➤ BY DAVID GEHMAN

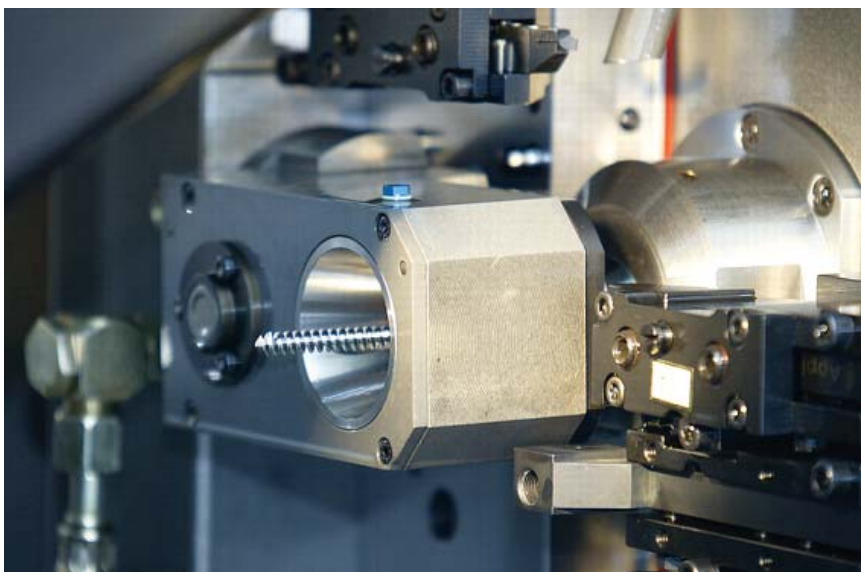
Healthy Manufacturing

Some of the factors to consider when looking into machining medical parts.

Whether a shop should add medical parts manufacturing to its arsenal is a recurring question in the world of metalcutting. Medical manufacturing can be a tough taskmaster. Profits can be good, but they are not as healthy as they once were. Still, everyone prizes health, and what people prize, they are willing to pay for.

There are three aspects of medical manufacturing to consider:

- business factors;
- quality and process requirements; and
- infrastructure elements.



All images: Tornos Technologies

A bone screw is held in an automatic multispindle lathe chuck (right). Tooling (center) turns thread cutters rapidly around the screw, which is turning in the opposite direction.

What is the Draw?

Making products used for health care delivery—surgical devices, diagnostic equipment, devices to deliver drugs and the like—has always been a specialized area. Growth was especially strong beginning in the second quarter of the 20th century, when skills in surgery and breakthroughs in therapies and drugs fueled huge increases in health care delivery.

By the 1960s, hundreds of small but profitable companies across the U.S. were both manufacturing and marketing their own medical products. Until the late 1980s, there were few caps on spending, so margins were highly attractive.

Since the 1980s, medical marketing has increasingly been separated from medical manufacturing—with acquisitions and consolidation, more and more products have been concentrated in large companies. These have increasingly focused on medical marketing, outsourcing their manufacturing and assembly—a pattern familiar in many other industries as well.

That said, the economic outlook for medical manufacturing is not as rosy as it once was. Making medical parts may no longer be a limitless source of income. According to Mark Saalmuller, sales and marketing manager for Tornos Technologies U.S. Corp., Brookfield, Conn., "Medical manufacturing has been quite lucrative in the past, but profits are tightening."

He said the reason is that medical procedures are increasingly paid for by insurance, and insurers are reducing their rates of payment virtually across the board. More and more, U.S. health care costs are being covered by Medicare, and Medicare's reimbursement policies can impose strict caps on payments.

Still, whether profit margins are high or low, compelling reasons for embracing medical manufacturing remain. Medical work can help smooth business cycles. Health care has its own ups and downs, but these are often independent of business in general. Plus, over the long run, health care will remain a business on the upswing.

