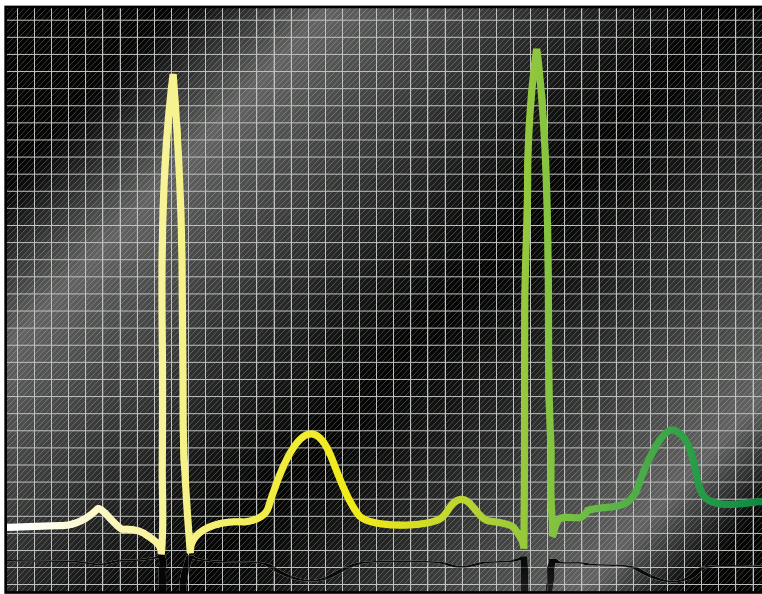


Taking the Pulse of Full-Service Outsourcing

The Heart of Component Manufacturing Is Still Beating,

but Finished Goods May Fill the Prescription for Future Industry Growth

American humorist and social commentator Will Rogers said, “Even if you’re on the right track, you’ll get run over if you just sit there.”



Medical device companies—and the executives who run them—tend to be a conservative, risk-averse lot. And rightfully so. Given the many risks (clinically and financially) involved in bringing products to market, it is critical to maintain control of the myriad variables required to bring projects to fruition. As a result, most medical device manufacturers have been slow adopters of outsourcing—particularly the full-service, finished-goods variety.

But, getting back to Rogers’ point, many medical device contract

manufacturers aren’t just sitting there. They’re responding to changing market dynamics and expanding an already successful service model to make their menu of services more palatable and attractive to device OEMs. While other industries—automotive and electronics, for example—have used outsourcing for many decades to reduce manufacturing costs, streamline supply chains and reduce time to market, device manufacturers finally are adopting this model and finding an industry prepared to offer a wide range of value-added services.

“Outsourcing has always made sense, but the medical device industry is inherently conservative. Up until this point a lot of executives did not want to give up control and do any outsourcing—period,” said Andrew Kinross, an associate director in the Burlington, MA office of Chicago, IL-based Navigant Consulting. “But little by little it’s happened, and some OEMs have brought in professionals from other industries that have gone through outsourcing and they’ve made the pitch to management, saying that they’ve done it and it works. In addition, outsourcing companies have proved that they can be relied on.”

Initially, outsourcing providers only supplied components for vertically integrated device companies, but it’s no secret that in the last 10 to 15 years, that formula has begun to change. Kinross described it as a 30-year evolution.

Christopher Delporte
Group Editor

“Thirty years ago, medical device companies did everything in-house. Twenty years ago, they began outsourcing components, which worked

well. Within the last 10 years has been the introduction of finished-goods outsourcing,” he said. “Device manufacturers have more confidence

in the process and they see it impacting their economics, which is really what it comes down to when you’re talking about finished goods. Components are such a small percentage of the cost of the end product. But when an [outsourcing provider] can tell an OEM they can reduce the cost by 10% and that it will have a 3-cents-per-share impact on earnings, all of a sudden it hits home.”

According to Ben Dunn, a partner in the firm of Covington Associates, a specialty investment banking firm in Boston, MA that handles mergers and acquisitions in the healthcare sector (among others), OEMs are under tremendous pressure to develop new products faster. They’re investing more money in research and development (R&D) activities and marketing.

“Medical device OEMs are focusing more of their resources on core competencies,” Dunn said. “And manufacturing and packaging aren’t necessarily among them.”

