

## EMS Gets a Charge Out of Medical Devices

*Electronic Manufacturing Service Providers' Role In the Medical Device Outsourcing Arena Continues to Thrive, Despite Medtech's Unique Challenges*

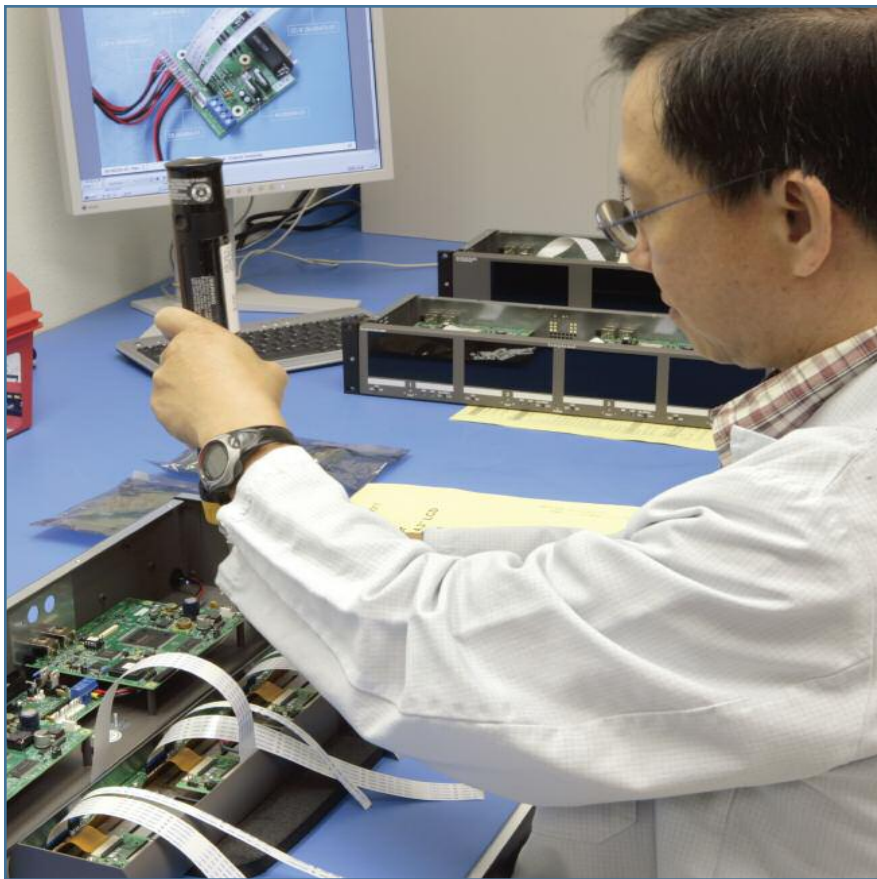
**Christopher Delporte, Group Editor**

To many on the provider side of the healthcare equation, the initials EMS mean “emergency medical services.” Should you be one of the many who toil in the outsourcing marketplace, however, the abbreviation takes on a significantly different meaning. EMS—or electronic manufacturing services—is the term used for companies that design, test, manufacture, distribute and provide return/repair services for electronic component and assemblies for OEMs.

Their handiwork is ubiquitous. EMS companies manufacture everything from personal handheld computers to the new Xbox

360 video game system you may have gotten for your kids (or yourself) during the recent holidays.

As a general rule, the business model for the EMS industry has been to specialize in large economies of scale in manufacturing, raw materials procurement and pooling of resources, industrial design expertise, in addition to creating added-value services such as warranty and repair work. This frees up the customer who does not need to manufacture and maintain large inventories. Prior to roughly 10 years ago, EMS firms primarily focused on printed cir-



EMS providers continue to expand the portfolio of capabilities they offer OEM clients, delivering more full-service options and total lifecycle repair. Pictured above is a box-build assembly at one of the Kimball Electronics Group's Medical Centers of Excellence. Photo courtesy of Kimball Electronics.

circuit board fabrication, leaving system assembly to the OEMs, and steered clear of industries outside of information processing and communications. But in recent years, EMS companies have shifted production to low-cost geographies; embraced non-traditional industries; and added substantial vertical capabilities, stretching from design through system assembly, testing, delivery and logistics, warranty and repair, network services, software and silicon design, and customer service.

