

A Strategic Charge

Electronic manufacturing services providers are pushed to increase services and lower costs.

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Outsourcing electronic manufacturing services (EMS) is a key business strategy for medical device manufactures, as well as for their contract manufacturers and suppliers. More than ever before, EMS providers are expected to operate as strategic partners to their OEMs, a relationship that allows these medical device companies to focus more on their core competencies, such as research and development, brand building and marketing. A well-functioning EMS-OEM relationship, according to industry experts, reduces overall costs, limits inventory, improves efficiencies and gets products to market more quickly.

Many OEMs without a solid supply-chain management strategy got hit with excess inventory charges in 2008 and early 2009. This was followed by a huge market upswing in late 2009 and 2010, where some parts went on allocation and forecast overdrive became prevalent.

“This, in turn, ultimately added extra cost in the form of expediting fees and excess inventory charges,” said Michael Tendick, medical sector vice president for Plexus Corp., a Neenah, Wis.-based company that helps clients with product conceptualization, design, commercialization, manufacturing, fulfillment and sustaining services.

A number of poorly managed EMS companies went out of business during the recession, allowing the more stable EMS companies to gain market share. Smaller companies that remained focused on their niche markets also weathered the downturn in relatively good shape, such as Minnetronix. Small companies that were not as focused (for example, Winland Electronics) either have been acquired or gone bankrupt.

“As we continue to pull out of the economic recession of 2008 and 2009 we’ve noticed an increased interest in outsourcing as an integral part of corporate strategies,” said Matt Giza, general manager for Cogmedix, a Coghlin Company and contract manufacturing firm of Class I and Class II finished medical devices in West Boylston, Mass. “Part of this heightened interest is presumably based upon the challenges and overhead costs of ramping up and down a manufacturing organization to accommodate dynamic market needs. Companies are interested in outsourcing across the board as an effective way to

compliment a smaller in-house manufacturing team or to replace services that would have traditionally been performed in-house.”

Aaron Nissen, electrical engineering manager for SourceScientific LLC, a designer, developer, and manufacturer of medical devices and laboratory instruments based in Irvine, Calif., reported that companies such as his are outsourcing more work and requesting more services from EMS providers to ensure leaner manufacturing.

“Reducing procurement burdens keeps cash flow up by reducing inventory and other operational costs,” Nissen said.

In general, most medical device companies have low-volume demands for electronics, making it more practical for them to outsource this function instead of doing it in-house. According to the “Electronics Outsourcing Report” published by the Venture Outsource Group in San Jose, Calif., partnering with an EMS outsourcer can result in savings as high as 10 to 15 percent. Also, OEMs count on sharing the burden of increased regulatory scrutiny from the U.S. Food and Drug Administration (FDA) and other agencies with their EMS providers, which often are in a better position to deal with the changing regulatory and quality-control requirements.

Lead Times Still a Challenge

One of the biggest issues for companies as they emerge from the recession is lead time. On the supplier side, electronic component manufacturers closed down a significant amount of capacity when the recession hit after the October 2008 financial crisis. As the world economy slowly recovers and business picks up, demand for components also is on the rise but, with less global capacity for electronic components, lead times have become extended.

“Although prices have been relatively stable, the availability of components continues to be a major problem in fulfilling customer orders on a timely basis,” said Joe Horvath, president and CEO of Sanbor Medical, a full-service contract manufacturer in Pennsylvania that also operates a FDA-registered manufacturing facility in China. “The situation is slowly improving but long component lead time is still a very real issue.”

“Since the credit crunch, no one wants to be responsible for inventory,” added Mike Duddy, project manager at World Electronics, a low- to medium-volume electronic contract manufacturer based in Reading, Pa., that specializes in full-turnkey assemblies and quick-turn prototypes. “The OEMs are pushing for shorter delivery times and the contract manufacturing industry is pushing for longer lead times. Some customers attempt to solve this dichotomy by issuing smaller, more frequent orders—for example, rather than giving us a purchase order for 6,000 pieces over six months we are getting a [purchase order] every month for 1,000 pieces. This is not the answer because there is no volume leverage when buying components, component lead times are exaggerated, and it doesn’t allow us to efficiently plan our manufacturing schedule.”

Susan Mucha, president of Powell-Mucha Consulting, an El Paso, Texas-based company that assists the EMS industry with strategic planning, market positioning and training, indicated that component lead times for medical products in the eight- to 16-week range were not unusual and some components still have a lead time of more than 22 weeks.

“Overall this is an improvement over the prior year, but still challenging in terms of supporting a variable demand manufacturing environment in an economy where OEMs are concerned about the cost implications of carrying liability for large amounts of raw or finished goods inventory,” she said.

