



Rx for work - Medical OEMs and their suppliers share what it takes to get (and keep) a manufacturing contract.

by Patricia L. Smith (AMWEBMASTER@PENTON.COM)

AmericanMachinist.com exclusive

Patricia L. Smith, managing editor, and Charles Bates, senior editor

Many shops find it difficult to break into medical manufacturing, which is both a capital-intensive and quality-driven business. Newcomers often find it takes years to build a reputation as a manufacturer that can deliver products on time and at the necessary quality levels.

"To win medical work, a shop has to sell its capabilities, which is not an easy thing, even for experienced shops," says the sales manager at an Oceanside, Calif., medical shop. Basically, he says, a shop starts doing work for a medical company when it is small. As the medical company grows, so too, does the shop doing its contract-machining work.

But it is difficult to get work from large established medical companies because they've already built up a list of reputable suppliers. "Shops must have that extra something that a medical customer is looking for -- such as engineering assistance or a good track record/experience. It is not always a price issue," says the sales manager.

"We don't need to look for suppliers," says a senior staff engineer at a medical-device manufacturing company. "We have a handful of preferred suppliers doing over 50% of our medical work, and they

were chosen for special reasons -- each having specific processes or technologies vital to our operations. Lately, we have been trying to narrow that list down to five or so that cater to us."

For many OEMs, quality and on-time delivery are what make or break deals when it comes to farming out work. Some OEMs prefer to keep work in-house to maintain control of these factors. "Our run rates are high, and our customers are demanding parts with greater precision and tighter tolerances," relates an executive working for a major provider of healthcare products and pharmaceuticals. "A higher level of quality is expected in materials and in machining accuracy, and then, with turnarounds, customers want their parts faster." For all these reasons, the company keeps manufacturing in-house.

A firm that makes orthopedic implants also keeps much of its work inside. "If we have a spike in orders, we go outside," says a team leader in the screw area. "But we stick with a list of certified vendors, and our in-house quality-control people monitor these vendors closely. When we do outsource, we bring the product back in so our quality people do the final inspection. And these products still go through our own sterilization process."

Although these companies are still manufacturing in-house, many small medical OEMs and startups don't have this luxury. They choose to invest in their core competencies and outsource non-core areas such as manufacturing. As for larger OEMs, outsourcing frees up capital that would otherwise be tied into manufacturing equipment and labor.

The trick for jobshops, then, is to prove they can handle whatever comes their way. This is easier for manufacturers already in the business. As an Alabama shop president puts it, "A lot of shops get medical work indirectly or by word-of-mouth because it is tough for contract-machining shops to get into a large medical company just to pitch their capabilities." The reason, he suggests, is that not all shops can actually handle medical work, and most large medical companies know this. It takes the right equipment and the engineering expertise to build quality medical parts. And it takes a shop that can hold tight tolerances and produce exceptionally smooth surface finishes (polished, with no tool marks or burrs). "Shops doing medical work spend a great deal of time making parts look good," he comments.

Keeping up on new technology is crucial to being competitive, claims a Connecticut shop, which regularly invests in new machines. However,

the company reports its greatest problem is finding quality labor to work with the new technology. "Compared to the cost of finding and keeping good labor, the cost of a new machine is not a huge factor," comments a company insider.

A subcontracting shop in El Monte, Calif., says the way it got into medical work doesn't really apply today. The shop developed a reputation over a number of years by working with engineers at medical companies who moved on to other companies. These relocated engineers then continued to work with the shop, which acquired a new customer, so to speak. However, this method of doing business also works the other way. A shop already getting the work may be ousted to make room for a new supplier.

Shops without connections have to strategically position themselves to focus on one medical area and then develop a marketing plan accordingly, says the California shop president. "Getting work in the medical environment means playing the angle that your shop can do or provide what others can't," he says. And by providing a solution to a medical manufacturing problem, a shop differentiates itself from the competition.

Solutions-based services

Given the FDA's stringent regulations, medical OEMs can't always make design changes as often as manufacturers in other industries. Therefore, it's important that design and manufacturing teams -- whether they're internal to the OEM or involve a supplier partner -- settle on the best materials and processes at the onset of their projects.