In the United States, 20% of all OEM manufacturing was outsourced to third-party vendors in 2005, resulting in annual market growth of 26% to \$4.4 billion, up from \$2.2 billion in 2002, according to a white paper recently released by Dunn and his colleagues. The firm also predicted that as much as 40% of all device sector manufacturing could be outsourced by 2010, leading to 15% annual growth.

The white paper also claims there are approximately 3,000 outsourcing suppliers providing machining, stamping, assembling, sterilizing and packaging services, ranging in size from small owner-operated machine shops to larger niche manufacturers of specialty components to

highly sophisticated, professionally managed organizations offering a broad range of services.

Notably, 50% of the market is controlled by no more than 12 firms, according to the Covington Associates report.

“Now that [OEMs] are more comfortable with outsourcing, they’re finding more partners to help them do those jobs,” Dunn explained. “This, in turn, is an opportunity for those partners to take on a wider range of products and services.”

While what Dunn terms the “best in breed” providers—companies that perform certain component manufacturing tasks very well—still make up the majority of the outsourcing sector, he said the number of firms offering a “one-stop-shop” solution will continue to grow, adding that the consolidation the outsourcing market has experienced is good for the sector overall.

“The larger OEMs don’t want to deal with 50 different suppliers,” Dunn added. “It’s our belief that component suppliers will need to improve and continue to invest in order to be a step above the full-service providers in the market. Their products will have to be substantially superior.”

Shifting Focus

To respond to all the positive growth indicators, many new outsourcing companies have opened their doors to cater to OEMs’ shifting needs. Other existing organizations have transitioned their component manufacturing to more of a complete design-to-package solution.

Randy Keene, president and CEO, of Avail Medical Products Inc., in Fort Worth, TX, sees the finished-device outsourcing market growing at an annual compounded growth rate of 27% through the end of the decade, while components are expected to grow at 11% over the same period.

“There’s going to be plenty of growth in the component business,” Keene explained. “Our market research, however, clearly demonstrates that the growth of the finished device segment will be radically more significant in the long term.”

Keene founded Avail in 1995 as a response to what he saw as a need for more of a complete outsourcing solution for OEMs.

“One of the things we felt was key was to be pure in focus and not to have any of our own proprietary finished devices or intellectual property (IP),” he said. “When we looked at the companies we were competing with, they were either a division of or part of a company that had its



A Solectron employee puts custom finishing touches on an electro-mechanical system. Solectron offers its medical device clients a global reach with a network of international manufacturing facilities, such as its Medical Center of Excellence in Singapore. Photo courtesy of Solectron.

own product line. We felt like if we wanted to be significant in this business, we had to be pure to our customers' products—a true partner."

Keene also noted that OEMs don't make money building manufacturing plants—they achieve greater profits through their IP and franchise with the doctor, hospital and patient.

"As an OEM, if I'm buying more components, I still have to put it all together," he said. "But, if I can set an entire product line off to one side and let someone else make it, I just freed up significant resources. Device finished-goods outsourcing provides a real solution to the OEM."

For the OEM division of B.Braun in Bethlehem, PA, which

Outsourcing's International Reach

To meet OEMs' myriad needs and cost pressures, outsourcing partners have responded by offering a wider array of services, further allowing customers to save time and money. One such way suppliers have done this is by leveraging global networks, either to give multinational OEMs better access to resources or to take advantage of low-cost manufacturing centers—or both.

Brian Moore, president and CEO of Warsaw, IN-based Symmetry Medical, said that that proximity to foreign customers has been key.

"We have a strong European presence for our customers—with facilities in France, Switzerland, the UK and Ireland—and a strong Japanese presence for dealing with our customers in Japan," Moore said. "Part of our philosophy is that if our customers need support around the world, we'll be there to help them."

Symmetry also recently began a move into Malaysia, in part to help serve Japan-based customers.

Clinton, MA-based Nypro also offers an international reach, with facilities in such locations as Russia, China and India.

"To be a full-service provider, you need design, engineering, mold-building capability, high-speed automation, assembly, cleanroom capability and distribution capability," explained Tom Taylor, vice president of global marketing and business development for Nypro's healthcare division. "But, to meet the needs of large OEMs, you also need a global platform."

Dave Busch, vice president of the medical segment of Milpitas, CA-based Solectron, agreed.

"OEMs are looking for partners that have global reach. You might want to manufacture in Asia, Eastern Europe or Mexico for your primary markets in North America and Western Europe to take costs out," he said. "Companies realize that it is easier to work off of another group's bricks and mortar in an area such as China. There are only a few of us with that capability and global reach."

