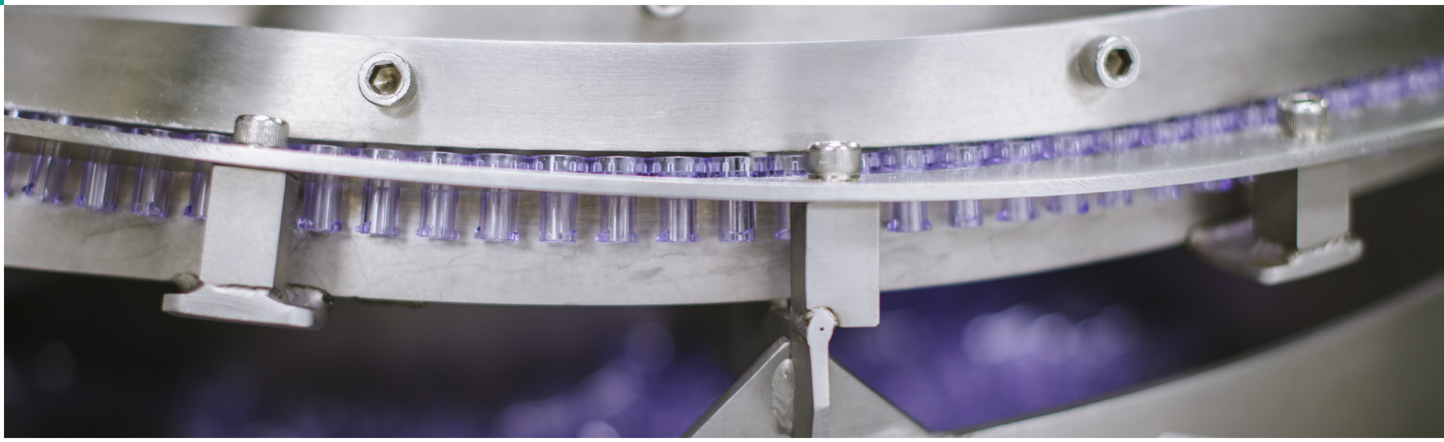

HIGH-VOLUME MANUFACTURING: ESSENTIAL POINTS TO CONSIDER BEFORE YOU SCALE UP

High-volume manufacturing typically involves the introduction of automation into the medical device fabrication and assembly process. A number of benefits usually follow: repeatability, heightened quality and lower (and more predictable) long-term costs of operation.

However, many medical devices begin their life cycle below the high-volume threshold, sometimes with manual procedures. Successfully scaling to high-volume manufacturing requires foresight and planning to streamline the production process and minimize changes that could make your move to high-volume manufacturing more lengthy and expensive. Weigh these important considerations early in the product life cycle.

DESIGN FOR MANUFACTURING

Device design needs to encompass more than end-user specifications. It is essential that devices are designed to be manufactured efficiently over the entire product life cycle. That means taking into consideration the equipment and processes that will be required should a device be designated for high-volume manufacturing. After all, the automated, high-volume processes could be slightly or significantly different than the benchtop or prototype equipment used for producing lower volumes. Early discussion with the manufacturing team is critical to understand how high-speed automation may affect the design so provisions can be made to avoid problems when scaling up.

For example, in an effort to minimize the use of raw materials or provide a slimmer product profile, an engineer may design a product with a minimal flange. However, lengthening the flange to 1/8" can make a huge difference during an automated feeding process or providing a better gating system in the injection molding process. Changing the external geometry slightly may have no effect on the function of the product. However, the increased accuracy and efficiency of the manufacturing process enabled by the longer flange can lead to a more robust, more reliable operation that lowers defects and, in the end, more than offsets the extra material use.

DESIGN FOR RELIABILITY

While design for manufacturing involves engineering the device or component to take advantage of the capabilities (and account for the limitations) of an automated manufacturing process, design for reliability involves the design of the machine itself with the goal of maximizing volume by minimizing downtime. This is important when accounting not just for the project time and cost but the value of an asset over its life – and automated machinery is certainly an expensive asset. When designing equipment, assure that wear components are easily accessible on the machine for preventative maintenance. You don't want to have your maintenance team performing the machine equivalent of open heart surgery to replace a component that you know will wear. Identify wear components in advance and monitor them as they approach breakdown instead of running them to failure. Sometimes the design of the device or component will affect how quickly components will wear. Your data may show that the ideal solution is a more robust component that is designed to handle higher speeds, bigger loads or extended life. The initial cost will be offset through less downtime. Ultimately, high-volume manufacturing can only be achieved when the machines are running.

MATERIAL SELECTION

A crucial part of designing for manufacturing is ensuring the materials selected are acceptable for high-volume processes. Devices with injection-molded components are a perfect example. Lower cavitation might be more forgiving with a material such as a polycarbonate than a high-speed system producing components in a 96-cavity mold. Some materials that are suitable for manual assembly might be incompatible with automated processes like sonic welding or mechanized high-speed clamping. The solution: select materials that you've already qualified for manufacturing with different processes at various volumes. Otherwise you'll need to burn time and money adjusting and potentially updating regulatory applications.

Similarly, if your medical device is comprised of a number of components, use validated, off-the-shelf components rather than spending time and resources developing something new. It's likely that you can find existing components with a proven a track record in high-speed manufacturing or assembly, allowing you to reduce or eliminate design work that could delay your project.

SUPPLY CHAIN AND PROCUREMENT CONFIDENCE

Given the importance of material selection – and the obvious need for higher quantities of materials when producing higher volumes – it's important to work closely with strategic procurement to ensure that the suppliers selected at the outset of a device's product life cycle will be able to continue supplying with the same quality and reliability when volumes increase. Will the suppliers be able step up when you ask them? Do they have a long-term commitment to producing the material or component? Will they have the financial resources and management stability to continue supplying you once you invest in automated processes? The time, expense and uncertainty of qualifying a new supplier can cut into the cost efficiencies of a high-volume, automated process.

TEAM APPROACH TO OPTIMIZE EFFICIENCY

The move to high-volume manufacturing isn't a once-and-done event. There are many opportunities to continue learning and improving after the process has been established. That demands involving the entire team, from engineers to machine operators. Each brings a unique perspective. And with high-volume manufacturing, even a small improvement in cost or efficiency can be significant when extended over millions of pieces. An exhaustive "lessons learned" can prove fruitful when leveraging previous successes or avoiding previous failures. Drawing on past engineering concepts for new designs can be beneficial it terms of time, cost and resources.

The team approach should also incorporate suppliers critical to the capacity to upgrade to high-volume manufacturing, such as custom machine builders and mold manufacturers. The more they know about the long-term project expectations and objectives, the better they can supply equipment that will meet the design intent and match the product's intended life cycle.

For example, development and testing on prototype equipment may show promise in the lab but speeding up the same process introduces a new variable in manufacturing that can lead to devastating results. It is often advisable to spend more money up front to engineer products for prototyping on a production ready machine– even if it's a one-up process. The lessons the team will learn by producing something at full-speed won't need to be repeated when you want to scale to a 4-up, 8-up or 16-up piece of equipment now or in the future.

Overall, high-volume manufacturing requires a product life-cycle approach that looks beyond immediate needs and anticipates future demand. As with most product design projects, foresight and planning are paramount. Early design changes can be accommodated with little impact to cost and time. However, the later a change is made the more costly and time consuming it becomes.

After long-term volume parameters have been established to complement product specifications, the team can determine how to meet both short-term and long-term volumes – and have a road map to scale and realize the benefits of high-volume manufacturing.

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