

Choosing a Contract Manufacturer for Medical Devices By Rich Smith, Sparton Medical Services

Summary

This white paper discusses the unique challenges and opportunities arising from the growing role of electronics in medical applications, and what OEMs should know as they choose a contract manufacturer for their products.

Chart 1: **Medical OEMs' Needs Differ From Other OEMs**

According to a Technology Forecasters Inc.(TFI) study, medical OEMs' needs differ from other OEMs, especially electronics OEMs, in four specific ways.

- They have high-mix, low-volume products with longer lifecycles.
- Industry regulatory issues require that product quality be robust
- Industry regulatory issues require that documentation be complete and easy to track.
- Medical industry experts must be involved in design and engineering.

What Medical-Device OEMs Need

Increased spending on hospital care, home health services, drugs and public health programs has added 1.7 million new jobs to the US economy since 2001, according to BusinessWeek. In addition, the baby boomer generation is now hitting its golden years, living longer, healthier and more active lives into retirement.

Better utilization of technology in healthcare to alleviate pain, improve healthcare delivery, restore health and extend lifespan is one of the biggest opportunities available to the electronics industry today and in the future. Equipment used in medical applications is inherently complex, and must accommodate requirements very unlike those in other less critical applications. These technological advances come at a high cost and the use of electronics in these previously unknown territories presents unique challenges to manufacturers.

Currently, most equipment on the market today falls into the medical imaging and diagnostic arena. But that's only the beginning. According to TFI Analyst Charles Wade, emerging medical products will be thinner, lighter, flexible devices with more emphasis on patient comfort. These products will combine biological and electronic systems into smarter devices with closed loop sensors. The following technologies will be on the leading edge in the development of medical electronics:

Leading Technologies in Medical Electronics:

Communications technologies (wireless-low power)
Information management and advanced user interfaces
Sensors and smart devices
Visualization and navigation technologies
Diagnostics
Biotechnology
Device miniaturization

Electromagnetic therapy
Advanced materials and tissue engineering

Getting these exciting new products to market will require a tight collaboration between the medical OEM and its electronics contract manufacturer (CM), with a heightened focus on design for manufacturability and the documentation requirements needed for the long FDA approval cycle. Many medical electronics companies are developing these strategic partnerships with CM design engineers to ensure safe, effective products that are in the medical profession's hands as quickly as possible.

Increasingly, OEMs designing medical imaging and medical diagnostic equipment are leveraging the electronics manufacturing knowledge and expertise of contract manufacturers like Sparton Medical Systems. By doing so they gain the ability to focus on core competencies; accelerate time to market; ensure product quality and consistency as they ramp up production to meet growing demand; and achieve cost savings.

But while it is a rapidly expanding market, the outsourcing of medical-devices presents unique challenges, for a variety of reasons.

What Medical-Device Contract Manufacturers Must Provide

Given the costs of serving a highly regulated market, many medical-device OEMs are looking for manufacturing support that is increasingly turnkey. That means contract manufacturers must be extremely flexible and agile, because the OEMs come to them with one of three possible scenarios: they want a CM to completely design a device; to manufacture a device from existing designs; or to redesign an existing device. That allows the OEM to avoid making huge capital investments in engineering and manufacturing capacity, but it requires the CM to have extensive capabilities in design, prototyping, testing, procurement, manufacturing, verification, and quality assurance. As with products that must offer the highest levels of reliability, this means that all these processes as well must be both reliable and repeatable.

It also means that the contract manufacturer must be highly conversant in the strict regulatory requirements of the U.S. Food & Drug Administration, the European Union's counterpart, and the quality standards of the International Standards Organization (see chart 2, "Standards for Medical Devices"). This requires high levels of understanding in the concepts of design-for-manufacturing (DFM) and design-for-assembly (DFA) — that is, ways to ensure that product designs can be easily manufacturing and assembled, and that design specifications clearly state how they conform to the aforementioned regulations.

Chart 2: Standards for Medical Devices
<ul style="list-style-type: none">● EN 46001 (systems quality, Europe)● FDA GMP (manufacturing quality)● FDA QSR (systems quality, U.S.)● ISO 13485 (establishment and implementation of quality processes)

Many CMs with experience in other industries such as computer or telecommunications are targeting the medical device market. According to one 2005 TFI survey, of the top 100 worldwide EMS providers, 72 now claim to serve medical OEMs, though only a handful of those derive a majority of their revenues from the medical-device market. Choosing from all these companies can be daunting. Not all of these companies have the industry-specific infrastructure and experience in place to effectively manufacture these complex products. Choosing the wrong manufacturing partner can be disastrous, as these relationships take time and resources to develop.

