

A Tradition of Innovation July/August 2008

By outsourcing their prototyping needs, OEMs can focus on what they do best: inventing new solutions.

Stacey L. Bell

History is full of prodigious inventors. Ben Franklin invented the lightning rod—and perhaps not so famously, bifocals and a flexible urinary catheter. Among his many creations, Thomas Edison developed long-lasting incandescent light bulbs as well as the fluoroscope.

Today, medical device OEMs such as Johnson & Johnson and Medtronic are continuing the tradition of innovation by creating life-saving and -enhancing technologies.

Helping to fuel OEMs' creativity is a rather new niche in the outsourcing arena—the outside development of prototypes. “About 10 years ago, the outsourcing of prototyping started to become popular due to OEMs wanting to maximize the technology, innovation and expertise that outside suppliers could provide,” explained Jason Howey, vice president of OKAY Industries in New Britain, CT.

After all, an OEM may create prototypes for perhaps a handful of innovations over the course of a year, whereas outside suppliers craft prototypes daily—and thus gain much more familiarity and know-how with possible solutions to a wide range of design and manufacturing challenges.

Outsourcing the prototyping process also can save money and resources. “It's very expensive for OEMs to develop prototyping capabilities in house because the equipment isn't used continuously throughout the year, so the initial capital outlay and high, ongoing overhead can be difficult to recoup,” noted Les Duman, sales manager for Peridot Corp. in Pleasanton, CA.

Photo courtesy of BIT Group.



In addition, Duman pointed out, in-house systems rarely can offer redundant machining capabilities, so delays will occur. Further, most OEMs don't have a craftsman or machinist on-site to fashion parts, so industrial engineers and designers must spend time physically creating prototypes, detracting from the time they could devote to their core competency: creating new innovations.

And today's innovations are increasingly sophisticated. “Our customers want complex instruments—a product that has a lot of electronics or software-related parts,” said Bruce Sargeant, founder and chief technology officer for Source Scientific, LLC, a BIT Group company in Irvine, CA. “In the United States, we are seeing more smaller instruments that have cosmetically complex styling and industrial design. [This trend is occurring due to] corporate branding, marketability and usability. But there is also more call for these stylized designs because it is now possible to offer more choices quickly and cost effectively.”

Unlike years ago, Sargeant explained, today changes to design can be made directly on the computer file—with no hand-making of parts required. This type of rapid prototyping has drastically cut development time.

A Growing Opportunity

Significantly more OEMs are recognizing the value that outsourcing prototyping can bring. Indeed, the experts who spoke with MPO noted that prototyping work has increased between 10% and 30% during the past year. Also increasing is how complex prototypes have become.

“Over the last two years, we've seen a drastic increase in prototyping requirements. Our dedicated rapid prototyping department includes metal stamping, high-speed CNC machining, wire EDM, conventional EDM, tube fabrication,

surgical knives and scissors, and complete medical devices,” said Will Lyons, president of Lyons in Meriden, CT.

As in any good business relationship, outsourcing prototyping benefits both parties: OEMs avoid the high costs and hassles of running an in-house prototyping facility and can leverage their supplier’s design, materials and manufacturability expertise; and contract manufacturers get in on the ground floor of producing new and revised products.

“During the prototyping stages, designs are enhanced and costs are addressed early in the process to ensure that manufacturing opportunities are tested up front rather than during the production launch phase,” Lyons said.

As a result, final products will make it to the marketplace faster, with fewer last-minute surprises.

Rick Holka, president of Hudson, NH-based Omni Components Corp., noted that his company also has strived to allow customers to deliver their new innovations to market faster, with fewer surprises. “We’re proactively going after prototyping work,” Holka said. To be able to deliver results quickly, the company has introduced dedicated Swiss/CNC multi-axial lathes/CNC machining centers, ram and wire EDM as well as precision cleaning (vapor ultrasonic cleaning with vacuum assist) to allow for chip-free parts, free of oils and machining fluids. “By offering these dedicated capabilities in house, we’re able to shorten process time and better control outcomes,” Holka explained.

