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Business Strategies for
Medical Technology Executives

The Changing Shape of Medtech Outsourcing

Continued growth in medtech's contract manufacturing segment could have implications for its medical device clients.

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In spite of mounting operating expenses, the medical device industry has experienced substantial growth during the past decade. Medtech company leaders have managed to maintain company and industry profitability by supporting an extraordinarily high level of commitment to product innovation and by adopting a variety of creative cost-cutting measures—including the increasingly popular strategy of outsourced manufacturing.

Structural factors within the device industry have created a pivotal role for companies in the contract manufacturing segment, generating significant attention from a diverse but related group of stakeholders—including incumbent market leaders, emerging device manufacturers, and private equity groups. Such increased attention from various stakeholders is driving opportunities for the continued growth of businesses in the segment. Ultimately, consolidation among the



many outsourcing companies that are operating in the medical manufacturing sector is expected to occur.

Market Growth

Contract manufacturers have certainly benefited from the growth of the medical device industry. However, growth of the outsourced medical manufacturing segment is outpacing

that of the device industry as a whole, indicating a trend toward the increased use of outsourcing.

Although approximations of the market size for outsourced medical device manufacturing remain imprecise, estimates indicate a U.S. market size of roughly \$4.4 billion as of 2005—with an estimated 20% of all medical equipment production outsourced to third-party vendors—up from a market size of \$2.2 billion in 2002. By 2010, it is projected that an estimated 40% of all medical device manufacturing could be outsourced, representing

a 15% annual growth rate over the next few years.¹

Industry Drivers

A variety of factors are driving growth in the contract manufacturing segment. Intense competition has forced device manufacturers to focus on their core competencies of research and development (R&D),

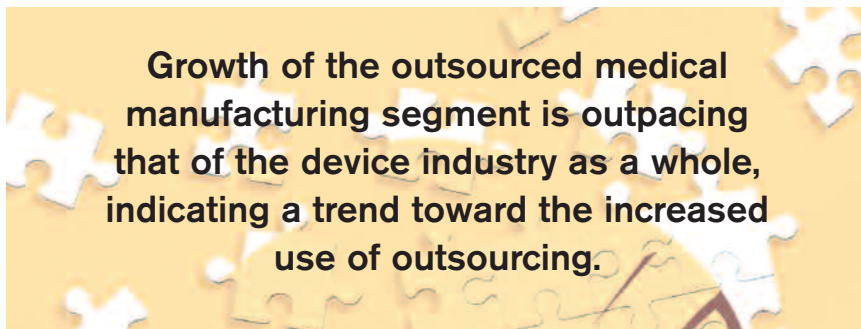
clinical education, marketing, and sales.

One major factor driving the growing trend toward outsourcing manufacturing operations is the need to reduce direct expenses and streamline supply chains while offsetting escalating operating expenses. The medtech industry has been successfully improving its gross margins through better productivity and more-effective product mix and management. These margin improvements are under constant

Strategic Rationale for Outsourcing

Contract manufacturing has a number of strategic benefits beyond simply reducing product acquisition cost. Incentives for device manufacturers to outsource their production include the following.

Quicker, More-Efficient Product Launches. Engaging full-service contract manufacturers in the design and development phase of a product's life cycle can do much to condense



pressure from competitive products and reimbursement rates. With pressure on margins, time to market for medtech products is a critical consideration. With a limited patent protection window, any development or manufacturing delays can be costly.

Another primary driver of the contract medical manufacturing segment's growth consists of not only the expansion of the overall device industry, but also the extent to which device manufacturers are choosing to outsource their manufacturing operations. Although the overall medical device industry in the United States is expected to continue growing at a strong rate, the outsourced manufacturing market is projected to see even faster growth. As medical device manufacturers strive to improve margins and time to market, outsourced manufacturing will continue to grow in acceptance.¹

launch timelines. Furthermore, manufacturing experts working in conjunction with product designers are better able to achieve productivity gains by implementing design-for-manufacture techniques and driving out production inefficiencies over the long term.

Ability to Focus on Core Competencies. Medical device manufacturers earn greater returns on capital by investing in product development and marketing than in manufacturing. Establishing manufacturing capacity is both capital intensive and slow going, resulting in a lower return on investment over a longer period of time.

Access to Specialized Capabilities. Contract manufacturers are able to become experts in certain niches in the market, allowing manufacturers the option to use these specialized production capabilities without spending valuable R&D dollars on projects that distract from

their core competencies.

Flexibility of Production. Contract manufacturers are able to use their capacity more efficiently based on a consistent flow of orders. They can better accommodate large orders when needed.

Keeping Projects In-House

Although the argument for outsourced manufacturing is compelling, there are instances in which manufacturers choose to handle projects for which they would otherwise rely on contract manufacturers. Such reasons include the following.

Surplus Capacity. Given the fixed-cost nature of manufacturing, manufacturers may look to leverage underutilized resources before outsourcing work.

