

Bettering Business

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As Outsourcing Evolves, Medical Device Manufacturers and Their Outsourcing Partners—Plus the Industry as a Whole—Benefit

“We see outsourcing as an integral part of our business. Over time, the process has evolved from our managing every step the outsourcing company takes to defining projects in the most basic fashion and letting the contract manufacturer determine product specifications and run the project completely. By outsourcing in this way, we’ve been able to launch one of our latest projects in half the time it normally would have taken, and the project ran spectacularly well.”

Photo Credit: Stereotaxis

So said David Jacques, vice president of software development for St. Louis, MO’s Stereotaxis, which recently introduced two innovations. Outsourcing partner Foliage helped make possible the speedy launch of the Odyssey project into the European market. Odyssey combines the eight to 10 screens traditionally in front of an electrophysiologist in a cardiac catheterization lab into one single, large-screen monitor. Rather than worrying about 10 screens and their corresponding keyboards and mice, with Odyssey, a physician watches one monitor and works one keyboard and mouse, viewing the on-screen presentation specific to the particular step in the procedure being performed, and planning and executing his or her application of therapy accordingly.

By simplifying a complex interventional situation, Odyssey aims to improve and speed medical care. But the simplification process itself proved challenging: new hardware, software and video processing needed to be created.

“Foliage developed the entire software project for us,” Jacques explained. “From developing project specifications through the verification phases, they handled it all.”

Stereotaxis is more likely to outsource projects today than it was several years ago, but the company makes its decisions on a per-project basis. “It can be more expensive to outsource, but performing the same work in-house may take twice as long, and timing of completion may be the most important factor,” Jacques explained, adding that Stereotaxis looks at four criteria when evaluating its outsourcing options. The company considers how quickly it needs to get a given product to market, the cost of outsourcing versus completing the same work in-house, the availability of internal resources given other, competing priorities and whether in-house professionals are the best-qualified people to perform particular

tasks—that is, would an outside firm have more recent technologies, more experience and more capabilities in performing a given role?

Indeed, more companies are finding that outsourcing is the answer to gaining the competitive edge in launching products more quickly (and possibly with more features). Furthermore, outsourcing frees internal sources to focus on new business and sources of revenue. In a recent Medical Product Outsourcing survey of more than 100 medical device companies, more than 56% of respondents said outsourcing is “very important” or “essential” to the strategic growth and profitability of their organizations.

Does More Outsourcing Equal More Innovation?

According to the US Patent and Trademark Office, the number of medical technology patents has more than doubled in a little less than two decades, from 4,178 in 1989 to 10,616 in 2006. In addition, AdvaMed has found that medical device firm investment in R&D more than doubled during the 1990s and currently consumes 12% of sales, which is four times the average for manufacturers in general. Could outsourcing be at least partially responsible for helping to speed the pace of innovation within the medical device industry?

Experts who spoke with MPO said the increasing popularity of outsourcing has helped fuel innovation as more minds collaborate on projects, and OEMs seek best-in-class partners to produce their products more quickly than they could if they were to rely solely on internal sources.

“Innovation has been accelerated by the freeing up of resources at the OEM by outsourcing, but additionally I believe that innovation has been accelerated by the degree of specialization and focus that has occurred through the consolidation of various component process technologies—for example, injection molding, precision machining and extrusion,” said Bill Ellerkamp, CEO of ExtruMed, LLC in Placentia, CA. “All of those areas have benefited from the growth of ‘focused’ component suppliers.”

Ellerkamp said two phenomena have affected growth in the contract manufacturing space. First, outsourcing has become more vertical—full-service contract manufacturers increasingly are taking over the entire scope of the vertical value chain from the OEM. Second, outsourcing also has grown horizontally. Contract manufacturers are expanding in a process or component core competency, building the scale and depth to be truly innovative in the execution of that core competency.

