

Design & Manufacture of Precision Medical Components



Medical Device Outsourcing Backgrounder

Market Overview

Outsourcing is contracting with a third party to perform business processes such as product design, prototyping, manufacturing, and inventory management that medical device companies have previously performed internally. By utilizing third parties or contract manufacturers (CMs) to perform these processes, medical device manufacturers (often called original equipment manufacturers or OEMs) can better focus their internal resources on their core competencies of clinical and technical innovation, sales and marketing.

Growth in medical device outsourcing is outpacing that of the overall medical device manufacturing market. While the device market is expected to grow at an annual rate of 6% - from \$98 billion in 2007 to over \$120 billion by 2013 - contract manufacturing is forecast to increase by nearly 15% per year, resulting in a total U.S. outsourcing market size of over \$12 billion by 2013, nearly double the 2007 market size.^{4, 5, 6, 7}

Market Landscape

A host of market challenges and opportunities are driving medical device manufacturers to increasingly seek strategic outsourcing partnerships. Among these factors:

New Medical Device Development Activity

Because outsourced manufacturing is well established and on the rise, growth in overall device demand translates directly into increases in contract manufacturing. In the first six months of 2010 there has been a 6% increase in medical device revenue, and spending on research and development for the biotech sector grew to its highest level in 6 years. Additionally, venture capital and other funding increased 20% year-over-year in the first half of 2010.⁸

Strong demand from China, India, Brazil and other nations is also driving growth for U.S.-based OEMs. "The bulk of our growth over the next decade is probably going to come (from) outside the U.S." said Stephen Oesterle, MD, Senior VP for Medicine and Technology, Medtronic Inc.^{7,8}

Shifting Demographics and New Treatment Models

While some of this growth is attributable to a gradually improving global economic climate, demographic factors such as an aging population, longer life expectancies, rising rates of chronic disease and under-served patient

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Medical Device Outsourcing Backgrounder

populations are also contributing to the upswing. These latter factors are fueling the demand for new, more complex technologies such as minimally invasive, implantable, wireless and wearable devices that can improve patient outcomes and drive down costs.

Developing these new technologies often requires specialized equipment as well as expertise in materials, mechanical and manufacturing engineering that would be cost-prohibitive and time-consuming for OEMs to acquire. Instead, they look to CMs who already have the equipment and people in place who can bring these technologies to market quickly.

Pending Changes to FDA Oversight and Approvals

In August of 2010, the U.S. Food and Drug Administration issued a [detailed preliminary plan](#) to amend the agency's pre-market review of new devices, otherwise known as the 510(k) process.

The new guidelines, widely debated among OEMs due to concerns that they will negatively impact innovation, are aimed at improving product and patient safety. If implemented, the recommendations will likely result in greater scrutiny of both new product approvals and existing manufacturing operations, and are expected to increase approval times for new devices and increase the overall cost of development^{7,8}.

Anticipating these changes, OEMs are feeling an increased burden on already strained internal resources and are seeking specialized contract manufacturing support to mitigate delays in new product introductions.

New Medical Device Tax

Enacted in March 2010 as part of the healthcare reform act, medical device manufacturers will be subject to a 2.3% excise tax on sales of most medical devices effective January 1, 2013.

According to a 2010 survey of 100 OEM executives, device makers plan to deal with the tax by reducing operating expenses, cutting the cost of goods sold and raising prices to consumers. However, because almost half of device sales in the U.S. are associated with Medicare and Medicaid, companies will be limited in their ability to offset this tax using price increases, and will look to outsourcing partners to find ways to cut costs by creating manufacturing efficiencies^{8,10}.

Healthcare Reforms

The impact of healthcare reform on the device industry is still somewhat uncertain. While many OEMs feel that increases in consumer access to care may drive overall demand for devices there will certainly be pressure to ensure that any new devices deliver improved patient outcomes while decreasing cost to the system.^{7,8}

As demand from government agencies for both innovation and cost containment continues to grow, there will be a greater need for outsourcing partners who can provide the specialized skills and resources to help OEMs capitalize on new technologies and the address specific business challenges throughout every phase of a product's life cycle.^{1,2,11}

Outsourcing Benefits

To achieve their business objectives, medical device companies will need to be able to drive innovation amidst mounting cost and regulatory pressures. Strategic outsourcing helps OEMs to achieve their revenue and technology goals more quickly by offering the following benefits¹²⁻¹⁶.