Manufacturing Control. Device manufacturers may keep projects in-house to more efficiently implement midstream process changes or to protect their proprietary processes or technologies. This occurs on a case-by-case basis, given that many larger outsourcing partners are becoming tightly integrated into the overall supply chain, including codevelopment of products.

Liability Issues. Device manufacturers are ultimately liable for products they market. There may be instances, such as intense inspection of a particular product line, that could necessitate ownership of the manufacturing process.

Market Share Breakdown

With more than 3000 individual firms providing a wide range of outsourced services to medtech companies, the contract manufacturing segment is highly fragmented. These firms have very different backgrounds and capabilities, and include everything from small owner-operator

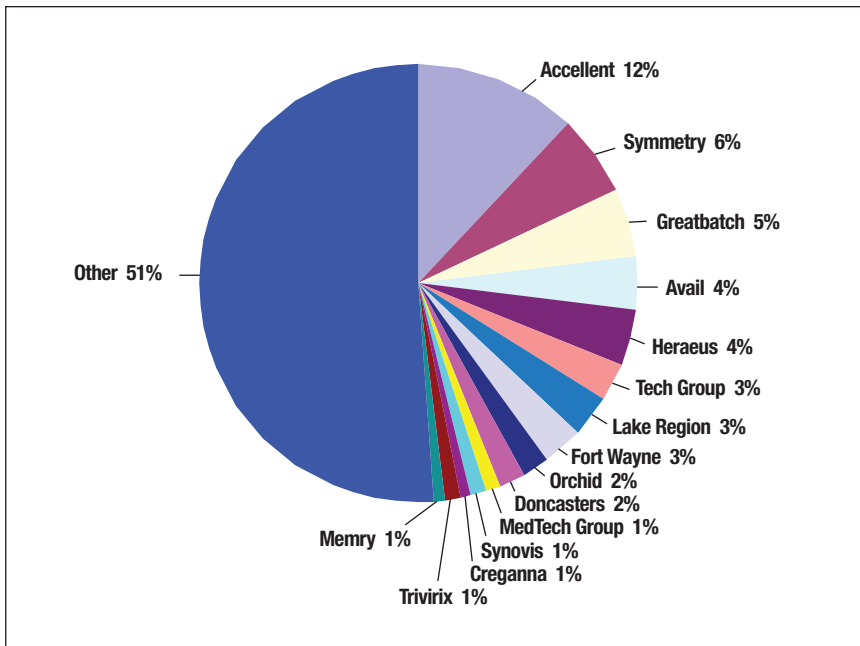


Figure 1. Contract manufacturing market share in 2005. Source: Millennium Research, Frost & Sullivan, company reports.

machine shops that used to manufacture aircraft parts to professionally managed, private-equity-backed providers of end-to-end services. The size of the market and the variety of tasks that can be outsourced—design, machining, stamping, assembly, inspection, sterilization, and packaging, to name just a few—enable this broad spectrum of providers to coexist successfully.

Approximately 50% of the contract manufacturing market for medical devices is controlled by no more than 12 firms, with leader Accellent Inc. (Wilmington, MA) controlling an estimated 12% of the market. Beyond the 12 leading firms, the other 50% of the contract manufacturing market is highly fragmented, comprised of firms that hold less than 1% market share each. Such a market structure effectively establishes two tiers of participants: large full-service organizations and small niche service providers (see Figure 1).

Fully integrated manufacturers provide a wide range of services to

device manufacturers that may include everything from design and manufacturing to packaging and distribution. Niche providers generally provide one specific task, such as component manufacturing, assembly, or packaging. Due to the growth of the overall market, both types of companies are thriving.

Full-service firms provide a number of advantages to medtech companies. The primary advantage is the ease of management. Rather than working with a complicated network of disparate service providers, device firms have one partner. This also enables better coordination of services throughout the entire process. During the design phase, manufacturing and packaging considerations can be fully taken into account by the organization that will be responsible for those activities. Such an arrangement creates a faster time to market and a more efficient process.

Full-service outsourcing is not without its disadvantages. To be successful, it requires careful coordination and communication among all

of the processes. Fully integrated providers that are unable to provide smooth coordination of these processes negate many of their advantages. It is also difficult for a medical device company to find a one-stop shop that is an industry leader in all services. Full-service providers may lack specific capabilities required by a medtech company. Certain materials and components may require specialized manufacturing and packaging that only a handful of companies can provide. In those cases, relying on a full-service provider that lacks certain specialized capabilities may cause compromises to the product.

Niche providers enable a medtech manufacturer to assemble a best-in-class outsourcing program by selecting the service providers that best meet the needs for each step. These providers give a developer the most flexibility in manufacturing and packaging alternatives. However, it goes without saying that as a firm uses more outsourcing partners, more oversight and coordination efforts will be required. The user is thus open to more risk should any one part of the outsourcing chain develop difficulties.

