

Faster, Leaner, Cheaper

Medical device companies are relying on prototyping to satisfy or exceed client expectations.

By Mark Crawford

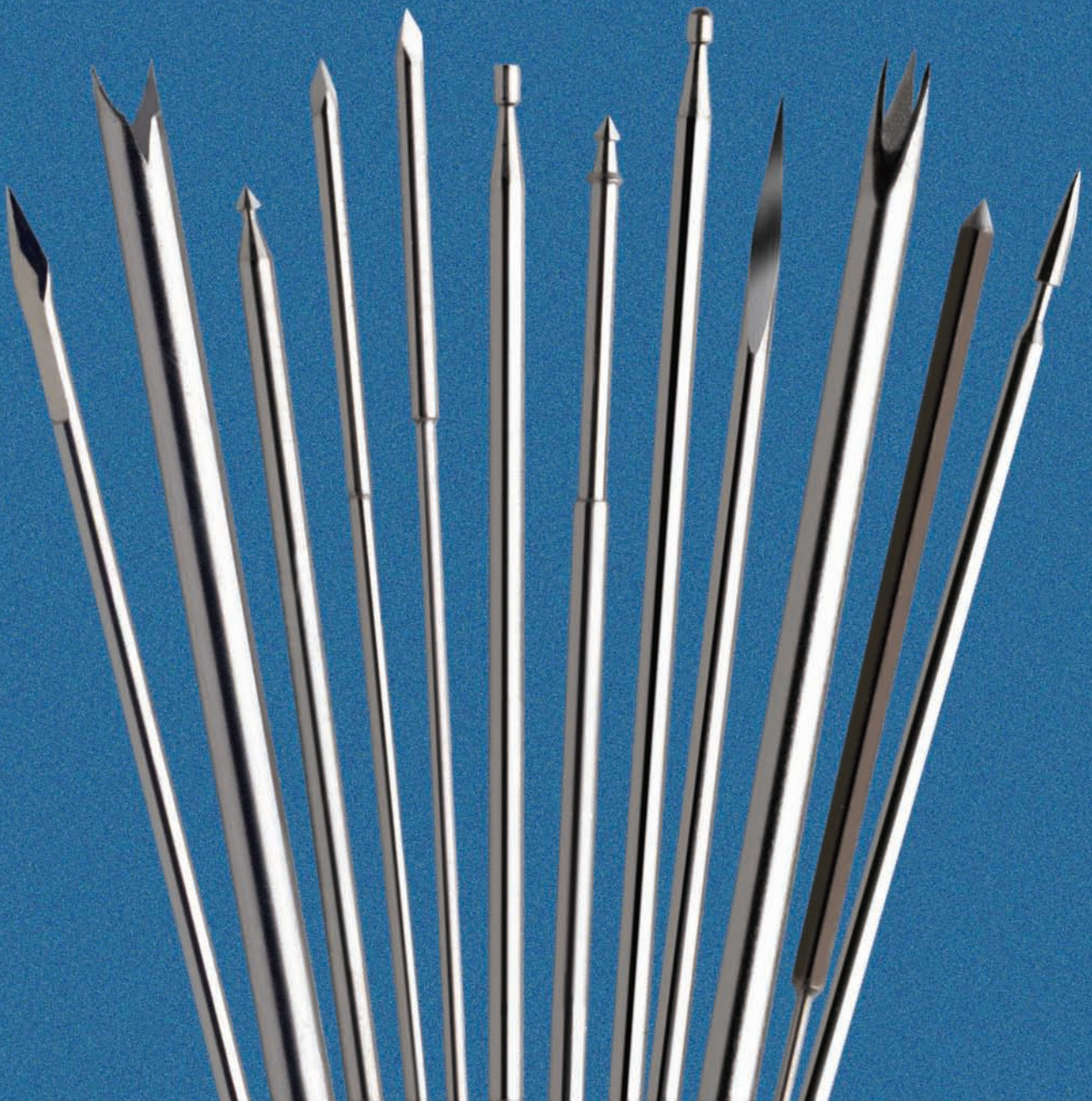


Photo courtesy of Tegra Medical.