No matter how far-reaching a supplier's network may be, Moore said the client remains the ultimate decision-maker.

"Distributions channels, logistics and outsourcing are very much the success criteria of tomorrow, but, of course, the customer would have the major say on where they want their product manufactured, obviously for quality reasons and time," he said. "In orthopedics we have to constantly remind ourselves of speed to market. Can you get a product to market quicker by several months by outsourcing it with the right margins for our OEM customers? That's a major win for them."

—C.H.D.

has been outsourcing medical devices since the 1970s, the component side of the business has been shrinking steadily. As recently as 10 years ago, component sales comprised 15% to 20% of the company's sales. Today, that number has shrunk to 1%, according to Tom Black, vice president of OEM sales and marketing.

"Back in the 1980s, two or four cavity molds were good enough with regard to price and capacity. As volumes grew, the industry has required higher cavitation tools in order to reduce costs and keep up with demands," Black said. "Now customers looking for strictly bulk, non-sterile components are either

working with standard, off-the-shelf components, which some suppliers have a variety available, or they are in need of custom components/tools—work that is better suited for mold shops. Our business is growing more on the finished goods side—either to build a complete set, an entire packaged product or a custom kit."

Nypro in Clinton, MA is an example of a company that has endeavored to transition itself from more of a component maker to a one-stop shop for OEMs. Fifteen years ago, 80% of the company's business was molding. More than 50% of Nypro's production today is value-added services, said Tom Taylor, vice president of global

marketing and business development of Nypro's healthcare division.

Why make the switch?

"The market was simply too big to ignore," Taylor said. "We already had a relationship with most of the big OEMs, and they continually asked us if we'd be interested in and had the capability to do start-to-finish manufacturing."

Wilmington, MA-based Accellent has leveraged an extensive network and component expertise to develop a "a supply-chain focus" that now represents 90% of the company's new business opportunities, according to Patrick Fabian, senior vice president for Accellent. The company was formed almost three years ago when

UTI Corporation and MedSource Technologies Inc. merged, creating a network of 19 manufacturing facilities. Fabian said the compa-

ny's extensive network of sites and expertise allows it to focus on a wide variety of industry needs and value-added services, including sub-assem-

bly, final assembly and complete supply chain solutions.

"You put all those facilities together and leverage their strengths, and you've assembled a complete supply chain solution," Fabian said. "We continue to add to our breadth of capabilities and resources."

Fabian explained that while the company started with "15 or so" of the larger device companies, Accellent has begun to work more start-ups and midsize firms into its outsourcing mix, and most of those are looking for complete manufacturing solutions instead of component manufacturing.

Out of the three sectors Accellent targets—endoscopy, cardiovascular and orthopedic—Fabian said endoscopy is the largest, but he also noted that the biggest growth recently has come from cardiovascular side.

"What we're seeing more from cardiovascular are opportunities to work from the development process forward," he said. "We also have begun to see a trend where we're being asked to go through the entire 510(k) process to help companies free up resources."

Bob Kelliher, founder of MRI Medical in Tucson, AZ, said his company "morphed" into a full-service company out of necessity. The company—which also has been handling more 510(k) and regulatory issues for clients—specializes in silicone catheters and provides design, assembly, engineering and supply chain services.

"Our clients will ask for help with packaging, regulatory issues, design or tool manufacturing, and we'll design a customer program around each of their needs," he said. "For many of the larger companies, it's been kind of a collision

of regulatory requirements and corporate structures. Larger companies are just not efficient in getting projects from concept to the marketplace. We've had large companies come to us and say they're so frustrated with themselves."

Brian Moore, president, CEO and director of orthopedic outsourcing giant Symmetry Medical in Warsaw, IN, said his customers are looking for "total solutions" and to dramatically reduce their supply chain.

"They expect their suppliers to do more," he said. "That means a supplier in today's world has to have many different attributes and capabilities. Clearly, you have to be able to make the parts, but you also have to handle all the regulatory and logistical issues as well."

The Right Tools

Industry players may jockey for market position and pick apart each other's capabilities to try and gain a competitive edge, but most agree—regardless of size—on the must-haves if an organization is going to take on (and keep) an OEM's full-service business.

Avail's Keene said the absolute "must" is a flawless quality system.

"The quality system designed for a finished device manufacturer is radically more complicated and sophisticated than the quality system for a component manufacturer," he said. "We were the very first company that Johnson & Johnson ever certified as an outside supplier. We were one of only three in the world at one point in time. They really helped make our quality system better, and that hasn't really stopped."

