

turn down the volume

What design options do you have when production won't top a thousand pieces a year? Plenty, if you know the ropes. *By Eric Schneider*



Manufacturing, in its earliest form, involved a skilled craftsman creating goods one by one.

Over time, the demand to make products cheaper and faster led to factories and mass production. Now, high-quantity production facilities can churn out millions of products each year.

But what if you only need to produce 1,000, 100, or even 10 per year? Low-volume manufacturing is fairly common in the medical device industry, for instance, as new concepts are tested in pilot markets or in clinical trials before larger volumes are necessary.

The reality is that manufacturing processes, design options, and product aesthetics become limited as the costs of tooling and setup become more significant components of the project budget. Vendors are less inclined to respond, and client expectations require more active management. For the industrious engineer, however, there are opportunities among the challenges.

Key Tech specializes in the design and engineering of electromechanical medical devices and high-tech test and measurement equipment—niches for which low-volume production is the norm. A recent project involved the design of a delivery system for a novel drug that consisted of two separate medical devices. The first device was an automated drug preparation system and the second was a cart-mounted delivery system to inject precise amounts of the drug into the patient with microliter accuracy.

The product was designed for a specialized market which would initially have a limited number of trained practitioners. Consequently, initial production estimates were only in the hundreds-per-year range. Furthermore, fewer than a hundred units of production quality were needed for clinical trials and for verification and validation testing. Regardless of the production quantities, as medical devices, they still needed to have the manufacturing controls and safety considerations required for licensing by the U.S. Food and Drug Administration.

For high-quantity production, common manufacturing processes (injection molding, die casting, etc.) offset a steep initial capital investment with a very low unit cost. The initial investment is sprinkled across the parts as pennies. However, for low-quantity production, such

Machining is a good choice for low volume production as there is little up front setup, but larger more complex parts can get expensive.

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Bent sheet metal enclosures usually lead to boxy or industrial looking devices.

capital investment can overwhelm the part cost. At some point, there is a balance between tooling costs and quantities, so individual projects may vary from “No Way!” to “Eh... okay,” depending on project budget, sales forecast, and other factors. Thus, processes with lower initial investment, such as machined plastic or metal, bent sheet metal, thermoformed plastic, and silicone-cast urethane may prove favorable for low-volume manufacturing.

While such methods can be more cost effective for low-volume production, they typically require designers to make some compromises on aesthetics and material properties. In the case of the drug delivery system devices, this became particularly troublesome in the shape and functionality of the enclosures. The enclosures needed to mount and enclose all the components required to make the device work, meet applicable standards and codes, and allow the user to interact with the product easily and intuitively. The finished product also needed to be aesthetically pleasing, matching the branded appearance of the client’s previous products.

Injection molding, one of the most common manufacturing processes for mid- to high-volume plastic parts, would normally be the first-choice method to meet all of those requirements. Mounting features are easily integrated, there are many materials available to meet strict codes and standards, and it allows for organic and natural shapes, allowing the designer a great deal of creativity when designing parts. However, tooling for the molds would have been expensive (\$40,000-\$60,000) and would have resulted in unacceptably high part costs over only a few hundred parts.

With the advances of CNC machining, similar parts could be machined from blocks of plastic for low-volume production, but for a large, complex component like an enclosure that requires a 5-axis mill and/or multiple tools, the per-part cost could be in the thousands of dollars.

Bent sheet metal works well for low- and even mid-volume production, as there is little up-front cost, but creativity is severely limited due to the nature of the process. Using bent sheet metal for a product enclosure usually makes it appear boxy and industrial. Thermoforming is often a good choice for low-volume production applications. Tooling for thermoforming is relatively cheap and it allows for organic shapes with a high quality