Outsourcing strategies for medical device companies take several forms. Many companies make their first foray into outsourced manufacturing with a single project. This may be a low-volume project for the manufacture and assembly of a device that is undergoing clinical trials. Often, the medical device company may not want to make the investment in manufacturing capabilities until the product has been approved. Once approved, the project may remain outsourced or be taken back in-house.

At the other end of the spectrum, medical device companies may choose to outsource the complete design, manufacture, assembly, and

packaging of a product. In such cases, medical device companies work closely with their outsourced partners and do not have to make any in-house investments into these processes. Some medical device companies, in attempting to reduce their investment in manufacturing and packaging, have sold entire plants to outsourcing providers.

Outsourcing, when done properly, requires much less capital investment in processes and leads to faster development and production times. However, medical device companies assume the risks associated with taking core processes outside of their control by trusting third parties to deliver. The partnerships become even more important when certain proprietary technologies or processes are provided to the outsourcing partners.

In today's marketplace, many manufacturers are using a combination of the aforementioned tactics. Certain firms still do significant work in-house and outsource select functions to niche providers. As these organizations seek to outsource more functions, they either move toward a full-service manufacturing provider or start to develop their own outsourcing network to provide the additional services. To the extent that their existing suppliers have added capabilities, they will be the likeliest candidates for the new business.

Consolidation among Contract Manufacturers

The growth and fragmentation of the overall contract manufacturing segment and the demand for more full-service outsourcing

providers will inevitably lead to consolidation. As full-service providers look to gain additional capabilities and market share, they will accomplish this in part through acquisitions. Niche providers will also seek selected acquisitions to broaden their market presence and capabilities. In general, some consolidation will be advantageous for both the contract manufacturing segment and its medical device clients.

From the medical device companies' perspective, having to work with

implement outsourced solutions. In addition, consolidation will attract new capital and expertise into the segment as it becomes more attractive to private equity firms and larger experienced outsourcing firms from other industries. This added capital and expertise will enable contract manufacturers to serve medical device companies with additional services and capacity.

Given the highly fragmented state of the contract medical device manufacturing segment, there is plenty of opportunity for consolidation. A recent example is Symmetry Medical's acquisition of TNCO Inc. (Whitman, MA). While focused mainly on the manufacture of surgical implants and instruments for the orthopedic device sector, Symmetry Medical also serves the dental, osteobiologic, and endoscopy sectors. Symmetry aims to be a one-stop shop for all its customers' contract manufacturing needs. Its latest acquisition, TNCO, specializes in designing, engineering, and manufacturing instruments for arthroscopic, laparoscopic, nasal sinus surgery, and other minimally invasive procedures.

With a market share of 6%, Symmetry is the second-largest player in the medical device contract manufacturing marketplace. In comparison, TNCO is one of the smaller players in the segment, holding a less-than-1% market share. Although TNCO had achieved success with a strong portfolio of patented designs, it lacked the size to compete with larger players in the crowded segment, as is the case with many of the small companies that make up the contract manufacturing segment. TNCO's strong business but lack of resources made it a



fewer suppliers is beneficial. The high degree of fragmentation within the contract manufacturing segment can make it more difficult for medical device companies to find and manage the best solution. Currently, a number of medical device companies are actively trying to shrink their lists of suppliers.

The outsourced medical manufacturing segment will also benefit from some consolidation. Having fewer, larger companies will help to better define the industry and make it easier for medical device firms to

prime target for acquisition by a larger strategic player that could maximize its potential.

Consolidation of the two companies opens the door for the merged firm to exploit economies of scale and other synergies to decrease operating expenses and increase sales. With Symmetry's larger scale and resources, the combined entity will be able to cultivate and expand on TNCO's intellectual capabilities and grow more quickly and effectively in TNCO's fields of specialty. Symmetry's acquisition of TNCO will enable the combined entity to expand the scope of its business and increase its market share. Much like within the medical device industry as a whole, these types of buyout benefits will continue to drive the medical device contract manufac-

turing segment toward a more consolidated future.

Conclusion

Medical device companies will continue to have a wide range of options in how they take advantage of outsourcing services to reduce their costs, capital investments, and time to market. The breadth of suppliers providing everything from component design and manufacturing to customized packaging services provides medical device companies with the opportunity to customize their outsourcing program.

The market for outsourced medical manufacturing is growing rapidly. The combination of this rapid growth with a highly fragmented market has created a ripe opportu-

nity for consolidation. This consolidation will help the segment to grow by attracting new capital and expertise, and allowing outsourcing firms to offer a wider range of coordinated services. In the end, medical device companies will benefit from the creation of a stable group of outsource suppliers that can provide flexible solutions to meet whatever needs they require.

Reference

1. B Dunn and J Finn, *A Strategic Review of Outsourced Manufacturing for Medical Devices* (Boston: Covington Associates, 2007).

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