Keene said Avail has a quality system that is fully integrated through all plants at all levels, adding that the company has had, on average, 50 audits a year by its customers for the past 13 years. Avail



According to officials with the OEM division of B.Braun, the company's sales of medical device components has dropped from 15% as recently as 10 years ago to around 1% today, responding to increased OEM demand for finished goods. Photo courtesy of B.Braun.

also spent \$12 million on its quality system last year.

“Every one of those audits yields improvements in the system,” he explained. “One of the benefits that we have that even the OEMs don’t have is that OEMs may have one or two audits a year—and they’re not looking forward to those because it’s usually the FDA. We’re dealing with a customer audit a week, and as a result, we have a very dynamic quality system that can accommodate the most stringent requirements of the most sophisticated OEM or a brand new start-up company that may not even know what it really needs, yet still be versatile, efficient and cost effective.”

Nypro's Taylor agreed, adding that big companies want to see a supplier's capabilities from a quality and regulatory side upfront.

"That's the one thing that really differentiates the Avails and Nypros of the world," he explained. "It's all about risk mitigation. They want to know that a company is big enough and has the depth of resources to make a high-quality device that's going to pass the FDA muster."

Keene added that while quality is always important, it's even more so when Avail takes on cutting-edge device design and manufacturing. "It gives OEMs confidence," he said. "We're rolling out some very exciting, care-altering products, and it was important that we had the quality infrastructure in place to make that happen."

Yet another key skill set for a company positioning itself to tackle an OEM's finished-goods requirements, according to many of the suppliers who spoke with *Medical Product Outsourcing*, is significant design capabilities.

B.Braun's Black called it "paramount," and Keene said that OEMs will "move on quick" if an outsourcing partner can't design a product from scratch all the way to finished device.

Taking this skill set a step further, a new entry into the medical device outsourcing market called Ximedica has built its business model around design and development for manufacturing.

Based in Providence, RI, the company is a spin-off of a product development company called The Item Group.

"Ximedica was founded almost two years ago and we're working to become a full-service, one-stop shop," David Robson, development director, told *MPO*. "The thing that differentiates us is that we're a product design and development company first. Who better to put your product together than the people who designed it? We've all got medical device technology backgrounds, so we know what a bad experience with a supplier looks like. We've been diligently working to make good experiences for our clients."

Robson said the company is ramping up its hiring of industrial designers, mechanical engineers, software engineers, electrical engineers and quality compliance specialists. He noted that the company has been engaged to assemble some finished goods, but mostly on major sub-assemblies. Robson said that, thus far, the company's clients are evenly split between larger OEMs and smaller companies with less than \$100 million in sales.

Another area of opportunity for full-service outsourcing providers is in post-manufacturing services, according

to Dave Busch, vice president of the medical segment of Milpitas, CA-based Solectron. His company and many other electronics manufacturing services companies have been successful in the device outsourcing industry. Solectron offers product design, new product introduction, supply chain management and Lean manufacturing, in addition to after-market services such as product warranty repair.

“We’ve been getting a lot of requests for post-manufacturing services, such as managing diagnosing services and return of medical instruments for service,” Busch said. “It’s an interesting phenomenon. Very often medical devices are non-optimized designs that you’d never see in a consumer electronic product, for example. And there’s been much more talk of how to design a medical device so that they’re more like a consumer electronics product—much more low-cost and reliable.”

Busch added that more and more medical device companies are looking for design-and-build services, along with help on all the regulatory paperwork.

“Their business model is that of a ‘spec-design-house’ and that’s where a contract manufacturer comes in,” he said.

The OEM Perspective

Medical device manufacturers may have been slow to adopt outsourcing as a viable tool, but once they’re involved, they’re pretty specific about their needs.

Todd McCaslin, global sourcing director, metals, for Natick, MA-based Boston Scientific, echoed the importance of design, research and development skills in an outsource partner. He said one of the “most difficult searches”

is finding suppliers that are experts in product development issues.

“We have a few suppliers that really understand catheter develop-

ment, for example—and they were an extension of our R&D group,” he said.

“Companies that can provide focused, skilled medical device development as

a contract service and then can roll into the small-scale manufacturing—that's something we've been looking for, for a long time. We have a lot of good companies that have excellent engineering on the component side, but we haven't found many for finished devices. It helps if the vendor has engineers with medical device experience."