A Growing Force

AdvaMed estimated that the US medical device market generated more than \$85 billion in sales by the end of 2006, and experts expect the

industry to continue growing by 8% to 10% annually for the foreseeable future. Just as the medical device industry has posted solid gains over the past few decades, supplier consolidation and scale have grown to better serve OEMs' needs. Before 2000, the largest suppliers were in the \$50 million to \$100 million range, Ellerkamp noted. "Today, through consolidation and growth of outsourcing, they are in the \$250–\$500 million range—for instance, Accellent, Flextronics Medical, Greatbatch, Symmetry, Avail, Teleflex Medical, Plexus, Tech Group, etc.," Ellerkamp said.

The large continue to get larger. On Aug. 30, Flextronics announced its purchase of Avail Medical Products, Inc., following on its \$3.6 billion acquisition of Solectron Corp. earlier in the year. "This is the first time a tier one EMS [electronics manufacturing services] company has bought a non-EMS company of significance in the medical industry," reported Andrew Kinross, associate director for Navigant Consulting in Burlington, MA.

"Electronics companies are very aggressive in the medical market now because they're looking for growth opportunities," Kinross continued. "Medical devices is the fastest-growing, highest-margin business for EMS companies. There is a lot of activity in this area right now—much more than in plastics or metals—and with more IT [information technology] being used in medical devices—more hardware, software and electronics are being incorporated—this area should continue to experience strong growth. Besides capital equipment, in the near future we will see the first consumer electronics medical devices on a large scale."

Assuming that both of these transactions close, Flextronics would command in the neighborhood of \$800–\$900 million in annual medical device industry revenue, second only to Jabil, Kinross said. He added that while there were about 5,000 outsourcing vendors 10 to 15 years ago and that number hasn't changed much over the years, the largest companies today eclipse the largest companies of a decade ago. "On the metals and plastics side, the top six vendors in 1999 accounted for \$350 million in revenue. In 2006, the top six produced \$1.6 billion in revenue. The same type of thing is happening on the electronics side," Kinross said.

Currently, a good portion of medical device manufacturers outsource some portion of their projects, Kinross said. "The amount of outsourcing is still not as high as the vendors wish it would be due to the inherent conservative nature of the industry. Executives want control over everything, and they're reluctant to 'let go' of too much of their manufacturing," he explained. "The ones that are most progressive—companies like Johnson & Johnson and Boston Scientific—have developed very sophisticated outsourcing arrangements and oversights, supply chain management and rate their vendors on all sorts of metrics. They've done well with outsourcing."

Doing Well With Outsourcing

Companies that outsource—and use manufacturing execution systems (MES) to track business trends, process controls and performance—also tend to perform better in the marketplace. “The medical devices [sic] companies using MES in our study have all gained at least 1% market share per year on average; this compares with one-third of those medical devices companies not using MES,” reported the Manufacturing Enterprise Solutions Association International and consulting firm Industry Directions in their 2006 executive brief, *Visibility and Control Minimize Risk: MES for Growing Medical Devices Companies*.

To better meet medical device OEMs' needs, contract manufacturers are developing proprietary techniques and acquiring new, significant production capabilities. For instance, the Hi-Tech Group has added top-of-the-line clean rooms and 300-ton injection presses that allow for greater efficiency. Photo courtesy of the Hi-Tech Group.

“Most medical device companies are using manufacturing execution systems in their own plants to streamline regulatory compliance,” noted Julie Fraser, principal and industry analyst for Industry Directions, Inc. in Cummaquid, MA. When their outsourcing partners incorporate such systems as well, providing real-time information and visibility into everything occurring in the manufacturing environment to the OEM customer, OEMs gain a new level of comfort—and profitability. (See “Increased Visibility Equals Increased Comfort—and Profits” on page 76.)

“With the advent of IT infrastructures and standards that facilitate access to information in real time, OEMs and their subcontractors are able to have more meaningful interactions across the product lifecycle, whether in R&D, clinical or manufacturing,” noted Daniel R. Matlis, president of Axendia, Inc. in Yardley, PA. “This means that issues can be caught early, before they have a significant product impact, and this visibility lends a greater degree of comfort to the outsourcing process, which in turn has helped to fuel the growth of outsourcing.”