One of the "non-traditional" industries that EMS providers have embraced has been the medical technology sector, and they have done so not reluctantly, but with open arms. To examine current business trends, *Medical Product Outsourcing* recently discussed the medical EMS sector with several providers and industry consultants.

### Right Place, Right Time

Jim Davis, president of OEMS LLC, told MPO that EMS companies are particularly

well suited to take on more manufacturing responsibilities. Davis, a former EMS industry executive who now owns his own consulting firm dedicated to helping OEMs in various industries find the right EMS partner and manage their outsourced manufacturing, explained that it's increasingly about OEMs becoming "virtual" companies.

"That's why EMS companies are adding these other services and capabilities to their portfolio," he said. "Technology—particularly in medical—has gotten so complex not just within the products, but also within the processes required to build the products, that it would be cost prohibitive—certainly for start-up OEMs—to even consider doing all of their own [manufacturing]. They wouldn't be able to do it effectively."

Todd Baggett, vice president of business development for Epic Technologies in Norwalk, OH, agreed.

"The greater the value content that the EMS provider can control in a given device, the more attractive the value proposition for the medical OEM via more attractive pricing and a virtual model," Baggett said. "In an effort to manage costs more aggressively, medical OEMs are seeing more and more the value of a virtual EMS solution that can provide end-to-end support from design services through field support and repair services."

He added: "Medical markets still offer reasonable margin potential relative to other segments, and medical demand is somewhat more stable and predictable relative to other industry segments such as industrial controls or military or aerospace."

Gelston Howell, senior vice president, medical division, for Sanmina-SCI in San Jose, CA, said EMS companies indeed may have focused more on medical because there is a belief that they can "make a little more money on it," though he cautioned that companies must understand the responsibility that comes along with the medical technology sector.

"When you do an iPod or an iPhone, it's a few different part numbers and products you're making in high volume," he said. "There are a lot of economies of scale. It's not like everyone who buys an iPod is going to buy a blood separator. The market is smaller, and there's a lot of regulatory overhead you have to be very good at. A lot of contract manufacturers think they want to do it, but you really have to make a commitment. Also, the suppliers for high-volume plastic or printed circuit boards often aren't interested in high-mix, low-volume business."

Thus, OEMs need to create good and lasting partnerships, according to Davis. "You just can't design a circuit board like you did in the old days and pretty much anyone could build it," he explained. "OEMs need to team up with an EMS partner early in the design phase to ensure the device is meeting all the needs for manufacturability, testability, quality and cost."

Howell said Sanmina-SCI is involved 18-24 months before the release of a new product as part of the design team.

"It's not just design feedback on the printed circuit board assemblies, but also for the second-level assembly—everything from cabinet design to how to design the

device to reduce labor content and for product reliability," he explained. "For many of the companies we have larger relationships with, we're part of their design team—doing the design in some cases. We do a lot of the work that just three or four years ago they would have done internally."