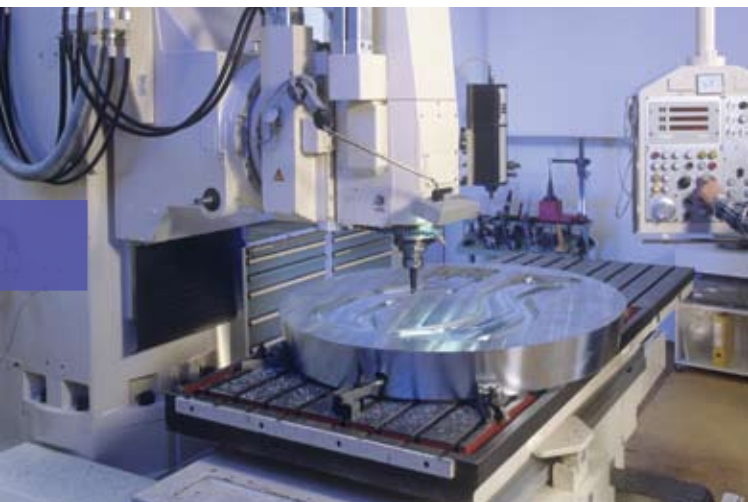
FREETECH PLASTICS

Thermoforming allows for organic shapes with a high quality finish, as in this multiple head semiconductor tester.

finish. However, it doesn’t provide the design flexibility of injection molding and generally holds tight tolerances only on one side of the part. It is sometimes necessary to include secondary processes with thermoformed parts to achieve critical tolerances, and they can substantially increase part cost.

Reaction injection molding has cheaper up-front costs for tooling than injection molding and allows for more or less the same aesthetic creativity. However, the mold lead times are similar to injection molding and there are fewer materials from which to select.

Urethane molded parts can be made quickly with inexpensive tooling, but the tolerances are not as good as an injection molded part and often fine features cannot be molded because of the lack of high pressure. Typically, fewer than 20 parts can be made from a single mold so there is a likelihood of variability from mold to mold. Additionally, the limited material properties of urethane castings are acceptable for some applications but not when UL fire ratings, drop test durability, or harsh-





FREETECH PLASTICS

Thermoforming, which created the parts of this enclosure for an ultrasound generator, forms flat sheets of plastic over a mold with heat and pressure or vacuum.

environment performance are critical considerations.

It always comes down to a balancing act among desired features, cost, and speed. All of the aforementioned techniques have merit and are the best choices for some applications. Ultimately, for this project, we chose urethane molding for the clinical trial and initial verification units, and thermoforming for the production units.

This compromise was made due to tight schedule constraints for the clinical trial units. We opted not to use urethane molded parts for the product because the limited material properties and part variability would have been problematic for this application. In cases where the material requirements are mild, such a process would have worked very well.

Aesthetics and creativity are also limited by the use of commercial off-the-shelf (COTS) parts in low-volume production. In low-volume production, off-the-shelf parts are much cheaper than custom parts, but this means the design has to accommodate pre-made parts.

The drug delivery system, for example, used off-the-shelf precision syringe pumps (essentially linear actuators that move the plunger of a common syringe to dispense fluid). The pumps were chosen to avoid the significant development cost of a custom design. However, the available pumps were fairly large, which influenced the

size of the devices and the mounting locations.

Software and electrical engineers are not exempt from challenges similar to those faced by mechanical engineers. Medical devices are usually expected to have well-developed graphical user interfaces, and the programming expense to create those interfaces can easily become a huge portion of the project.

For complex devices, an embedded operating system may be needed to provide the necessary functionality of multi-threaded processes. Unfortunately, the expense of investing in either a commercial or a custom OS, and then validating the OS for the application, can prove excessive if it's not distributed over thousands of units.

By reducing feature complexity, computer engineers

may be able to forgo the OS for tailored drivers and process schedulers. With respect to assembly, by purchasing microcontrollers in large quantities, they can arrive pre-programmed. In low volumes, the manufacturer has to program chips individually, which requires a skilled assembly technician and adds to assembly time per device.

Designing complex products for low-volume production usually involves some degree of compromise. But, that does not mean that the available processes are going to be inadequate. By understanding the limitations of each process, an engineer can tailor the design to make great parts with low-volume techniques, for instance, by adding compliance features to reduce the need for tight tolerances, reinforcing the walls with ribs, or combining processes. While the enclosure may be best suited for cast urethane, other components may be better suited for machined aluminum and sheet metal to increase strength or to create a high-tolerance internal frame. And, while it's likely that a product only has one enclosure, other components may qualify as high quantities. A designer can amplify the part count by making the left and right sides the same or by using the same part in multiple places. The principles of design for manufacture extend to all processes.