It is difficult for companies who are not focused on medical-device manufacturing to maintain excellence in that area, for a variety of reasons. There is tremendous pressure on manufacturers to make devices smaller, lighter, and less expensive. The added complexity of biotechnology requires a significant investment in engineering talent that spans both the medical and electronic fields, not to mention the ubiquitous emphasis on quality and reliability. (For a complete list of important services, see Chart 3, “Services EMS Providers Offer Medical OEMs.”)

At the same time, the fundamental requirements for CMs in general aren’t lessened. They must be proficient a in procurement and sourcing; in inventory management; in collaboration with and management of its own suppliers; and in knowledge of government regulations as they relate to environmental concerns. In addition, a medical-device OEM should determine what kind of technology an EMS provider uses to ensure that information it tracks about resources and products — whether in a manufacturing resource planning (MRP) system or product data management (PDM) system — and determine whether it can easily exchange data with its own systems and its suppliers.

Chart 3: **Services EMS Offer Medical OEMs**

- Regulatory services
- Design cost reduction review
- Design services
- Printed circuit board manufacturing
- System build
- System testing and integration
- Software development, verification and validation
- Test equipment development
- Order fulfillment
- Corrective and preventive action notification
- Warranty repair/support

Sparton Medical Systems

In response to the requirements of its broad base of new and existing medical customers, Sparton established Sparton Medical Systems (SMS). SMS is a group within Sparton Inc. that specializes in systems and procedures targeted to the requirements of medical original equipment manufacturing (OEM) companies.

As outlined above, in a tightly regulated industry, success depends upon processes and controls. A necessary component for SMS to be competitive in the medical device market is adherence to FDA regulations. ISO 13485, a quality standard specific to

medical devices, provides industry-recognized guidelines for Sparton to meet the stringent FDA design and manufacturing requirements. Sparton has four facilities that are ISO 13485 certified: Brooksville, Florida; DeLeon Springs, Florida; Jackson, Michigan; London, Ontario, Canada; and Strongsville, Ohio.

In addition to offering design services during any product design phase, SMS has developed specialized processes and support services that focus on the early stages of the product development cycle. This is particularly important in a highly regulated industry where time-to-market is dependent on stringent documentation and products must be thoroughly tested for safety and reliability. Electronic components are being introduced into medical products in ways that haven't been seen before. Electronics manufacturing issues relating to patient safety and convenience must be considered during the design stage. Medical OEMs that bring Sparton engineers into the design cycle can bring their products to market sooner.

Other SMS services include a cost-reduction analysis that reviews an existing device for cost reduction opportunities via design change / upgrade. One example of this is the integration of the functions of multiple electronic chips into fewer devices, reducing both cost and size. Because more devices are relying on embedded software, SMS also has a team dedicated not only to software development but also to software quality.

Sparton manufactures assemblies that are used in electronically controlled blood pumps, incontinence devices, pneumatic tourniquets, and defibrillators.

As the medical device market matures, Sparton will continue to evolve with the latest systems and processes. Soon other Sparton facilities will obtain ISO 13485 certification. The acquisition of medical device OEM, Astro Instrumentation Inc. has further enhanced Sparton Medical Systems' capability, adding expertise, people and capacity to meet current and future customer needs.

In 2004, Sparton opened a manufacturing facility in Ho Chi Minh City, Vietnam, in order to take advantage of lower manufacturing costs overseas. One of the unique characteristics of the facility is that it replicates Sparton's six factories across North America so that it can use the same equipment, processes, and training as it does in the United States. This helps with support and diagnostic issues, while still being able to take advantage of a lower-cost labor force.

Sparton is dedicated to customer service. Ongoing customer-service surveys, are distributed to its customers on a monthly basis in order to ensure customer satisfaction. The surveys are compiled and addressed either immediately or in quarterly business reviews during which Sparton engineers meet with customers to discuss ongoing projects. As one Sparton executive notes, "We're in a service business, one in which each customer has a different set of needs. If we don't take the time and effort to find out what makes each customer successful, we can't help them be successful. That's why we listen intently to what they say in the meetings and in the surveys."