A general manager for an integrated supplier to the medical industry says that OEMs want to work closely with their suppliers on the manufacturability of their parts. "They want us to be upfront with them, as early in the process as we can be, about where we see the cost drivers in a particular design," he explains. "It can go as far as the OEM wanting to understand all of our costs and how our business practices impact these costs."

He says being this open isn't easy, but it's essential in today's business environment. "I won't tell you it's easy to do, but it is fast approaching the point where if you aren't willing to work with these guys, they won't continue to do business with you. And they'll find people who will."

A precision welding jobshop in New England says that supply-chain management appears to be the next manufacturing practice to hit smaller shops. "The customers are gradually placing the burden of material management and special process requirements of their products on a single source. The welding jobshop may now be required to get the parts machined, plated, cleaned, brazed, assembled, labeled, tested, and packaged," he explains. "In return for providing this valuable service, the customer will offer a lifetime sole commitment to purchasing from the supplier. The concept here eliminates the need for constant bidding, which creates unnecessary cost in the value stream."

According to a Minneapolis manufacturer, supply-chain management includes having a well-maintained paper trail for many aspects of material handling as well as the manufacturing process. For example, manufacturers must document what materials arrived and where they came from, as well as where and how they were stored. They must also record manufacturing times and conditions so that, down the road, investigators can trace back any problem to its root cause.

"Implants require that we maintain accountability and traceability from raw material through the manufacturing process," says the team leader at the orthopedic company. "It continues through our stocking location and out to the customer. If an implanted screw breaks -- however many years down the road -- we must be able to go back and tell exactly who had their hands on it. So there's a tremendous amount of FDA involvement as far as I'm concerned."

Documentation requirements go even further. For example, as manufacturers bring new programs into their manufacturing processes, they have to qualify lines and train their staffs -- and keep records. And once a production line starts rolling, these shops need to keep the FDA apprised of alterations to workflow. In addition, shops must document even minor tweaks, such as replacing machine tools, that are made to improve yields.

Maintaining quality -- and proving it

Manufacturers in the medical industry cite quality as one of their greatest challenges. "The medical industry's demand on your quality system is enormous," states the general manager at the integrated supplier. "The needs to ensure consistent, long-term quality and to demonstrate that you're achieving it are important to the medical OEMs. But many jobshops simply don't have the quality systems in

place to address the needs of medical customers. When you're working in this business, you're not just concerned about the quality of the product; you're concerned at the moral level about the end user, or the patient, who is exposed to that product. So it's a completely different manufacturing mindset."

He adds that shops have to be more concerned with computerized tracking of their quality results, using statistical process control (SPC). "That's almost a minimum standard that you have to demonstrate with these customers," he remarks. "You also have to be able to talk their language. Each industry has its own terminology, and you have to have an understanding of what FDA's requirements are at the manufacturing level. This industry talks in terms of Six Sigma today, a lot more than it did in the past."

A contract manufacturer specializing in creepfeed grinding vouches for this. "We have to provide detailed statistical information to our customers as to quality and capability measures." To meet this demand, the company has invested in more sophisticated gaging and data-acquisition systems.

It's true that many shops aren't exposed to the FDA auditing process. But while the FDA isn't breathing down their necks, shops working in the medical field still have to abide by their customers' demands. "The FDA is very rigid in its review of an OEM's quality system -- this involves making sure the OEM's vendors are supplying quality products," shares the integrated supplier. "It eventually impacts us. For example, we deal with one OEM whose quality system demands on the vendor are explained in a three-ring binder that's about 3 1/2-in. thick."

According to one OEM, it keeps close tabs on its suppliers. "Even the ones we have been working with for years," comments the orthopedic company's team leader. "We regularly inspect them and check their records -- to revalidate the company, if you will. We want to ensure their compliance is in line with our compliance."

He adds that maintaining status as a vendor is easier than getting into the business. "The medical market is very stringent in its requirements," he states. "It's a lot easier to maintain your status as a good vendor, provided that your quality is there and your delivery dates are good. As for new suppliers, we constantly have requests and calls from people asking for vended work. But we don't want to get

spread that thin. And there's a lot of regulatory red tape to get someone established, set up, and qualified as a supplier."

Copyright © 2003 Penton Media, Inc.
[Copyright Notice](#) | [Privacy Policy](#)