Ten years ago, companies might have outsourced only a small percentage of their manufacturing. Today, it's becoming more common for some companies to outsource their entire manufacturing process. These OEMs simply hold the license to a product and focus exclusively on R&D, new business development, sales and marketing, Matlis added.

John Gorski, president and CEO of NAMSAs in Northwood, OH, said two more trends have added to the outsourcing phenomenon. “People are more willing to consider outsourcing today because they've seen how well it has worked in other industries, particularly in pharmaceuticals,” Gorski said. “Secondly, as more VC [venture capital] dollars flow into the

healthcare field, that is prompting more start-ups and virtual companies, and these firms tend to stay lean and outsource a great deal.”

The VC interest in the medical industry is at an all-time high, according to the MoneyTree Report by PricewaterhouseCoopers and the National Venture Capital Association based on data from Thomson Financial. In 2006, medical device company investments rose 29% to \$2.7 billion, a new record. Biotech won a record \$4.5 billion in funding, up 15% from 2005. Together, medical devices and biotech attracted nearly \$1 for every \$3 of venture capital invested.

Of course, interest in outsourcing isn't the sole province of start-ups. As Tom Black, vice president of OEM sales and marketing for B. Braun in Bethlehem, PA, pointed out, large OEMs have experienced dramatic growth over the years, and many are simply running out of manufacturing capacity. “It raises the question for them, do we expand, or do we outsource?” Black noted. “Building a new facility and investing in new technology can be pricey, so many of these companies will outsource some of their older products.”

New Services, Capabilities

While OEMs of all sizes are finding it beneficial to outsource projects for various reasons, their contract manufacturing partners have made the decision even easier by adding new services and capabilities that can produce products to ever more rigid specifications and timelines.

“Over the last five years we've developed proprietary molding techniques and acquired significant new production capabilities,” said Bill Sherman, president and chief operating officer of the Hi-Tech Group in Anaheim, CA. “Medical products today are more intricate, and the overall quality, dimensional and visual requirements are more strict than they used to be. Some parts are the same as they were 20 years ago, but to produce the more complex, newer parts, you need more efficient molds and state-of-the-art liquid injection molding (LIM) presses.”

The Hi-Tech Group originally started with 40-ton LIM machines, and now it is using 300-ton injection presses. But having to incorporate an even larger number of cavities in the mold with faster cycle speed can become a challenge in real-life, high-volume production, Sherman said. “Of course, this is precisely why most of our OEM customers seek our engineering and manufacturing expertise.”

Contract manufacturers are seeing more outsourcing work come in, especially as they diversify and enhanced their capabilities. “We can effectively combine thermoplastic, thermo-set rubber and silicone elastomer in a finished molded, fabricated and assembled device. We now also offer OEMs high-tolerance, multi-lumen silicone extrusions from our

new contract manufacturing facility in the Midwest,” Sherman said. “By helping OEM engineers avoid having to go to five different sources, we’re able to attract more medical device projects. In essence, our flexible structure drives our growth in the industry.”

Also driving growth are new demands from OEM customers. “Years ago, we focused just on getting new products to market. Today, we need to think of ways to support customers’ products in the field,” said John Carey, vice president and medical division general manager of Foliage, a technology consulting and product development company in Burlington, MA. As more medical devices incorporate software and electronics, more OEMs are seeking long-term support solutions since support accounts for 80% of a software product’s costs over its lifecycle.

“More and more, we’re being asked to build remote diagnostics or e-diagnostics capabilities into systems in order to lower support costs and to help customers plan support strategies,” Carey said.

ExtruMed has responded to customers’ demand for faster turnarounds by instituting a “quick turn” service that allows the company to deliver in less than five days a wide variety of near-spec prototypes using readily available materials and tooling. “This service can significantly accelerate the iterative process early in the development or design change phase,” Ellerkamp said. “In manufacturing, ExtruMed has concentrated on rapid throughput, with build-to-order releases often shipping in less than four weeks. We also offer kanban inventory management and Web-enabled integrated supply chain management for larger customers with stable demand patterns. These services often result in releases within hours of call-off.”