Several years ago, Molded Rubber and Plastic Corp. (MRPC) in Butler, WI added small part (or micro-part) molding to its line-up of offerings. “We’re able to mold tiny parts of 1 gram or less of material, and we’ve been adding more automation and manufacturing equipment with precise controls, vision systems and quality inspection systems to meet this growing need,” reported Greg Riemer, MRPC’s vice president of sales and marketing.

He added that MRPC is focusing its growth efforts on what it sees as two of the largest, fastest-growing areas in the prototyping market today: micro-molding and two-shot molding, or over-molding. “Multiple material molding—using plastic, rubber and silicone—improves the performance of products and gives customers the ability to work with one supplier, reducing the supply chain that must be managed. We see this as a good growth opportunity,” Riemer said.



Another good growth opportunity may be found in marketing to design houses, said Scott Pakenham, medical national accounts manager for Vernay Laboratories, Inc. in Yellow Springs, OH. “More design houses are focused not only on industrial design, but on prototype development as well,” Pakenham said.

Vernay’s John Madewell, director of sales, North American operations, added that design houses now account for nearly 30% of Vernay’s customer base. “Larger OEMs outsource design work to design houses,” he noted. “We see medical as our high-growth area, and we recently held a kaizen event to determine how to penetrate this market more. This is one area we’ve decided to actively pursue.”

Other areas ripe for suppliers to target include incubator organizations, universities and venture capital firms, given that so many start-up organizations need assistance with prototyping. “We’ve seen a considerable amount of activity from new start-up companies that don’t have production firmed up. They’re doing early show-and-tell samples for investors and regulators,” Holka noted.

Trends in Prototyping

While both the number of products being developed and the number of potential audiences for prototyping services continue to grow, experts are noting several trends.

“In today’s economy,” Lyons said, “we’re seeing more revisions as opposed to doing one set of prototypes. Instead, companies are making multiple versions to make sure it’s right, which saves money and time in the long run.”

Indeed, customers’ interest in saving money is one of the top trends all suppliers report seeing. “Companies are prototyping not only for product enhancement, but also for cost improvement—to reduce the total number of components in a device,” Lyons reported. “In most cases, by coming to us early, with our expertise in medical device contract manufacturing we can find a more cost-effective way to manufacture a part or to enhance function by changing materials or component features.”

Material selection is a key component in reducing costs, Riemer agreed. “A customer may think X about a particular material, but our on-site chemist potentially has worked with that material on numerous projects and may be able to

recommend an alternative raw material instead. By pointing out properties or capabilities of a material, or by recommending a material with better physical properties or a less expensive alternative, [a supplier] can provide real value,” Riemer said.

Creating multiple iterations of a design simultaneously also may shave dollars from the bottom line. “If one prototype costs \$500 and takes one to two weeks to create, we may advise a client to let us create three sets at once that are similar but with some differences,” Duman said. “This latter approach would cost \$700 to \$800 and all be completed within that two-week window, allowing customers to improve time to market and saving them money compared with first performing one iteration and waiting to perform the next.”

For this part manufactured by Lyons, the company participated in design modifications and made a series of different versions prior to finalizing. In the end, the following processes were used to manufacture the part: wire EDM of a flat blank pattern; forming the metal housing through a series of forming tools; forming the needles; resistance welding the components together; grinding the needle tips; and electropolishing the finished component. Photo courtesy of Lyons.



That said, Duman warned, five prototypes won't always cost half as much as 10 would. “The majority of the cost is in set-up and fixturing,” he explained.

Another big money saver is ensuring that whatever process is used during prototyping can be used later during production. “You must consider the ultimate quantities of the final product so you can ensure the translation of prototyping processes into production processes,” Duman said.

While the software and equipment used in prototyping today continue to see incremental improvements, the sum of those improvements over the years has led to faster turnaround times—much to OEMs' delight. “With the advances in software and machine programming, we can move more agilely and quickly from customer files to our machines,” Duman said. “Today it's possible to cut parts within an hour of receiving a file. Keep in mind, however, that you need to think through the processes carefully.”

In other words, don't let excitement about technology's capabilities lead to unfortunate shortcuts.