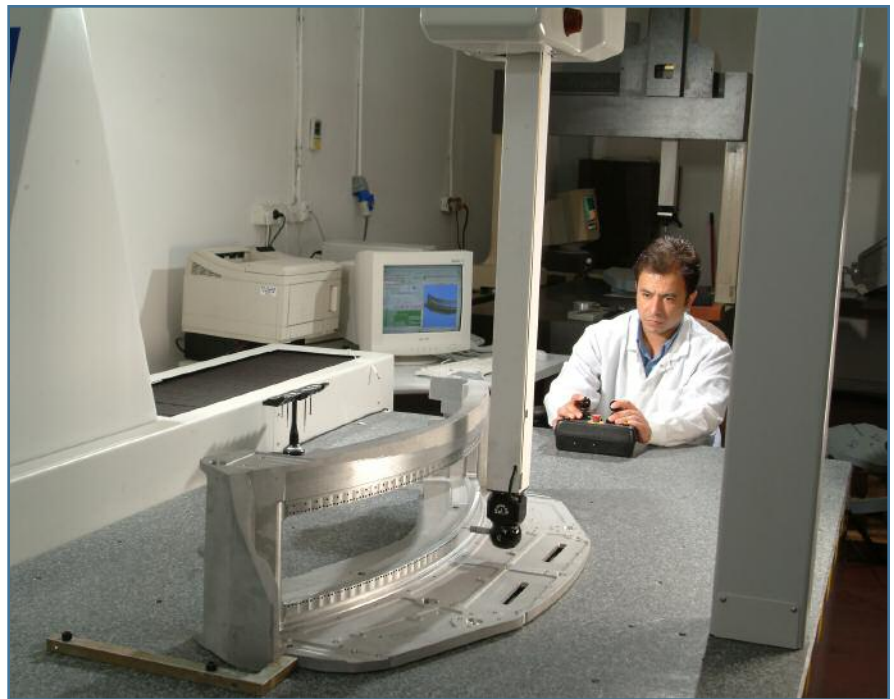
For companies that have entered the medical device arena or are weighing the benefits of taking the plunge, current research reveals bottom-line trends that bode well for EMS providers' expanding role in the medical device industry. A new report from consulting firm Frost & Sullivan estimates that the North American EMS medical device market will reach revenue of \$8.1 billion by 2013. The industry's domestic revenue in 2006, by comparison, was \$3.8 billion.

According to the report, opportunities for EMS appear set to increase significantly as OEMs of medical devices look for ways to reduce capital costs and time to market for new products and focus on core business activities such as product development and marketing.

"Times have changed since EMS providers focused only on assembly manufacturing for OEMs," said Frost & Sullivan Research Analyst Julian Harris. "The design-for concept—which includes design for assembly, testing, manufacturability and supply chain—is very viable and important to increase value for an OEM."

Continuous growth in end-user applications within the medical device market also will create good outsourcing opportunities for EMS providers, the report said. For instance, cardiovascular devices and monitoring equipment will see a growth spurt due to the widespread prevalence of cardiovascular disease and cancer. Minimally invasive surgery and the emerging neurostimulation segment also will contribute to the growth of EMS providers in the medical device market. Other potential high-growth areas highlighted by the report include therapeutic devices, endoscopy, infusion systems, diagnostic and monitoring equipment, audiology and instrumentation devices.

"The permeation of electronics into a wide range of medical devices such as dose counters, inhalers [and] handheld surgical instrumentation, for example, is really driving OEMs to look at EMS companies com-



**Continuous growth in medical device end-user applications will create good outsourcing opportunities for EMS providers. A recent report showed that cardiovascular and monitoring equipment should increase due to the widespread prevalence of cardiovascular disease and cancer. Minimally invasive surgery and the neurostimulation segment also will contribute to the growth of EMS providers. Photo courtesy of Sanmina-SCI.**

pared to other component suppliers and contract manufacturers," said Dan Croteau, president of Singapore-based Flextronics Medical. "Electronics are finding their way into everything—smart catheters, cameras for the GI and diagnostic systems."

Art Rutledge, president of Timonium, MD-based Fawn Electronics—a regional EMS provider with facilities in North Carolina and a joint venture in China—said technology in the wireless data arena also is driving growth in medtech's use of EMS. He additionally noted that EMS companies are making more of an effort to understand the nature of medical technology from the beginning of the process rather than just responding to customers' needs.

"Hospitals are looking for digital solutions to help them control inventory and things they've done manually for years and may not be as effective," Rutledge said. "We see lots of doctors on the boards of companies we're working with, and you didn't see much of that before. People would come up with a product and tell healthcare why there was a reason for it. Now, there's more of an effort to see what's going on in the healthcare industry to find out what they really need, not what we think they need."

## High Mix, Low Volume

Though the profit picture seems to be rosy and new technology is driving sector growth, there has been a learning curve for many EMS firms entering the medical device market.