MANAGING EXPECTATIONS

Managing client expectations can be difficult in low-volume production. Clients can be other companies, bosses, marketing departments, or end users. They might not be aware of the challenges of low-volume production. They might want a device with features similar to high-end consumer products. Unfortunately, this is often impractical.

It is best to let the client know the challenges and compromises involved in low-volume manufacturing early, so that everyone knows what to expect. By understanding the fabrication volume and selecting an appropriate manufacturing process early, the design can be optimized

for the best form and function for the selected process. This is usually a far better choice than trying to push the limits of a manufacturing technology to achieve something that is not appropriate for the technology.

In the drug delivery system, the client decided the cost of injection molding the enclosures was just too high, and agreed to make compromises that used cheaper manufacturing processes to meet schedule and production performance needs. Monochrome displays were used and a simple, but highly functional, graphical interface was incorporated to keep engineering and part costs down. Being informed of the tradeoffs and challenges from the beginning enabled the client to decide what to compromise and didn't leave anyone disappointed with the end product.

Whether they know it or not, vendors can provide one of the more frustrating challenges in low-volume manufacturing. In a world of mass production, more product equals more money. Vendors tend to be less responsive to small-quantity orders typical of low-volume manufacturing unless they are specifically set up for that scale of business.

For custom parts, getting quotes, samples, discounts, and responses to questions is often more difficult. For off-the-shelf parts, component manufacturers typically forget to, or even refuse to, consider your inventory needs before modifying or discontinuing a product line. This is especially common with electrical PCB components, but can occur with pumps, motors, and other mechanical components. It is a critical concern for medical products.

When dealing with custom part manufacturers, the key is finding vendors that specialize in lower-volume production. They'll be set up to run several small jobs at once with easily configurable manufacturing and assembly areas. However, it is important to confirm their capabilities, because they don't always have the process controls that higher-volume vendors have.

Perusing Web sites and talking over the phone can be helpful, but often there is no substitute for visiting a vendor early in the process to observe the company's facilities, capabilities, process controls, and attention to detail. In addition to verifying a vendor's capabilities, early consultations can help speed and improve the design process. They can provide valuable input on how to best tweak a part to reduce the cost of manufacturing.

When ordering off-the-shelf parts, it is good practice to use parts that come in standard sizes or have multiple sour-

es. That way, if a part is discontinued, another can be substituted without requiring a substantial product redesign.

Sometimes this kind of backup is not possible and a low-volume manufacturer must rely on a single-source part. In that case, we develop contingency plans that consider the possibility of a part's going obsolete. For instance, the off-the-shelf syringe pumps used in the drug delivery devices were from a single source. They did not come in standard sizes or mounting configurations, and no other manufacturer made a pump that could just be plugged into the design. We did our best to confirm with the manufacturer that the part would not be modified or be discontinued, and we put contingency plans in place to ensure availability.

ADVANTAGES OF LOW VOLUME

While low-volume manufacturing has its challenges, there are some advantages. By using processes well-suited to small batches, prototype and production units can have similar components and materials. This facilitates early performance testing and preliminary verification and validation exercises, and reduces many of the surprises that can show up in first article builds.

While injection molding tooling often takes eight to twelve weeks to complete, first articles for CNC machined parts can be delivered in less than a week because the process has very short setup times. It is also rather inexpensive (and less difficult) to revise a product halfway through a production run, compared with changing an injection molding tool. There is also less need to "cost engineer" a part, which can be a painful process. While spending a few thousand dollars of engineering time to save a few pennies on each piece has the potential to save lots of money on high-volume parts, it has less value for lower-volume products.

Being aware of the challenges involved with design for low-volume manufacture early in the design process can make it much easier. Knowing the limitations of the processes can shorten design time and help with managing clients' expectations. Compromises may need to be made, but with good design practices and some ingenuity, it is possible to bring a successful, aesthetically pleasing product to market in low volumes within a reasonable budget. ■

The extremely high cost of developing elaborate graphical interfaces like those in high volume consumer products usually makes them impractical in low volume devices.