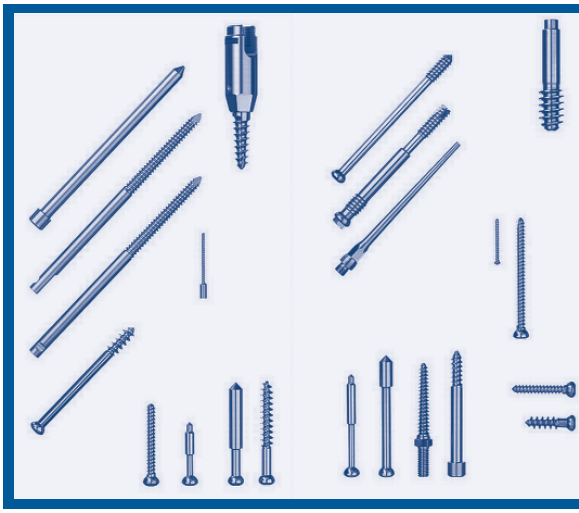
New discoveries about the ways drugs work, new surgical techniques and new designs for medical instruments emerge almost weekly. Any one of these developments can create the impetus for a new product, or at least a new prototype, that has to be made.

Furthermore, unlike products in the commodity or consumer world, health care products go to market in a meritocracy. This means that a new product that has been proven effective will probably enjoy success in the marketplace, assuming basic marketing tactics are followed.

Beyond financial rewards, psychological rewards can be found in medical manufacturing as well—assuming you're not just making instruments for the most frivolous of elective cosmetic surgery. Put simply, shops making medical parts often feel that they are doing something to improve lives.

There's a second psychological aspect—soon after jumping into medical parts, you are going to have to master production to the highest of quality standards. Therefore, if you do not feel comfortable about doing high-quality work—and furthermore, if controlling your processes does not sound like a good thing—you probably should avoid medical manufacturing.

Finally, beyond economic and psychological rewards, medical manufacturing favors approaches familiar to metalworking shops. Almost no metal-intensive medical products are sold in the millions. (Million-seller medical products are likely to be made of plastics.) Thus, most products with high metal content are low- to medium-quantity items that beg for the kind of agility, flexibility and quick-change artistry common to shop operations.



A variety of screws used for bone fixation and skeletal reinforcement. The threads have nonstandard pitches, and the screws themselves vary greatly in diameter.

Enter the FDA

Assuming you are attracted by the pluses of medical manufacturing, the next step is to take a long, hard look at the regulatory requirements. In the U.S., the primary set of guidelines and regulations is the Food and Drug Administration's 21 CFR, Parts 808, 812 and 820 regulations—or, more simply, GMP, good manufacturing practices. (You may also see this referred to as CGMP, or current GMP, which is pegged to updated GMP specifications that came into force in 1997.)

GMP is a collection of ultimate quality and documentation procedures. In fact, the similarly documentation-intensive ISO 900X certification is an excellent stepping stone to achieving GMP compliance.

The extent to which GMP affects you depends on the work you do. Judy Andrews, manager of quality and compliance services of Andover, Mass.-based Medical Device Consultants Inc. (MDCI), said, "The full level of your quality-procedure qualification depends on the type of manufacturing. The closer you get to a finished device or its labeling and packaging, the more you come under the requirements of 21 CFR.

"Of course," she added, "in any manufacturing concern, it's always a good idea to have systems for handling quality issues. Tracking of materials and traceability—who made what, on what day—are going to be more important to medical devices."

GMP is at its most stringent when applied to critical components. There are a number of shades of activity within metalcutting for medical manufacturing in the U.S.

If, for example, you are making a panel for a medical instrument or the handle for a surgical tool, you probably do not need to focus on anything other than transforming stock into finished work.

The story is different if, for example, you are making pump heads for heart-lung machines. Here, because the failure of a pump head is equivalent to heart stoppage, mechanical failure threatens human life. If you are machining a critical component like this, you must be completely compliant with FDA guidelines, and have complete process controls, control of machining parameters, testing records and the like. "The more you get into critical areas, the more records you need to keep," Andrews said.

When making critical components, every element of your shop and processes must be under continuous control. In addition, you must maintain records of every procedure and every point of inspection.