Medical device manufacturing is a rapidly evolving market where regulatory changes, OEM demands and tough competition are driving innovation and best practices among manufacturers and suppliers. To stay competitive, contract manufacturers must be sensitive to market conditions and embrace new technologies and processes. They should especially focus on the use of computer software and design analysis technology to test the design and functionality of new medical products and get them into the marketplace more quickly (sometimes without even building a prototype at all).

Several key points should be considered when evaluating a prototyping opportunity. "Important things to evaluate are the customer's needs against the manufacturer's capabilities, communicating with the customer to ensure a clear specification, identifying internal resources, establishing timelines and setting clear expectations with the customer regarding what, if any, limitations the prototype will have," indicated Michael G. Brown, vice president of operations for TechDevice Corporation in Watertown, Mass., which manufactures guidewires, balloons and catheters. "Funding and/or internal costs must also be considered," he added.

A detailed review of the component or part design is especially important. For example, what is the component's end use? What is the primary function? What are the critical features? What materials have been considered? What are the cost drivers in the current design, and how can they be minimized? "These questions may need to be answered before a company can reasonably make any recommendations," said Will Lyons, president of Lyons Tool and Die Company in Meriden, Conn., a provider of rapid prototyping and production of medical devices, welded and mechanical assemblies, metal stampings and high-speed CNC-machined parts.

Tom Burns, vice president of business development for Franklin, Mass.-based Tegra Medical, which does wire and hypotubing, precision grinding, CNC machining and laser welding, agreed. "Well-defined customer requirements, understanding the final product function and establishing unit cost parameters really have to be understood up front. Close communication between the prototype group and the product design team also creates a willingness to



Prototyping clients want faster speeds to market and lower costs. Photo courtesy of Tegra Medical.

exchange ideas and experiences, which accelerates the entire development process."

For example, having the technical leads from the OEM visit the prototype maker is highly valuable, especially during the earliest stages of the project. "Inevitably, there is a healthy exchange of ideas, a working relationship is established, and more folks from the supplier can be involved," said Burns. This rich interaction fosters creativity, more buy-in from the team and also can create long-term relationships (and even friendships) that strengthen the working relationship between the OEM and the prototyper.

OEMs also expect their manufacturers and suppliers to have deep knowledge about raw material properties (including new advanced materials) and a reliable, well-tested supply chain. Having enough resources to execute projects on a very tight timeline, often with multiple iterations, also is highly regarded within the industry.

What Customers Want

The biggest demands from clients continue to be faster speeds to market and lower costs. Unfortunately, OEMs aren't always willing to pay up front for these achievements. In some cases, they try to reduce prototyping costs by dangling the potential to earn the volume production business. "Other things companies look for are improved cost-to-value ratios and green considerations, especially with material selection," said Brian Jarvis, director of U.S. op-

erations for BIT Group in Ludlow, Mass., which does SLA, SLS, cast urethane and rapid machining for both single components and assemblies.

OEMs are eager to establish a solid working relationship and open communications with their prototypers. "Clients also want a quality system capable of handling their specific regulatory requirements, which is another critical consideration when they select a vendor," said Brown.

Medical device designers expect their supply bases to provide the increasing array of services they desire, either through internal growth and capital investment or by partnering with other industry experts. Cost is always a key consideration, but when speed to market is the top priority, timing becomes the driver. "The competition in the medical field is tight, and securing your market position or launching your product first can be very important," Lyons commented.

Maintaining a greater awareness and focus on what manufacturing costs will be once production starts is another way to add value for the client. "OEMs expect their partners to bring a higher level of sophistication, including an understanding of the market and product application, the experience to challenge chosen material and process methodologies and rock-solid reliability to execute on commitments," said Burns.