These firms have had to, as Howell mentioned, adjust their manufacturing model to meet the very specific demands of medical device customers. They also have had to get their arms around more of a high-mix, lower-volume formula, often with more domestic production for medical devices than with their high-volume consumer electronics cousins that are routinely manufactured in low-cost Asian countries.

"This early collaboration may very well allow the OEM to use a domestic EMS provider and get a competitively priced product—especially if one considers all of the 'hidden costs' associated with offshore suppliers. Nonetheless, there will always be products that are better suited for offshore production. To support this, there are many EMS providers that have both domestic and offshore solutions, and that can be ideal for an OEM that wants to have domestic-level control during a product's first couple of years," Davis said. "Once the

design is tight and stable and other OEMs come out with a competitive product, an offshore arm can likely do it for even less, managed through a domestic facility. And I think that's a real nice solution to have available."

Croteau told *MPO* that depth of experience in other markets has prepared EMS companies for the lower volume that often is part of manufacturing for the medical device market. "EMS companies have gained a tremendous amount of experience in global design for manufacturing that can now be applied to industries with lower-volume, high-mix applications and deliver significant speed and cost capabilities," he said.

Flextronics, one of the world's largest EMS providers, has made a big splash in medical device contract manufacturing in recent months. Last summer, the company announced its plans to acquire Fort Worth, TX-based Avail Medical Products Inc. Around the same time the company also negotiated the big-ticket acquisition of one of its largest EMS competitors—Soletron—for \$3.6 billion.

In many ways, however, Croteau said he believes that it isn't as much about low volume versus high volume as it used to be.

"Over the last couple of years, the level of complexity and volume required to realize a significant cost savings by making a product in China or Mexico has come down significantly," Croteau said. "So you don't need to make millions of units a year to have a great reason to save money by making a product in Eastern Europe or China. The system and factories have become very efficient at running product in lower volume and localizing the supply chain to lower-cost suppliers as well as delivering lower-cost labor to make it attractive. I think the point is that you really need to have options. What one company thinks is unattractive, another company may think is very attractive—even considering concerns about intellectual property (IP).

### Cost Cutting and the Offshore Option

The EMS providers who spoke with *MPO* agreed that OEMs continually look to drive costs out of the manufacturing process. That's no secret. Going offshore to manufacturing facilities in China, Vietnam (see

"What Do Medical Device Manufacturers Need to Know About Vietnam?" on page 60), Mexico or Eastern Europe to pursue low-cost labor options certainly is one of the most obvious ways to drive down cost.

Quality is king, however, and all the providers interviewed noted that they wouldn't even consider taking a medical product overseas if quality couldn't be maintained. Opinions varied, however, as to when in the process—if at all—companies turn to an offshore production option as way to improve the bottom line. Sanmina-SCI's Howell said the decision to stay closer to home or seek low-cost foreign options depends on a mix of customer preference and the type of medical device being manufactured but added that larger medical OEMs are "very driven" by cost reduction. In addition, he noted that larger OEMs are more willing than small and midsize firms to embrace the offshore option.

"It really depends on the priorities of the OEM. Every company looks at things a little differently," he said. "Some may want the manufacturing close to where they're doing product development, particularly if the product is complex. If the system is brand new and just being introduced to market, we'll usually keep production in the US or Israel for six to nine months. Sometimes the customer is very driven by cost and they want to take a product right to Asia, which is common in the consumer category [such as blood glucose monitors]. We give customers different options and show them differences in pricing."

Within the first few months of this year, Sanmina-SCI's "global footprint" for medical manufacturing will expand to 10 FDA-registered plants from just eight last year. Locations include Mexico, India, Singapore and China. Most of the firm's growth in the medical device arena has occurred over the last six years. Howell said that about 70% of what's manufactured overseas by Sanmina-SCI is sent back to the United States or Europe, though that is changing slowly. He also was quick to note that his company isn't just producing high-volume consumer-type products in Asia. Sanmina-SCI also is producing high-tech imaging systems, for example, in its China and Singapore facilities.

