Perspectives on Time to Market—Part 2

For your area of the industry, what is your best recommendation for getting a medical device to market faster?

Sandra Ketchen
Vice President, Healthcare, Celestica

For medical device companies to introduce new products to market faster, they need to break away from the traditional “silo approach” of managing the entire product lifecycle in-house. Instead, they need to focus on their core competencies, such as R&D and sales and marketing, and select a strategic partner who can work as an extension of their team to bring products to market faster.

The partnership model provides a more nimble, modular structure—a far cry from the traditional outsourcing approach of companies managing multiple vendors to support the product lifecycle. The right partner has an extensive supply chain network, the manufacturing power to bring multiple products to market in tandem, and, most importantly, deep design and engineering capabilities to help accelerate the prototyping and development cycle of a new product. As well, a partner with deep experience in regulated industries can help navigate through the complex and evolving regulatory requirements in different regions to ensure the global success of a device.

By engaging a trusted partner in the entire product lifecycle, not only can medical device companies mitigate traditional outsourcing risks, they will also gain

significant time and cost efficiencies to sharpen their competitive edge.

Oscar Audelo
Sr. Director, Life Science and Sales, Northwire Inc.

Northwire Technical Cable understands the importance of velocity during the development and approval process for medical devices, equipment, and technologies. To help accelerate this process, our rapid-response model delivers high-quality custom medical-grade technical and retractile cables in as few as five days with no minimum order quantity or length requirements. This model includes finite element analysis, design services, and rapid prototyping.

Using advanced materials and manufacturing techniques, Northwire engineers build and rigorously test custom disposable and reusable cables to exceed customer specifications for quality, performance, and safety standards. Performance characteristics for proprietary and custom-configured designs include low bio-burden and pyrogens, triboelectric noise-free components, continuous motion, torsional flex, composite designs, bending and ergonomic demands, tactile qualities, electromagnetic shielding, FDA-grade materials, private labeling, legends, custom colors, and more.

In addition, Northwire’s technical specialists have the experience to help [OEMs] navigate complex national and international standards and environmental regulations. For decades, leading medical-device companies internationally have depended on Northwire for consistent, durable, cost-effective, high-quality products that are test-proven to exceed application demands.

Newton Defaria

Business Development Manager for Life and Analytical Sciences, National Instruments

Among many, I would like to offer six pieces of advice.

1. It is imperative to identify, understand, and follow the stages of a medical device lifecycle. Look up!
2. Define and respect the moment when research stops and development begins.
3. During development, do not design a product without a comprehensive and verified requirements document. Many develop prototypes based on assumptions and know-how as well as choose their tool chain based on familiarity. These actions tend to strongly influence and limit features and functions. Instead, first build a functional equivalent prototype using COTS, verify communication, interfacing and protocols, operation, performance, GUI, algorithms, and other aspects of the new device.
4. During deployment, adopt as much COTS as possible and use development environments that lessen rather than raise complexity. After gaining market share and securing reimbursement, focus on refining your design for the future product generations.
5. Predict and plan accordingly for the needed corrective actions and evolutionary changes in order to provide a less taxing re-verification and re-validation process.
6. Finally, adopt a common hardware and software development platform capable of taking you from concept to deployment and test. This will help you re-use IP developed upstream, avoid re-verification upon changes in platform, reduce time, and minimize risk.

Patrick Pickerell

President, Peridot Corp.

It has always been our goal to provide medical device designers and developers with the smart strategies and services that ultimately lead to a quicker, and safer, path to getting new products to market. I believe there are a few factors critical to successfully accomplishing this.

First of all, as most experienced designers and developers know, it’s extremely important to get your manufacturing partner involved early in the game—as early as the design stage, in fact, before the material and manufacturing specifications are set in stone. The benefits of this are logical. Manufacturers already have experience with material costs and availability, so they can make recommendations that may bring down costs, or make materials easier to obtain.

In terms of speed to market, working with a manufacturing partner that can provide a wide spectrum of capabilities can really help keep turnaround times to a minimum. “Vertical integration,” which is essentially having a full range of services available, often in-house and on-demand, can significantly lessen the time spent coordinating and communicating between multiple suppliers. It also reduces surprises along the way, giving the customer better control of the whole process.

Unlike situations where multiple suppliers are all focused on just their individual part of the project, having a single source partner means everyone involved sees the whole picture. It expedites communication and eliminates the need for a customer to develop and manage its own manufacturing infrastructure. We take on the responsibility of reviewing how all the components of a device will fit together and that reduces delays and surprises. We’ve also found that having our cleanroom facilities, warehousing, and other services all in one location is a big benefit to our clients; it definitely helps increase the speed of getting their medical devices to market.

Bob Evans
Business Development Manager, KMC Systems

Budget constraints brought on by trying economic times have forced medical companies to rethink their new product development methods and challenges them to find ways to reduce costs and time to market in order to recognize revenues sooner. KMC Systems implements a holistic approach of rapid product development for getting medical devices to market quickly and cost-efficiently by focusing on three key components: people, processes, and technology. This proven process of rigorous communication (people); appropriate documentation, testing, and control (processes); and the leveraging of tools and off-the-shelf solutions (technology) not only streamlines design and manufacturing but also helps reduce many other new product introduction costs. The process assists medical companies in achieving their goals of introducing reliable, safe, and efficacious products rapidly to market.

KMC Systems offers rapid product development as an integral part of its KMC 360 program, the company’s complete program for contract design, manufacture, and maintenance. Designed to support OEMs and start-ups throughout the entire medical device and instrumentation product lifecycle, the program centralizes all outsourcing support. The KMC 360 program provides medical companies a means to deliver high-quality medical devices and instrumentation to market on-time and within reasonable budgets.

Frank Shen
Product Marketing Director, American Portwell Technology Inc.

The embedded module is one good solution to help faster time to market for medical devices. The industry's ever-expanding modular computing solutions include a great portfolio in COM Express, Qseven, and ETX form factors.

The modular computing approach includes a module of computing core and a carrier board with fundamental computer functions and interfaces for additional functional expansion. The advantage of this modular computing platform is easy for future processor upgrade and parallel time to market design.

Specifically, the modular bootable host computer engine is plugged into the carrier board, which connects to the power supply. The application-specific system functions and peripheral expansion are all built on the carrier board. The concept is simple: install the latest CPU now and when it comes time to upgrade, just change out the CPU module. Medical design engineers save time because the carrier board can be designed and developed in parallel to the design of the CPU module. This helps shorten the development time so product time to market can be faster.

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