"We can work with our clients to create scenarios where fewer rounds of prototyping need to be executed and also find ways

to learn lessons without having to build a complete prototype—perhaps by producing a simple partial model or by just ‘playing’ with a piece of material that is close to the specified material,” said Les Duman, sales manager for Peridot Corporation in Pleasanton, Calif., which does laser cutting, EDM, CNC machining, laser welding and hypotube bending. “We try to learn enough about our clients’ projects so we can find out what is truly a firm requirement of the project versus a flexible requirement. This allows us to apply our manufacturing suggestions most effectively.”

Latest Trends in Prototyping

Customers are coming to manufacturers with smaller and more complex designs that require different materials and material combinations. “Everything continues to get smaller, and that can create very demanding tolerance scenarios,” said Burns. “The idea is not to sacrifice on performance or increase cost while minimizing size to reduce procedural time, improve patient comfort and reduce length of stay and time away from work.”

Duman said: “We always want to be certain that the processes we use during prototyping can be effectively translated to production processes as the project ramps up. We assure that the documentation of all processes and the traceability of all materials is maintained. Medical device OEMs expect their suppliers to be up on these details and be development partners, not just parts providers.”

A growing number of companies are embracing the idea of developing their products with the prototyping process. “Whether it’s an improvement to a new component, such as a material or process change, or developing a new technology, the trend continues to favor the process of quantifying performance first,” said Lyons.

Prototypers also are getting more involved at the concept stage with virtual designs and testing. Using sophisticated CAD and simulation analysis software, the performance of virtual prototypes can be tested through design analysis technology. Virtual testing speeds up the prototyping and production process and can be an advantage in winning faster U.S. Food and Drug Administration approvals. OEMs are more likely to seek out and partner with suppliers who have this ability to accelerate

development during the initial stages of product design.

Improved prototyping processes in recent years have decreased processing time and costs. “A year ago, ‘bench-top’ systems were just entering the market,” said Jarvis. “The process/system offerings are now extremely cost-effective for many engineering firms to move RP in-house as a value-added development process. Firms can confirm designs in a matter of minutes instead of the routine two to three days for outsourcing.”

Regarding advanced materials, there continues to be a strong demand for components made from nickel-titanium. In machined plastics, more OEMs seem to be interested in PEEK. “There is a certain excitement to successfully developing processes that effectively work with new materials,” said Duman. “‘New’ processes, in most cases, actually means being more innovative and creative with existing technology for new applications, although sometimes we do create new types of project-specific tools and fixtures that play a key role in product development.”

The Most Expensive Part of Prototyping

For many companies, the most costly part of prototyping is simply the amount of time it takes—if you can save time, you can save money. “We stock some materials for R&D prototype runs,” said Brown. “Some-

times, depending on the request, tooling can come into play, but the most common expense is utilization of resources for engineering and documentation time.”

Having to churn through multiple iterations can be costly and time-consuming. “We often collaborate with our clients to find ways of running multiple iterations together, saving money and moving the design process along faster,” said Duman. One example would be to laser-cut multiple blank designs using the same material type and thickness. The additional programming time is minimal, and all the other set-up and form costs would be common to both designs. “This can save as much as 85 percent over the cost of two separate runs,” Duman added. “Plus, the lead time might be only a few additional hours.”

Sometimes the most expensive part is not doing enough prototyping. When OEM companies are developing new technologies or challenging the limits of manufacturability, this is the time to engage the experts up front. “Production tooling can often be partially completed while the prototyping process corroborates the design intent,” said Lyons. “This presents a strong case for partnering with a company that provides both rapid prototyping as well as production services.”

Even if the part or assembly design is not frozen, the production tooling design can often be completed to the point where tooling components can be partially manufac-



The most common expenses with prototyping are utilization of resources for engineering and documentation time. Photo courtesy of Tegra Medical.