The more intensely you must follow GMP, the more likely that you will want insurance and a good lawyer as well. In this litigious society, lawyers are armed with extraordinarily broad product liability precedents. If your customer, the medical product marketer, is brought to court, you can be involved if you supplied a critical component.

Making the Leap

"A shop moving into medical will find itself with a lot to think about," Tornos' Saalmuller said. There are many interlocking needs, from identification of prospective customers to machine and process qualification that require initiatives that involve everyone from the head guy to the broom pusher.

There are a couple of modes of execution: ramp up slowly, building up expertise over time and eventually moving into deeper levels of commitment, or take a quick plunge into the deep end of the pool.

Working your way slowly into medical manufacturing requires less disruptive emphasis on procedures and quality control. In this mode, a shop seeks out noncritical components. Over time, consistent quality and increasing acquaintance with your customer's needs and medical specialty can lead you gradually into more GMP-intensive jobs. Alternatively, you could carve your own niche and be well-satisfied.

A case in point of a shop that has made its own place is Bulling Metal Works Inc., San Leandro, Calif. Bulling has developed a solid niche in the fabrication of process equipment for pharmaceutical development and manufacturing. The shop makes pressure vessels, tanks, fermentors, filtration units, agitators and piping components. The shop's processes include high-purity welding, a full range of machining and plate fabrication.

For the company's markets, Walter Bulling, president, said: "We don't need full FDA compliance. We're not ready for GMP, but we are accredited by the American Society of Mechanical Engineers and make product to the ASME pressure-vessel code. Granted, a lot of equipment we make does not need that stamp, but it shows that it was built to standard and this gives our customer peace of mind."

Rather than bidding on jobs once they have been engineered ("Frankly, when someone else has done the entire design before we see it, they're usually just looking for the low bidder," Bulling said), the shop prefers to work with customers early in the design process.

"We focus on work at a certain level," Bulling explained. "Typically, we are in at the start of development for a pharma product. We can bring process-equipment design skills to the table, and we know our materials and how to work them. And we can do full documentation as well as design. That's one thing our customers definitely need."

The shop typically will continue to develop equipment for a given pharmaceutical product as the pharmaceutical company progresses from research to pilot production. If, as happens in a small percentage of pharmaceutical research projects, a product moves into full production, Bulling's involvement most likely fades.

"When a product moves to mass scale," Bulling said, "the search—and the price—goes global, and that's not where we can compete. We do make production-scale equipment for a select few customers, because we go back many years with them. But, for most others, we don't service beyond a certain point."

The shop's specialization in making pharmaceutical development and manufacturing process equipment enables it to do things that others will not or cannot do. "We have full capability for tracking specialized stainless or other materials," Bulling said. "We have in-depth understanding of their composition, especially how the makeup of the material affects forming, cutting and welding. Getting to this point has been time-consuming, but it's worth it for our customers. Specialized knowledge gives us an edge over the competition."

Plunging In

Others may want to become involved in full-bore medical parts production. A shop that wants to move directly and quickly into GMP will almost certainly need to call in outside resources. "Learning GMP by yourself is very costly," said Tornos' Saalmuller. "Most medical companies will ask for ISO certification as a baseline and go from there."

At the very least, he said, you are probably going to have to change your inspection methods. His example: ensuring that bone screws meet specifications requires more than a micrometer and a thread gage. Bone screws have highly specialized thread forms. "You almost certainly will need the capability to make overlays from CAD/CAM geometry, place them on an optical comparator that projects an image of the part and the overlay and make sure the part matches the CAD/CAM overlay—that is, use shadowgraph techniques," he said.

Working with third-party suppliers can provide the needed outside assistance. "Specialists in GMP procedures or in audits for ISO certification are typically the most cost-effective resources," Saalmuller said.

MDCI is a good example of the kind of third-party specialist that can help a shop understand what is needed when moving into medical manufacturing. "We can talk about how to implement medical quality programs without turning the place upside down," Andrews said. "We've worked with several companies that supply the medical device industry, including design houses and companies outsourcing their manufacturing. As detailed as it is, setting up systems that are compliant is a lot more fun than explaining things later to the FDA."