Paul Plante, vice president of Medical In-

dustry Solutions for the Kimball Electronics Group, a division of Kimball International in Jasper, IN, agreed with the global footprint model, though he also noted that his customers understand that every product isn't immediately—and may never be—a candidate for an offshore solution.

"I think medical OEMs are just now feeling the cost pressures that other industries have been experiencing for some time, and I am surprised that more haven't developed a low-cost solution. For newer products when the design is not yet stable or the product is ramping up in terms of market acceptance—if we're at the front end of that bell curve of growth—customers typically are more comfortable in looking for a local solution." Plante said. "We primarily focus on US and European medical OEMs, and, in general, they prefer their manufacturing to be conducted closer to home. When their products or markets become more cost sensitive, we help customers by transferring their manufacturing to a low-cost solution. We execute a well-documented transfer-of-work process involving a detailed project plan to help migrate from a domestic facility. We manage the schedule changes and communications from our local sites but have the bulk of production coming from a lower-cost country."

Kimball has medical manufacturing operations in the United States, the United Kingdom, Thailand and currently is moving medical production to an existing facility in Poland to provide a low-cost option in Eastern Europe.

Plante said Poland has a high level of technical expertise in the work force, and the wage structures are still low enough to make it cost effective. He said customers see Poland as a welcome alternative to China, as it lacks some of the IP concerns.

"Of course medical customers are concerned with IP protection, but they get more comfortable when they're dealing with a partner they've dealt with for a while," Plante continued. "So despite the fact that the manufacturing is located in Thailand or Poland, they're confident that we're keeping their IP out of harm's way. We have a facility in China, but we find that most medical customers aren't comfortable or interested at this point in time in a China manufacturing site except when it's for the China market. Customers are

not comfortable with the IP risks, and even more than that, they are concerned with components and part substitution in China. I can't say whether those fears are well founded, but we don't see too many medical OEMs who want a China solution right now."

Rutledge agreed with Plante, explaining that though his company now offers EMS manufacturing for other industries through a partnership in China, all of Fawn's medical manufacturing—the largest segment of its business—remains stateside. But even smaller companies without the global reach of a Flextronics, Sanmina-SCI or Kimball are wrestling with the off-shore option.

"I think it's a good trend that this wasn't a group [medical device OEMs] that quickly migrated to China. But we now see customers looking to China and not standing as pat on that good old 'made in the USA.' There's more of a willingness to move that really wasn't here a few years ago," he said. "We used to say that we love the medical industry because there's no chance they're going to China. And I don't think you can say, 'no chance' anymore."

Rutledge added that his customers also have expressed doubts about maintaining control from far away, while at the same time facing competition from other OEMs that have already moved some of their manufacturing overseas.

"They're really battling over what the proper role is," he said. "We have the ability to still maintain control but migrate the manufacturing and assembly to whatever level is mutually agreed but still under the control of Fawn. We have a VP of operations who is [in China] the bulk of the time, but he is a US resident and an employee of Fawn. So I think there are ways to keep stateside involvement. Now we don't promote doing the manufacturing there, but if it's going to go there we want to be part of it. We're not manufacturing anything for the medical industry in China now, but I don't see it being very far away."

Beyond going offshore, another option for reining in cost, experts said, is design for manufacturability, using the latest technology trends to simplify material cost and the supply chain as well as improve functionality of the product.

"Anytime you can get involved early and can deploy an integrated design and

## The Repair Depot Challenge for EMS

Talk to most EMS providers and chances are one of the biggest challenges they face as part of an ever-expanding list of services is preparing for long-lifecycle products and repair depot requirements.

Some medical devices, such as ultrasound machines, can have a standard life of 12 years. Who's responsible for warranty work, software updates and repairs, or maintaining spare parts? In many cases, it's part of the complete package OEMs negotiate with their EMS partners. Some EMS providers even serve as sources for certain out-of-warranty repair work. The industry standard seems to be anywhere between seven and 10 years, according to most sources who spoke with *MPO*.