“These days, prototypes can look and function very close to production devices—so close, in fact, customers often believe full production can be realized sooner than may actually be possible,” warned Thomas Eck, chief operating officer of BIT Analytical Instruments GmbH, headquartered in Schwalbach/Frankfurt, Germany. “A production device still requires proper material selection, complete documentation and testing—both functional verification and process validation.”

For this reason, Eck added, BIT Analytical Instruments' “Platform Technology” concept has been well received. While the company's benchtop instruments are very complex, sophisticated systems, over the past three decades, it has built up a bank of subsystems that have proven technology and are ready to pass regulatory testing, he said. “These subsystems can be used to speed up the prototyping process,” Eck explained. “Such a launching pad in development can save the customer significant time and money.”

In fact, saving time is another common request heard by prototype suppliers. In addition to bringing more capabilities in house to shorten lead times, some suppliers are looking for new ways to combine existing technologies and processes to speed products to market. “A lot of people use Finite Element Analysis, or FEA, to help determine how a product will work. Plastic is easy to analyze, but rubber can be more difficult to predict. In the past few years, Vernay has married FEA and CFD [Computational Fluid Dynamics] systems to allow for increased predictability so prototypes can be hit right the first time,” Madewell said. “Both of these systems have been around for a while, but it's a new concept to join them together.”

Pakenham added, “This electronic modeling process is able to look at where stresses will occur in a valve and how they should be handled. By pinpointing design flaws, it saves time and money.” Using this newer concept, one Vernay customer was able to avoid its usual process of cutting several iterations in hard steel; it needed to cut only one, he noted.

Customers also can save time and money by using standardized mold features. “We offer platform technologies that allow OEMs to choose some off-the-shelf products and features in addition to creating custom molded parts,” Madewell said.

Success Stories

Certainly, outsourcing prototyping makes sense for many companies. After all, they will free internal resources to focus on core competencies and leverage the best practices and top expertise within the industry by working with outside firms. But perhaps nothing speaks so well about the possibilities and promise of outsourcing prototyping as real-world success stories.



Howey told the story of one recent customer's experience. "A company was producing its product at another supplier, but the manufacturability was too difficult," he recalled. "We reworked the design to allow for automated manufacturing and assembly, and the customer realized a 30% reduction in costs."

Source Scientific also helped a customer shave costs—and time—from its production schedule. "We created several design alternatives for a hand-held device using stereolithography rapid prototype techniques. We were able to create multiple variations of the plastic parts in just a few days, thus saving thousands of dollars and weeks of time versus using traditional prototyping methods," Sargeant said.

And Peridot Corp. recommended that one of its clients use stainless steel tubing rather than the specified nickel titanium tubing for its surgical device, netting a savings of hundreds of thousands of dollars. "It's important to ask the right questions to make sure a product prototype is the best it can be," Duman said. (See "The Ideal Prototype: Ask and Answer" on page 116.) "We looked at the drawing and asked the customer, 'Why are you specifying nickel titanium? Where does it go? What does it do?'" The answers were such that making a material substitution ended up being the best solution—both for product performance and function, as well as for cost.

By asking—and answering—the right questions together, OEMs and their outsourcing partners can make sure the medical device industry's tradition of innovation stays strong.

Stacey L. Bell is a freelance writer who specializes in business and marketing issues. She is based in Tampa, FL.

SIDEBARS:

The Ideal Prototype: Ask and Answer

You've likely heard the African proverb, "It takes a whole village to raise a child." In the medical device industry, it can be said that it takes a whole lot of creative minds to develop a prototype. From the initial inventor's drawings, to the design teams' additions, to the expertise in materials, process and production offered by an outsourcing partner—many hands will touch the project before a final product debuts in the marketplace.

Experts believe that to create a prototype that will best meet its intended purposes, each group of individuals should ask—and answer—several questions.

The original innovator and the OEM's design team should address the following questions, said Les Duman, sales manager for Peridot Corp. in Pleasanton, CA:

- What does the product need to do?
- What will it cost in the marketplace?
- How long will it take to produce (when must it be in the market)?
- Do we have the resources to create all prototypes in-house?
- How many units will we ultimately produce annually?