OEMs continue to apply pressure on their contract manufacturers to fulfill orders on short notice, even though they know the raw material pipeline is now being severely stretched. “Although over the last six months or so the component manufacturers have been slowly adding capacity and reducing lead times, it's a slow process and we have to continue to work our supply chain hard as things improve,” Horvath said. “This type of cycle is not unusual in the electronics industry, so processors like us are quite used to these demands.”

Sanbor Medical is managing these supply chain limitations by notifying customers of the extended lead times, as well as working with them to get orders placed farther into the future.

“In situations where this isn't possible, we're asking them to commit to the raw materials and then we'll place orders against their level of commitment,” explained Horvath. “We're also expanding our sourcing efforts to try to find needed components from any credible source. This can sometimes be done, but usually at a higher price.”

It also can be costly for medical device manufacturers to change the approved vendor list because a new product qualification process may be required. If the component isn't available direct or through franchised distribution, EMS companies have the option of increasing inventory (guessing what their customers are likely to need if the customer won't provide the visibility) or going through brokers for the approved allocated part.

“The problem with materials purchased through brokers is that they may have higher failure rates—for example, excess inventory which may be old or have been mishandled or stored improperly, or in the worst case even counterfeit parts,” said Mucha. “Counterfeiting is a real concern because there are a lot of good counterfeit parts out there. Component manufacturers, distributors, legitimate brokers, OEM, and EMS companies all work to fight counterfeiting through a combination of understanding prior ownership of materials, testing, keeping lists of part numbers that are suspect, and sharing information on sources selling bad parts, but there are some very determined counterfeiters out there and in an allocated market bad parts will slip into the system.”

In Duddy's view, the ideal solution to these issues would be to have banks open or extend their lines of credit to OEMs and component manufacturers.

“Limited lines of credit cause everyone to question every expense,” Duddy said. “More business lending will also allow the component manufacturers to increase their output capacity by either adding more shifts or investing in more equipment. This will provide significantly shorter lead times to the contract manufacturers.”

Reconsidering Onshore & Near-shore Locations

A 2008 study by Charlie Barnhart & Associates LLC discovered it’s not always that easy to save money by offshoring EMS services. Depending on the site, OEMs may spend more money on internal costs to manage those offshore relationships than the services themselves. In addition, what were once considered to be low-labor-cost regions are showing increasingly burdened labor rates and changing risk factors.

“Costs are increasing in markets that have recovered more quickly, such as China,” said Mucha. “This is making some OEMs rethink their sourcing strategy.”

As a result, some OEMs have decided to bring their offshore EMS services to onshore or near-shore locations, where risks are more stable and communication and quality control are more easily managed.

Giza has observed the same trend. “It seems that an increasing number of companies are gaining clarity on the differences between outsourcing and offshoring and the criticality of understanding these differences,” he said. “Both models make sense in different situations. Outsourcing should be part of every company’s business strategy. When a company offshores a product or service, unintended consequences may arise around intellectual property (IP) protection, unforeseen costs, compliance with regulatory bodies such as the FDA, labor force and infrastructure maturity, quality, new product support and innovation, and the overall ability to manage high mix and variable demand. Due diligence must be thorough.”

Nissen said larger EMS firms are starting to provide more subassembly capability and a larger variety of offshore options in cheap-labor countries.

“It’s really more of a capacity issue with the expansion of sub-assembly services,” he said. “There are an increasing number of avenues for establishing offshore capabilities. The key is finding an organization that you can develop a good relationship with and maintain quality.”

In previous years many OEMs looked at low-cost regions with the main focus on pricing, to the exclusion of all other related expenses. Today, OEMs are paying more attention to fully landed costs.

“I believe the OEMs are seeing that there are additional costs in purchasing from places like Asia that were not being considered previously,” said Michael Goering, vice president of operations for Arc-Tronics, Inc., an electronics manufacturing services firm in Elk Grove Village, Ill., that specializes in medical, military, aerospace and industrial instrumentation.

“OEMs were just looking at the purchase price and believing this was the true cost. There are additional costs in freight, engineering changes, communication, quality, expedites, etc.”

Because of these offshore concerns, companies are starting to look again at nearshore locations for EMS outsourcing, such as Mexico, Costa Rica and Brazil, which remain low-cost but provide more economic and political stability, stronger infrastructure, and closer proximity to the United States, simplifying communications and business travel.

Arc-Tronics, for example, is building a facility in Mexico to support its North American OEMs. The new 17,500-square-foot facility in Guaymas will open in the first quarter of 2011. “We are purchasing approximately \$3 million of new capital equipment, which includes a surface mount technology line and 3-D post print solder paste inspection system,” said Goeringer.

