effective manufacturing solutions. North America leads the market with established infrastructure, while Asia Pacific offers the fastest growth opportunities due to favorable investments and emerging manufacturing hubs. With outsourcing services enabling innovation, compliance, and operational efficiency, companies are increasingly leveraging third-party partnerships to deliver high-quality medical devices to meet global healthcare demands. As the market continues to evolve, strategic collaborations, technological innovations, and regulatory expertise will remain critical for sustained success.

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