1. Faster time to market.

Engaging full-service contract manufacturers in the design and development phase of a product's lifecycle can help streamline product launches and accelerate launch timelines. Additionally, contract manufacturers eliminate the costs and time associated with establishing internal manufacturing capacity, helping to initiate revenue streams earlier.

2. Improved efficiency and ROI.

Full-service contract manufacturing experts often work with product designers at the earliest stages of new product

Medical Device Outsourcing Backgrounder

development to implement design for manufacturability concepts that improve long term production efficiency. As part of the value engineering process, CMs can evaluate the OEMs existing device portfolio for opportunities to reduce manufacturing complexity and/or manufacturing costs.

3. Focus on core competencies.

Outsourcing design and manufacturing services helps medical device OEMs focus increasingly scarce internal resources on their core competencies of product development and marketing. CMs reduce the time and cost of producing a new device, allowing device companies' most talented scientists, clinicians and others to focus on innovation.

4. Instant expertise.

Contract manufacturers are able to become experts at niche markets and competencies, such as device miniaturization, allowing OEMs access to deep talent pools, diverse knowledge bases, and emerging technologies. This saves valuable R&D dollars and enables OEMs to break into new markets faster.

5. Flexibility and Scalability.

Contract manufacturers provide OEMs with the operating agility and flexible capacity to support unexpected changes in demand due to scientific, regulatory or market shifts.

IntriMed Capabilities

IntriMed Technologies' team of engineers and innovators design, prototype and manufacture components with nano-scale precision and quality to help medical device companies launch products that improve patient care. IntriMed focuses exclusively on outsourcing solutions for the medical device manufacturing industry, and delivers on three value pillars – ongoing innovation, deep collaboration, and engineering and operational excellence.

Drawing on a legacy of 23 years of engineering innovation, including 57 pending and granted product and process patents, IntriMed provides access to instant expertise across a broad range of capabilities: product design and development; rapid prototyping; advanced tooling; precision metal stamping and forming; secondary processing including custom heat treatment, surface functionalization and precision cleaning; custom metrology; continuous improvement and compliance; over molding; and final assembly. IntriMed's Innovation Center is an FDA registered facility.

REFERENCES

1. "Strategic Product Lifecycle Management Partnerships as the New Means of Competitive Advantage for Medical Technology Companies," [Frost and Sullivan Whitepaper](#), October 2010
2. Stommen, Jim "The New Normal," [MPO Magazine](#), November/December, 2010
3. Medical Devices Industry Assessment," [U.S. Department of Commerce, International Trade Association](#), PDF, 2010
4. Dunn, Ben "Market Opportunities in Outsourcing," [MPO Magazine](#), July/August 2007
5. Dunn, Ben "A Strategic View of Outsourced Manufacturing for Medical Devices," [Covington Associates](#), PDF, 2007
6. "Service Outsourcing Opportunities in Medical Device Market," [Markets and Markets](#), 2009
7. "UPS 2010 Pain in the (Supply) Chain Survey," [UPS Research Report](#), PDF, 2010
8. "Pulse of the industry: Medical technology Report 2010," [Ernst & Young](#), PDF, 2010
9. "Capitalizing on Complexity: Insights from the Global Chief Executive Officer Study," [IBM](#), May 2010
10. "Survey: Device Tax Could Force Job Cuts, Higher Prices," [MassDevice](#), May 2010
11. Barbella, Michael "Game Change," [MPO Magazine](#), November/December 2010
12. Dunn, Ben "A Strategic Review of Outsourced Manufacturing for Medical Devices," [Covington Associates](#), PDF, 2007
13. Zajac, Jeffery "Making the Case for Outsourcing," [MPO Magazine](#), July/August 2010
14. Rastogi, S. "Medical Technology Innovation in a Time of Upheaval," [PRTM Management Consultants Survey](#), PDF, 2010
15. Barbella, Michael "Fulfilling the Vision for Full Service Outsourcing," [MPO Magazine](#), May 2010
16. Jacobs, Bruce E. "Outsourcing as a Strategic Advantage," [MPO Magazine](#), September 2010