A viable option to nearshoring or offshoring is simply outsourcing to a company that can source components worldwide and pass those savings on to the OEM.

“There exists a middle ground that offers the advantages and flexibility of outsourcing within a mature market space such as the United States, while taking advantage of certain aspects of offshoring in established and/or emerging markets,” said Giza. “Our model at Cogmedix takes advantage of a global supply chain focus for best value on components and in some cases sub assemblies. The final integration, qualification and compliance are managed here in the U.S. This provides a great blend of using offshore resources while maintaining critical functions, accurate cost control, IP protection, and compliance by a highly skilled workforce with a strong infrastructure—quality, innovation, supply chain, etc.”

Value-Added Services

OEMs want their EMS contract manufacturers to provide higher value add assemblies and finished devices to their services. This is true especially for emerging medical device companies, which prefer to outsource the manufacturing of their finished devices rather than perform the final assembly and testing within their facilities. By outsourcing this key function companies can focus more energy on marketing and product development.

“We have seen evidence of this with our in-house printed circuit board assembly (PCBA) manufacturing capabilities,” Giza said. “It’s often the case where we manufacture PCBAs for a customer and then a short time later we are asked to provide more value by providing a higher-level sub assembly that integrates the PCBA.”

OEMs also are deciding that it is easier to let EMS providers take care of more advanced manufacturing techniques, such as miniaturization, instead of tackling them in house.

“‘Smaller is better’ seems to be the trend with most of our customer’s designs. They’re

utilizing smaller component packages which ultimately give the finished product a smaller footprint,” said Duddy.

This translates directly to component package type.

Other companies are looking to their EMS providers for assistance with engineering services, ranging from turnkey design to design for manufacturability to managing engineering change order (ECO) traffic once the product is launched into production. “More customers are interested in outsourcing what we call ‘ECO change traffic,’” said Giza. “Frequently making incremental changes to an existing product is more cost effective and efficient with an outsource partner; this allows the OEM’s in-house engineering team to focus more on higher-level product development, next-generation products, or new technologies.”

Clients can take advantage of these types of services through the engineering services or product development groups within larger companies.

“We have roughly 65 engineers within our sister company, DCI Engineering Services, including mechanical, electrical, systems, software, and manufacturing,” said Giza. “We are structured in such a way that customers can engage with us at any point in their product development lifecycle, from the initial concepts to volume manufacturing of PCBAs, assemblies, and turnkey products.”

Although adding these new services can be a financial and logistical challenge for smaller EMS companies, many of them are moving forward to keep pace with OEM demands.

“Smaller historically consignment-only EMS firms are now looking at offering more turn-key solutions, additional test capability, and more sub-assembly work,” Nissen said. “My experience with smaller companies is good and I think they need to be even more diligent about quality, because losing business has a greater impact on them than say a larger EMS. Word of mouth plays a huge role in this business.”

With significant commitment from the OEM some EMS companies are starting to provide lean manufacturing, just-in-time manufacturing, and agile manufacturing to address an unexpected acceleration of deliveries. Other EMS providers are being asked to help with regulatory compliance and quality systems, especially from young innovative companies launching disruptive technologies. There also is more online collaboration between OEMs and EMS providers—another effort to accelerate time to market.

“I also see more web-based design/quote submission and DFM feedback directly available to the engineers for both PCB and PCBA,” said Nissen. “For example, Advanced Circuits in Colorado allows PCB designs to be uploaded from its website. From there they will analyze the design-for-manufacturability issues and reply with a summary and quote often within an hour. There are some companies that provide PCB layout tools for free, as well as very inexpensive low-run prototype PCB and board assemblies, if you use their tools.”

Supplier Lists Continue to Shrink

With OEMs continuing to shorten supplier lists, it is absolutely critical to have the resources and skills needed to satisfy or exceed their ever-increasing demands. Although this is an ongoing challenge that requires constant vigilance, it also is an opportunity to dazzle the OEM and become a valued partner that is consulted in all phases of product development.

“As a contract manufacturing and engineering services company we embrace this movement toward shorter supplier lists,” said Giza. “A great example would be any company manufacturing its own products, where they are sourcing many components and sub assemblies. In this situation a company can be faced with managing tens or even hundreds of suppliers, depending on the complexity of the assembly or product. Creating a strong outsourcing strategy that consolidates many suppliers under one responsible party is an effective way to proceed. Companies that are accustomed to managing the entire supply chain and manufacturing finished medical devices are in a great position to add immediate value to organizations that are looking to reduce their supplier lists.”