MDCI itself is ISO 9000:2000-certified, though it is clearly not a manufacturer. "We feel that having successfully gone through the ISO-certification process makes us more knowledge-

Collaborating efforts

Kent Gladish, director of marketing for the Tooling & Manufacturing Association, puts the attractiveness of metalcutting for medical product makers in perspective.

"We think there's significant opportunity," he said. TMA has unveiled plans for a collaborative effort that brings key TMA members together to target medical product companies looking for metalworking expertise. A formal announcement will be coming soon.

"The control inherent in using local suppliers should prove attractive to medical product makers," Gladish said. "We plan to offer expertise for complex, high-tech surgical products as well as more basic products, such as beds and medical carts. People in procurement or purchasing at medical product companies will benefit from having a single point of contact for a broad range of metalworking needs.

"Our membership benefits as well," he continued. "We feel there will be less pricing pressure [than in automotive or commodity products]. Plus, for the most part, companies that market medical products understand the economics of medical manufacturing."

—D. Gehman

able," Andrews said.

Ultimately, she said, the importance of rational manufacturing quality systems should not be underestimated. Equally important is control over the design side, especially specifications and engineering changes.

"There's nothing more frustrating than to be working on something that's undergoing changes," Andrews said. "If things change and you don't get updated drawings, you'll provide wrong parts."

Outsourcing Activities

There is a middle ground. If a shop decides that it does not want to invest in an in-house, GMP-compliant program but still do critical work, it is possible to outsource aspects of production to accredited, third-party groups. Inspection is one such activity that can be entrusted to an outside firm.

Dimensional Inspection Laboratories, Newark, Calif., offers this kind of service. DIL provides contract inspection for a variety of customers, including shops that are happy to offload the inspection and documentation chores involved in certifying a given production lot.

"Companies making medical products, like everyone else, are increasingly picking up their pace, and they increasingly want to minimize head count," said Al Faccini, president of DIL. "We can step in at any point and provide the right quantity and depth of resources for quality control."

DIL also works with medical marketers, the shop's customer, serving as a bridge between a product marketer and the shops sourced for metalcutting or assembly. On one side, the laboratory gathers inspection criteria from the marketer. On the other side, DIL works with the shop to fine-tune processes to ensure output matches the specifications.

"We're a good resource for young companies beginning the FDA-approval process," Faccini said. "We're a fully accredited facility, and it helps tremendously as you go to the FDA for approvals when you have all your ducks in a row, with certified vendors, certified labs and plenty of controls over testing, manufacturing and assembly."

For a company with its first product, for example, DIL can bypass the need for the staffing and capitalization of in-house inspection. "We can draw from 20 years of experience and apply the right set of processes for nearly any situation. Then, along the way, if this first product booms, they can make the decision to add staff or stay with us," Faccini said. "At a certain level, many companies bring quality in-house."

Equipment Investments

Quality, documentation, FDA and compliance concerns aside, the final element for any shop moving into medical manufacturing is ensuring that it has the right equipment. In the final analysis, the accuracy and efficiency of machine tools are the most important issues.

"The more price-sensitive the area, the more shop efficiency becomes important," Tornos' Saalmuller said. Tornos manufactures automatic lathes (Swiss automatics) and has supplied medical parts shops for more than 20 years.

Swiss automatics are good for making bone screws, fixation pins, dental implants and skeletal repair plates. They also are well-suited for components for instruments such as forceps, cutters, tiny cameras and cauterizers. In addition, the flexibility of automatic lathes favors the extreme variation seen in the medical products industry. Many metal implants are available in a broad range of sizes and shapes to accommodate variations in human anatomy.

As one veteran put it: "Medical manufacturing is one of the most satisfying things you can do—satisfying to you personally and to your wallet. At the same time, it can be one of the most intensely challenging things you'll ever take on. Medical manufacturers are a hardy breed, and that's an understatement." △

The following organizations contributed to this report:

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