Perspectives on Time to Market—Part 1

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

Heather Dunn
Director of Engineering, CIRTEC Medical Systems

CIRTEC Medical Systems is commonly requested to perform accelerated product developments for our clients. The CIRTEC approach in those situations involves a few key tactics.

First, we drive for extreme clarity on both the requirements and the risk analysis documents. Our experience is that projects started with these documents incomplete have more iterations through the design freeze and pre-DVT testing phases.

Second, focusing on the top two to three feasibility concerns immediately is critical. The pressure is always there to run everything in parallel, and we see many plans approached that way. However, typically the success of two to three key technical factors will drive the schedule and should be addressed first. Our broad device experience gives us an edge in identifying these factors, and we perform intense development on those areas to define the technology and product requirements early.

Finally, working with an outsource partner or broad internal/external team is the fastest way to ramp resources fast and manage the high flux of departmental resources at key times in the development cycle (documentation rush, DV testing burden, pilot unit builds, etc).

By employing this strategy up-front with our clients, CIRTEC Medical Systems is able to save overall time and significantly reduce risk on the development cycle for a wide range of medical devices.

Don Garcia
Director of R&D, Boyd Coatings Research

As medical devices become smaller and more invasive, but less intrusive, in their design, coatings and finishes are becoming more crucial to the performance and efficacy of these devices. For example, stents vs. open heart surgery.

Designers should “start with a finish” to ensure that the design elements and manufacturing concepts are compatible with the ultimate finish that will be required. Fluropolymers are excellent finishes for invasive tools as they minimize the possibility of thromboses.

Not considering the coating as part of the systemic design process can create issues that could have a major impact on completion of trial components and, ultimately, product launch.

A simple example: An electro surgical device is designed with some components that operate at low temperatures. When it’s time to design the electrically insulating, non-stick coating that will best suit the application, a polymer (e.g., a Teflon fluoropolymer) requires 700°F to cure and cannot be employed. A 30 minute conversation with our engineering department could have saved days, weeks, or even months of redesign or compromise.

Mark Shal
Manager, First Medical Source

To speed up the time to market, medical device companies need to gain a better understanding of FDA’s risk-based approach to quality management. Unable to see

the big picture, most engineers perform local risk optimizations and procrastinate processing what they are unfamiliar with. The sum of these local optimizations is a globally sub-optimal project that is at the core of the product development costs and delays and their impact on the company's success, and its ability to create jobs.

To speed up the process, companies need to establish a solid global risk assessment process. As soon as a local risk question arises, this process would amplify the signal to management (sense of urgency is critical) who, in turn, would come into a meeting with the appropriate members to perform a global risk assessment. This process, along with standard policies and procedures that produce cooperation, focus resources on prevention, and create a sense of urgency with managers and suppliers, will lead organizations to improve cost, quality, and delivery on its existing and new projects. To be effective, the management of this process must be the responsibility of the CEO or a competent person who directly reports to the CEO.

Thomas M. Richardson, PhD
Business Development Manager, Global Medical, Tyco Electronics Elo TouchSystems

At Tyco Electronics Elo TouchSystems, we develop touch products for a global healthcare market and, therefore, take a number of factors into consideration when defining requirements and getting products to market as quickly, yet safely, as possible.

During early product scoping and development, we have found it wise to take into account regional preferences for features, screen sizes, color, and type of power supply, which can vary greatly depending on the country and various regulations. We work closely with developers and ISVs to provide touch solutions that meet the demands of a variety of applications in healthcare settings. Of particular consideration are emergency settings, which have unique requirements due to extremely fast-paced and chaotic environments. Every environment is strongly

considered, since where a product is used dictates its own unique set of design factors, such as temperature, humidity, shock, vibration, and liquid-resistance engineering.

Product naming and costs are also significant considerations. Elo TouchSystems manufactures several types of touch screen technologies and each has its own feel, features, benefits, and price points. Creating a product with the right mix of desired features at an attractive price point is critical to any product's market success.

Lastly, and of greatest importance, is compliance with worldwide electromagnetic and product safety standards. Our engineering staff is diligent in working with applicable regulatory agencies to develop products that meet regional safety testing requirements in order to distribute products worldwide. Some countries have unique regional requirements and testing procedures while others accept international testing results. We take extra care to be sure that our products meet high standards for quality and safety.

Lewis Shanks
Co-Founder, Shanghai Outsourcing International Ltd.

Today's medical device manufacturing sector is witnessing significant growth in two areas: the increased demand for design accuracy, efficiency, and cost-driven value, alongside a decrease in in-house manufacturing capabilities and expertise. These factors are driving medical device manufacturers to focus greater management attention to the outsourcing of component and product engineering.

This trend reveals challenges that, unless addressed early in the design process, can often morph into chronic redesign incidents, unmet customer standards, and costly production and shipping delays.

At Shanghai Outsourcing, a manufacturer of component parts and complete

assemblies, we stress a total sourcing strategy via in-depth and seamless coordination between medical device designers and off-shore production engineers at the earliest product design stages. We often find that what looks good on paper, such as over-specified CAD drawings or disproportionate material requirements, can easily result in problematic samples and unnecessary tooling delays due to a lack of manufacturing process expertise on the designer's part.

To this point, production delays can be significantly reduced if coordination occurs early on and involves up-front specifications. Delay-reducing steps include conducting detailed team studies of client drawings; early notification of high-end, costly, and difficult-to-obtain material requirements; confirming tolerances of parts to establish manufacturing practicalities; and even jointly selecting the appropriate factory and off-shore engineering experts to conduct tooling/production.

Additionally, for companies with little importing experience, it is imperative that purchasing managers coordinate shipping/freight and forwarding/customs clearance functions with their contract manufacturing partner in advance. We often find that there is a push to ship product, but on the client's end, little has been done in advance to organize this process. By collaborating with their contract manufacturing partner well in advance of the actual desired shipment date, a great deal of time can easily be saved.

Gabriel O. Adusei, MSc, PhD
Founder, Consultant, International Association of Medical Technology Consultants

There are several approaches that may be considered in getting a medical device to market faster. However, depending on the size of the organization (manufacturer) and the resources available, the best recommendation for getting a medical device to market faster may vary.

One of the most cost-effective and rapid ways to market is to set up as a virtual manufacturer with a plan to outsource everything, or nearly everything, involved in manufacturing a device. Contracting out much of the production has the attractiveness and the benefits of saving time and the promise of saving money,

especially for start-ups, for which seed capital is at a premium.

Own Brand Labeling (OBL) is another means of getting a medical device to market faster and for regulatory purposes, the process for the certification of OBL is, in many instances, by document review only as all the actual manufacturing processes have been done by the OEM.

The longer the processes involved, the longer it may take and the slower it may be to get a medical device to the market; hence, the manufacturer may consider some fewer aspects of manufacturing in-house and outsource other processes, such as design and development.