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tured. In many cases this can reduce the production launch date significantly. "Usually in the latter stages of the prototyping process we are making only minor changes to features and the customer is in more of an 'enhance' mode," said Lyons. Changes to raw materials or component features usually don't impact the overall design envelope of the tooling or fixturing required to produce the finished product.

"Prototyping requires a combination of resources and good communication to effectively meet the 'rapid' aspect of the process," added Lyons. "Understanding the function of the part or intent of the device up front allows us to potentially prevent the processing of design iterations that may not be necessary."

This communication process also would include discussions regarding past history with similar parts or devices including successes and failures. Having the proper equipment is necessary, but more important is a sense of urgency throughout the organization. "When the customer says 'go,' you need to keep the process moving," said Lyons.

Lyons pointed out the most significant cost associated with rapid prototyping services, aside from capital equipment, is the willingness to maintain excess capacity (hours). "You cannot provide rapid service without having capacity," he said. "There are always going to be peaks and valleys in regards to demand. You just need to accept that fact."

Another expensive part of the prototyping process can be selecting the wrong supplier. Make sure you select with a firm that doesn't waste money or, more importantly, time. Executing plans and meeting deadlines are critical.

"Picking the right partner will yield large dividends such as improved design for manufacturability and assembly, resulting in a lower product cost," said Burns. "Other benefits are reduced time to market by compressing product development cycles and

greater productivity for the OEM's R&D staff as they can rely more on their prototyping partner, thereby spending more time designing and less time micro-managing."

Dealing with the Economy

Overall, medical device manufacturers are hanging tough during the recession and have adjusted operations wherever possible to save money. The best way to maintain or improve business is by becoming a "one-stop" shop that provides everything the client needs—consulting advice, new technology and specialized services. Relationships need to be maintained and deepened to become the "go-to" organization, as well as having the resources and commitment to back up that claim.

More companies are keeping a strong inventory of semi-finished tooling and raw materials so they can respond quickly to shorter lead times for orders.

Lyons also is providing more testing services as related to the fit and function of the prototypes it produces. "Customers often provide mating components that allow us to adjust parts for better performance," said Lyons. Testing services may include fitting mating components, test-firing devices, checking staple formations and performing load-testing on components or destructive testing of weld joints.

"We have reduced our pricing in certain work centers and have been very willing to offer reduced pricing during prototyping," added Duman. "Peridot also sees the extreme value of developing positive relationships with start-up enterprises, as well as the product development groups of existing companies. Our goal is to be matched with our clients through development and on to production."

Tegra Medical has taken advantage of the economic downturn to bring on skilled employees from other industries and purchase capital equipment at a tremendous discount. "Adding more resources that focus on prototyping has really pleased our customer base," said Burns.

Moving Forward

When developing novel medical devices or processes, prototyping is the key to reducing production costs, as well as increasing the performance of the instrument or device. "With a good working prototype, manufacturing engineers can also develop enhanced assembly methods that streamline the production line," said Jarvis.

Although being agile and responsive to a client's prototyping needs is no doubt impressive, it also can create logistical challenges to the overall production schedule—therefore it is imperative not to try so hard to meet one client's needs that you jeopardize the production commitments to others. One way to minimize this is by finding the projects that are best suited to your capabilities.

"We are willing to help just about anyone whose requirements map well into our expertise," said Duman. "However, our resources are limited, so we need to keep an eye on and assess where our resources are best invested."

"Maintaining discreet resources for prototyping and volume production is important," said Burns. "Otherwise, priorities tend to shift to the higher-value production when capacity constraints surface. The two groups must work well together to bring value to the OEM. When a company manufactures one-of-a-kind prototypes, there is a lot of learning that takes place which is extremely helpful in ramping up for full commercial production. That provides a real advantage to the prototype maker as well as the OEM—reducing time to market is good for everyone (except the competition)." ♦

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