Standards Change the Outsourcing Landscape

Another area significantly impacting outsourcing efforts is the increased role standardization plays in the medical device industry. In fact, the MPO survey found that 93% of medical device company respondents said it was most important for an outsourcing partner to have good quality systems, and 77% tapped ISO certification as crucial.

“In the last 30 years—particularly the last 15—standardized testing through ISO and other international standards organizations has leveled the field in what to do and how,” Gorski said. “But newer product innovations don’t necessarily fit neatly in a box. With the rate of innovation and change in this industry, we must look at and evaluate safety and efficacy through new, creative, non-historically addressed approaches. It forces change, and OEMs seek help in this area. Smart companies seek our help about materials and design at the beginning of a process to ensure biocompatibility and other needs are met. We can speed time to market when we’re involved at the design phase.”

NAMSA stays abreast of the latest regulatory changes by serving on numerous ISO committees. “We can see what is happening and advise our clients before changes are mandated to the market. We also invest in equipment, personnel and expertise to meet these changes so our clients don’t have to,” Gorski noted.

In addition to publishing an e-newsletter about regulatory updates, NAMSA also hosts industry seminars on updates and their implications for the industry. “We offer these seminars in the United States two to three times a year, in Europe once or twice annually, and we’re planning courses in Asia,” added Terry Langenderfer, NAMSA’s director of global marketing.

Education about regulatory changes also is a concern in contract sterilization—but more so for contract manufacturers than for OEMs, said Thad Wroblewski, director of sales for STERIS Isomedix Services, which is headquartered in Mentor, OH. “Contract manufacturers now have ownership of a larger piece of the supply chain—including all the associated responsibilities, work and risk,” Wroblewski explained. “Trucking damage, sterilization management, process non-conformances and associated liabilities are passed on to the contract manufacturer.”

Too often, he said, contract manufacturers don’t fully appreciate the responsibilities, costs, benefits and potential liabilities associated with sterilization and will bill the service as a non-value added operation, simply passing on direct costs. However, even one lot that doesn’t meet specification could bankrupt a supplier, so contract sterilizers are spending more and more time educating contract manufacturers about “the real world of sterilization,” Wroblewski said.

He added that many advances have occurred in sterilization over the years, and regulatory changes may be on the horizon as well, further underscoring the importance of customer education. “Processing in alternate atmospheres, cold temperatures and other variations are being evaluated, along with the SAL [sterility assurance level] question: Why 10-6? Would 10-3 be acceptable, especially for a product that medically affords great promise?” Wroblewski said. “We have greatly expanded our TechTeam capabilities to help evaluate all of these areas, and we’ll continue to educate our customers about any development that could affect their products.”

In the Future

While the medical device industry and outsourcing business are booming, experts advise that companies must continue to embrace a mainstay of medical manufacturing to remain successful: caution. After all, the lending environment is volatile, and client business can dry up unexpectedly. Overleveraged companies can face perils.

“Outsourcing fundamentals are going in the right direction,” Kinross said, “but the orthopedics market had a bad year last year, and although it’s uncommon, OEMs can take away their business overnight. Negative surprises can have an unforeseen impact.”

Negative surprises can harm not only individual companies, but the industry as a whole, as the energy sector learned when Enron imploded.

That said, contract manufacturers should continue to diversify their capabilities and service offerings. “Increasingly, the OEM will expect the supplier to understand the end application and to deliver product innovations rather than just product solutions,” Ellerkamp concluded. “Many contract manufacturers today are simply resources for hire. This relationship will have to change to the point where the contract manufacturer begins to look, and act, more like an OEM. In fact, many contract manufacturers of the future will become private label manufacturers to leverage the OEM’s investment in sales and marketing scope. The OEMs of the future are likely to have very limited manufacturing capability and capacity.”

Editor’s Note: Next month, the second installment in this two-part series on the evolution of outsourcing in the medical device industry will discuss how the day-to-day practice of outsourcing has changed.