McCaslin said Boston Scientific's use of outsourcing may buck the current finished-product trend, helping component outsourcing to remain the largest slice of the contract manufacturing pie.

"Component manufacturing has always been an integral part of product development at Boston Scientific, he said. "We spend five to 10 times

more on the component side than the finished goods, just roughly."

He did say, however, that—finished product or component—the decision to outsource ultimately comes down to allocation of resources and core competency.

"We have the capability to do injection molding in-house, but we're outsourcing more injection molding than we do in-house right now," he explained. "We have to ask ourselves what the best use of our core technology is. We do a make-buy decision on just about everything. Does it make sense for Boston Scientific to do this in-house? Is this where we want to be investing our resources and money strategically? Can some-

one outside do it better and more cost effectively?"

For a product such as the company's Taxus stent, Boston Scientific keeps the majority of the process in-house. Only the metal tube that eventually gets cut into the stent comes from an outside supplier, McCaslin said. However, as is the case with most large OEMs, Boston Scientific more readily will turn to a finished-goods supplier when the product is not a core business and it no longer makes financial sense to keep internally, he noted.

"When we've done that, we've had instances where there were improvements in production, improvements in cost, in yield across every metric

you could possibly think of. The product may have been a small fish in a big pond in our facility, but when we moved it to the supplier, it was a very significant portion of their business and they focused on it much more than we did internally.

McCaslin cautioned, however, that just because the company isn't using much finished-goods outsourcing doesn't mean it won't do more in the future or that it shies away from supplier partnerships.

On the component side, the company has a preferred group of strategic suppliers. On the finished-goods side, he said the company uses "only a handful."

"We are looking for new companies," he added. "That's been an objec-

tive for us. We want a stable of horses with finished-goods capabilities. We've been out there kicking the tires, and we're making plant visits. We need to find the mix we feel comfortable with."

Smaller OEMs, however, don't have the infrastructure of a Boston Scientific, and—as suppliers have counted on—use a full-service outsourcing solution to get their product to market quickly without the investment in brick-and-mortar production facilities.

Immunicon, a developer of diagnostic and research products for rare cell analysis and molecular research, has used full-service outsourcing from Day 1, said Michael Kagan, the com-

pany's vice president of operations.

"We're a small company and we know we can't do everything," Kagan said. "Our core competency is more on the reagent side than the instrument side. Does the customer care if the instrument is made here or in Ohio? Not really ... as long as it meets their quality objectives."

Kagan said the Huntingdon Valley, PA-based company is transitioning to fully outsourcing all of its instrumentation products. Until very recently, the company had been doing final assembly, testing and shipping in-house.

Similarly, a vice president of manufacturing for a midsize medical device company who asked that his

company not be identified because of contractual and proprietary concerns, told *MPO* that, until recently, his company's growth had been pretty organic and outsourcing didn't fit into his manufacturing model, with the exception of a few component suppliers.

"We preferred to keep things in-house," he said, adding that as the company has begun to make acquisitions, it's using more finished-goods suppliers probably will increase its use—particularly on the design side. The first criteria for evaluating partners would be the experience and the record of success. The company, much like Boston Scientific, is beginning to vet finished-goods providers to help with an expanding product line.

"We're looking at most of the bigger players," he said. "But we also have begun using smaller companies that are very good at what they do but are very niche—with software development, for example."

Growth for Both?

The component market is still the largest sector of the device outsourcing industry, according to Navigant's Kinross, but finished-goods manufacturing is going to continue to grow at a faster pace.

"Components are still profitable," he said. "The profit margins for component manufacturers are higher than for finished-goods manufacturers, but some of the component manufacturers could be vulnerable if the trends toward finished goods turn out to be as pervasive as they could be."

Consolidation is expected to continue. As this game of cat and mouse continues, bigger players are taking more market share and the smaller players become more vulnerable—both for finished goods and components—analysts predicted. Despite the shrinking number of suppliers, the growth of the device industry over the next few years (from \$74 billion in total US sales to an expected \$86 billion by 2010, according to IBISWorld market research) portends well for both outsourcing sectors.

But, as Will Roger's warned: Don't wait around on the right track for too long.

"If you're a niche component supplier, 50% to 60% of your business may come from one customer. Be careful about where that customer is going and how the customer may feel about one-stop shops," Covington Associates' Dunn cautioned. "You may unexpectedly find the need to quickly diversify your customer base, add more capabilities or merge your business." ❖