Therefore, to remain a “go-to” contract manufacturer or supplier at the top of the supply chain, the EMS provider must be able to offer as many additional services as possible, including stocking programs, Kanban, consignment, and design for manufacturability. Experts say medical device manufacturers are looking for the EMS provider to align its facilities with the OEM’s plants in order to support requirements in other regions and maintain the reduced supplier base. This can be a challenge that, depending on the situation, can be handled with existing resources or might require additional investment in equipment and manpower.

“The potential sales dollars, however, have to justify the plant setup,” said Goeringer. Giza added: “This actually ties into what we were talking about earlier with increased demand for higher value added assemblies and finished goods. Some customers will source multiple subassemblies from various vendors and perform the final integration at their own facility.

An increasing trend is to simply outsource more of that work to key suppliers. So, for example, we could provide a higher-end assembly that includes 10 subassemblies instead of one, or build the entire device and take on all sourcing and materials management responsibilities. The benefit to the customer is placing the order with one supplier, rather than 10, 100, or 1,000 orders with multiple suppliers. Negotiation is always involved, but we use an open-book policy so everyone is pretty clear on costs, hours allocated, etc.”

In the past, most of World Electronics’ work has consisted of populating and testing printed circuit boards—this, however, is rapidly changing. The current trend is geared toward the complete box-build or higher-level assembly. This requires the contract manufacturer to insert the PCB in the housing, chassis or fixture, test and/or burn-in the

complete unit and usually package the unit in the customer's box along with manuals, cables, etc.

“To accommodate this trend we have had to hire mechanical assemblers and acquire job specific tools and test fixtures,” said Duddy. “An evaluation of our production space was also necessary as we need to maintain an efficient flow throughout our plant. We are truly becoming an extension of the OEMs.”

This, of course, is a great thing. The OEM is investing more resources in developing a deeper relationship with the contract manufacturer—ultimately increasing the value of that contract manufacturer within the supply chain and creating deeper feelings of trust and reliance by the OEM. By being a more integral partner that is involved in multiple phases of product development, the CM is less likely to be replaced by a cheaper competitor in the OEM's supply chain.

“We strive to create long-term, mutually beneficial relationships with our OEMs,” said Duddy. “This is key to our relevance and/or growth—it is also much easier to grow an existing customer than it is to find new customers.”

Customers continue to look for ways to build assurance into the supply chain—not only for quality of parts and processes, but speed to market as well. OEMs are urging their EMS outsourcers to become proactively involved and work collaboratively with them to find new ways to reduce extended lead times—by giving them more responsibility in managing the supply chain.

“OEMs are truly excited about services that allow them to focus on their core competencies and/or help them gain market share,” said Tendick. “These include engineering services. It seems nearly every company has a need for some type of engineering service; some need the full menu of value-added engineering services from product conceptualization through commercialization, while others need highly targeted services, like thermal analysis or development and implementation of a manufacturing test strategy.”

EMS companies also can provide order fulfillment and sustaining services. “The ability of an EMS company to support an OEM's needs after products are produced has become a greater value add,” Tendick said. “One example would be direct-order fulfillment, where the EMS provider ships to its customer's customer. After-market services that sustain products already in the market, such as repair and refurbishment and product upgrades, also are seen as high value-added services.”

Collaboration with the EMS provider also is used in order to bring products to market in a faster time frame.

“An example would be working on eliminating sole-sourced components, along with evaluating financial stability of suppliers using tools such as Z-scores,” Goeringer said. “Some customers want their contract manufacturers to set up operations near their own

manufacturing facilities. They are willing to allow us to dovetail on their financial capabilities which are much greater than ours. A concern I have with this, however, is you can be perceived as being a captive EMS provider for that OEM and it can give a wrong perception to other potential OEM customers or even existing customers.”

OEMs are getting very comfortable with receiving extra services and asking for more is getting easier for them to do—but can this be maintained? Mucha doesn't think so.

“During the early part of recovery, EMS companies jumped through hoops for their customers, trying to deal with short lead-time-order increases and lengthening component lead times,” she said. “Now some customers expect this to be part of the business model and it isn't sustainable. It actually adds non-value-added cost on both sides. I think the smartest OEMs are tapping their EMS suppliers' design and procurement resources to build approved vendor lists that give them competitive cost and availability, plus finding ways to share reasonable forecast visibility. With the variable demand found in the recovery and the rising cost structure of China, the most popular sourcing trend now seems to be focused on evaluating total cost and making sourcing decisions based on that rather than unit price. As one of my U.S. clients put it, ‘OEMs are pushing us to deliver high service and a price that is lower than we've typically given, but they aren't expecting China pricing.’”

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