Duman noted that suppliers will have additional queries that they must answer before proceeding:

- How soon do you need these parts?
- Where does each part go? What does it do? How does it interact with the other parts?
- What will the ultimate quantities be? (Quantities make a big difference in determining which processes will be optimal, Duman said. Surgical devices or equipment produced in quantities of 1,000 per year require a different approach than devices that will be produced at a rate of 500,000 units annually.)

Jason Howey, vice president of OKAY Industries in New Britain, CT, added that suppliers also should ask customers what their biggest concerns are, the product's anticipated lifecycle and how open they are to making changes.

Greg Riemer, vice president of sales and marketing for Molded Rubber and Plastic Corp. in Butler, WI, noted that it's essential to understand what the customer wishes to learn from the prototype. "Some customers want a prototype to study product functionality; others are determining what dimensional tolerances can be held. You need to establish up front whether you're looking for direction on material selection, product performance issues or a variety of other information to ensure that you and your customer are singing off the same sheet of music."

By working collaboratively, and taking care to thoroughly address each question, OEMs and their outsourcing partners will be able to create prototypes that not only meet current needs but also allow for a smoother journey into full-scale production later. —S.L.B.

Going Green to Save Green: Environmentally Friendly Measures

The issue of global climate change has gained more national attention during the past year, with major international concerts and even television networks sponsoring special activities to raise awareness. Within the medical device industry, companies have long strived to be environmentally friendly.

"Paying attention to green is good for a manufacturing company," said Les Duman, sales manager for Peridot Corp. in Pleasanton, CA. "It's a good sales tool, and it helps the environment. We use only as much power as we need, and we recycle as we can. Being green also saves customers money. We determine exactly how much packaging is actually required and use only that amount, and when manufacturing L-parts, we flip-flop the parts to fit more on a sheet of material. Thinking about the most efficient, cost-effective—green—way to complete jobs uses less material and minimizes costs. We're also looking to minimize the VOCs [volatile organic compounds] in cleaning solutions." As a result, Peridot has switched to using alcohol and other more Earth-friendly cleaners.

New Britain, CT-based OKAY Industries recently spent \$250,000 on an energy audit, from which it expects to see a payoff in electricity costs in just over a year. Jason Howey, vice president for the company, noted that the savings gleaned by being as energy efficient as possible are reflected in overall pricing.

Omni Components Corp. in Hudson, NH also prides itself on being a green company. It recycles all waste metal, paperboard, cardboard and office paper where possible.



"As part of our effort to go green, we've upgraded our compressed air system in our manufacturing facility to a variable-speed drive that saves a large amount of kilowatts a year," Rick Holka, president of Omni Components, additionally noted. "It runs to the load that's needed, not to full horsepower. We're also installing efficient lighting throughout the entire plant—office space, warehouse and manufacturing floor."

Thomas Eck, chief operating officer of BIT Analytical Instruments GmbH, headquartered in Schwalbach/Frankfurt, Germany, has seen similar trends overseas. "The go green movement definitely does play a part in prototyping. Right now, it is bigger in Germany—they have been following strict legal requirements for many years. In the United States, we are more focused on RoHS [Restriction of Hazardous Substances Directive] and electronics [the WEEE initiative on Waste Electrical and Electronic Equipment]."

The RoHS law requires that new electrical and electronic equipment put on the market not contain any of six banned substances—lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)—in quantities exceeding maximum concentration values.

"Aspects such as recycling were introduced years ago," Eck continued. "The new developments are all RoHS-compliant, and manufacturing methods are chosen based on environmental aspects. For example, utilization of aluminum parts and tools for plastic parts drastically saves energy in the CNC machining process. All of our electronic design is based on RoHS-compatible parts."

Eck added that a law in Germany requires companies to reduce the content of certain gases/fluids, and all paint chips must be water-based—not chemical. "RoHS is not just electronics—it also has to do with paint or corrosion protection of sheet metals, etc.," Eck said. "There is a growing list of materials that are no longer allowed."

While going green in one's home can lead to a healthier environment and cost savings—use a dishcloth rather than paper towels, and you'll add less waste to landfills while saving at least \$20/year—going green within the manufacturing world can provide significant bottom-line benefits for suppliers, OEMs and the world at large. —S.L.B.