"In most cases, we're doing all the product repair," said Gelston Howell, senior vice president, medical division, for Sanmina-SCI in San Jose, CA. "We'll bring the product in if it has to be repaired or if software has to be updated and installed. We even maintain a hub of spare parts for medical OEMs. We'll configure and fulfill the order and send it to the end user, and the OEM bills the end user directly. We even create the design history file for a product. There is an FDA regulation for documentation of device history records that need to be maintained for the life of the product."

manufacturing solution is a big source of cost savings for customers later on," said Croteau. "The second area is localizing the supply chain to get the materials from lower-cost suppliers that can drive big savings as well. It's more difficult on an existing, mature product to make process changes that support cost improvements for validation reasons, but there's a tremendous amount of savings opportunity when we do that, and it can often extend the life of a customer's product."

Howell agreed that having a network "on the ground" closer to offshore manufacturing sites is critical.

"We can show companies our supply chain. They won't have to go and look for and qualify those suppliers," he said. "They

Part of the repair depot services can involve an inventory balancing act, according to Art Rutledge, president of Timonium, MD-based Fawn Electronics.

"Along with engineering support, design and development support, OEMs look for our ability to carry inventory, etc. It all becomes part of the services we provide," he said. "OEMs don't really want to deal with warranty repair or modifications or the need for storing and tracking spare parts."

Long-lifecycle medical product support involves careful forecasting due to constant component obsolescence issues and supply chain availability, said Paul Plante, vice president of Medical Industry Solutions for the Kimball Electronics Group in Jasper, IN.

"We are often working diligently with our customers to get ahead of that curve to determine which products are next to go end of life and look for a substitute from a design standpoint that meets specs for the product or make arrangements for last-time buys. That's a very big issue," he explained. "We use software tools to help us predict the lifecycle of components so we can stay ahead. Customers also are asking for repair depot services, to help them better deploy their own finite resources. We look at that as an opportunity to add more value in the relationship."

know we've already got a cadre of key suppliers for sheet metal, cables, plastics, components for the large imaging systems, casting and machining. It is a huge savings for them, in addition to being a significant benefit from the standpoint of risk."

In addition to low labor cost, design savings and supply chain economies of scale, Plante said if companies are planning to repatriate their goods, transportation costs have become a big factor.

"With fuel costs as high as they are, freight becomes a bigger issue," he said, reiterating that the entire formula depends on total landed cost and a customer's comfort level with the process. "We have a multibillion-dollar client that still does not source printed circuit boards in Asia, though that

will probably change in the future," he added. "When the day is done, there are many of companies that feel the cost pressures but still feel uncomfortable taking that leap to far-away countries and their extended supply chain."

### The Regulatory Hurdle

While the future for EMS providers appears highly promising, stringent guidelines implemented by the FDA pose a barrier to entering the medical device market, particularly with maintaining quality in international facilities. Adhering to FDA regulations and others such as ISO 13485 quality management standards has become critical since medical OEMs often select EMS providers for their outsourcing needs based on compliance with current regulatory standards.

"Attaining regulatory compliance in the medical device market is extremely important for EMS providers to successfully enter it and increase penetration levels," Harris said. "Understanding the guidelines set by regulatory bodies will give EMS providers an edge when pitching for outsourcing contracts from medical OEMs."

Howell added that OEMs must immediately feel comfortable with the EMS provider's ability to handle quality and regulatory issues.

"You don't just 'do' a regulatory system; it's a challenge," he said. "All our plants—in the US and abroad—are FDA and ISO 13485:2003 registered. New medical OEMs wouldn't engage with us unless they felt completely confident that we could manage an FDA audit, work with the agency, fully understand FDA regulations and implement those in a manufacturing environments, and I think we have achieved that."

According to Plante, regulatory savvy and capabilities are paramount.

"We recently had a medical OEM from Europe looking to us to prepare their entire 510(k) filing for the FDA and be the custodian of the device history record from the manufacturing and design standpoint," he explained. "Previously, customers would never have asked us to get involved with an FDA filing. It's now beginning to be considered part of a full-service offering." ♦

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