Conquering the Big and Small Challenges of Micro-Manufacturing

By Raghu Vadlamudi
Chief Research and Technology Director

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Meeting the extremely tight tolerances of micro-sized components and features for critical medical devices requires absolute precision. It also requires having the experience to know what you don't know, so you can confidently try new approaches to meet the highly technical needs of creating parts that generally weigh less than one-tenth of a milligram and are 10 times smaller than a grain of table salt. That's because, as far as advanced micro-manufacturing technology has come, it still has ways to go.

For manufacturers interested in taking advantage of this evolving technology, a series of challenges must be overcome end to end and an integrated process must be implemented to consistently and repeatedly design, develop and produce micro-sized parts. Several key considerations for meeting these needs follow.

Raw materials and characteristics

With the pellet size of raw materials, controlling for variation becomes an issue for micro-manufacturing. A process needs to be implemented and followed that ensures the consistency of the pellets made and from one shift to the next. In addition, because materials behave differently at the micro-level, manufacturers need to exercise due diligence to characterize and evaluate materials and finished products to be sure they perform as desired. Accordingly, it becomes intrinsically critical to leverage scientific process principles, including design for manufacturability (DFM) and process validation methodologies, to understand how physical phenomena, such as static, force and stress, impact the materials being used to design and develop a given micro-sized part.

Equipment and technologies

Many manufacturers are well-versed in making the macro-sized devices and components – such as surgical device handles, medical device and programmer housings, and diagnostic equipment – that come readily to mind when you hear the term "medical device." However, you cannot simply scale down the macro-level equipment and technologies to make micro parts. In most cases, technology gaps will be present that require creative, knowledge-based problem-solving.

Experienced medical device manufacturers often can find solutions, such as by combining existing technologies to achieve the desired outcomes. For example, integrating lasers with conventional machine tools can help improve precision and productivity for a micro-sized part. Experienced manufacturers also will be aware of what's possible but remains out of reach until the existing ideally suited technology becomes more readily available commercially and budget-amenable.

The good news is, innovative equipment and technology is emerging and developing to meet the needs of micro-manufacturing. For example, in just the past few years, femtosecond lasers migrated from "if onlys" and "nice-to-haves" to "got-its" for cutting and drilling micro-sized parts and features for implantable devices, like cardiovascular and orthopedic stents. For another example, additive manufacturing (3D printing) is rapidly advancing for creating plastics and metal components or devices with micro features.

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Handling

Because of the difficulty in handling micro-sized components, the vision systems and handheld instruments commonly used in macro-manufacturing cannot be used for micro-manufacturing.

Micro grippers that are capable of sensing forces can be used to handle micro parts. In addition, electrostatic contactless handling, which depends on the materials' electrical charges to move the parts, is another effective way to handle micro-sized parts, but it is not yet a mainstream technology. Other handling methods need to be innovated.

Meanwhile, until handling methodologies advance further, product developers need to consider how to handle a micro-sized part or feature and incorporate those ideas into the initial design concept, which adds complexity and cost to the product program. Product developers are approaching this in a few ways, including creating a functional feature that makes the part easy to handle or creating an extra feature and figuring out how to either use it in the part or device or remove it later in the process.

Inspection and analytic methods

For macro parts and features, manual and automated inspection techniques using vision systems and handheld instruments are popular. When a component is micro-sized, however, these techniques are not suitable because of the difficulty in handling these parts. Surface characterization methods – e.g., atomic force microscopy (AFM), nanoindentation techniques and non-contact scanning methods – are needed for inspection at the micro size. Until those are readily commercially available, manufacturers are using CT scanners as a non-contact inspection method. This method uses computerized tomography to visualize, measure, and evaluate internal structures and porosity of micro parts and features.

Inspection and analysis

To best meet the price needs of micro-manufacturing, manufacturers need to deploy processes in which sensors are embedded in equipment and networked through computer systems to generate data that can be used to monitor, control and improve manufacturing processes. By using smart technologies, connected machines also can communicate with one another to automatically initiate processes to overcome handling challenges, and ultimately provide the consistency and repeatability critically needed for these lifesaving parts.

In addition, data analytics can be used to improve the process. For example, data history can be analyzed to determine process interdependencies among variables, identifying which parameters have the greatest impact on variability, yield or other characteristics of interest.

Collected data also can be used to inform future product development efforts and business decisions.

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Furthermore, micro-manufacturing is very sensitive to environmental changes, such as pressure, temperature, and humidity – a temperature shift of even two degrees can cause a change in the dimensions of a micro part. This being the case, manufacturers must contain and control the environment, using sensors to monitor for out-of-range conditions, enable machine-to-machine communication and automate necessary environmental adjustments.

Robotic and human resources

Manufacturers need the right mix of resources for micro-manufacturing, which may require significant investments in capital and operating expenses. First, to meet the tiny specifications and requirements, micro-sized parts and features generally require robust automated, lights-out manufacturing capabilities to perform virtually all of the production steps with the necessary level of precision and consistency.

In addition, the medical device industry is highly regulated and has numerous, often complex, regulations and international standards that must be followed for automated systems in manufacturing applications. Proper installation and operational and performance qualification, including process validation of automation systems, are musts for micro-manufacturing, just as they are for macro-manufacturing. These require compliance experts.

Highly skilled human resources also are needed to properly oversee the sophisticated management software and use a data-based approach to monitor processes for consistency. So are skilled workers who can perform routine maintenance and repairs on the advanced technologies.

Considering the ongoing labor shortage in the industry as a whole, manufacturers interested in micro-manufacturing must find ways to attract, train and retain skilled personnel.

Process integration

Most importantly, manufacturers need to understand how all the above can work together to realize a robust micro-manufacturing process integration model. In this model, all processes are integrated using sensors, data and analytics, everything is handled, programmed, sensed, monitored, controlled and inspected within one system.

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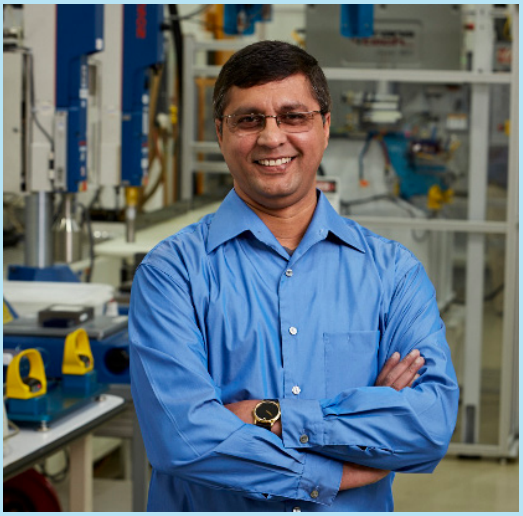

About the author

Raghu Vadlamudi is our Chief Research and Technology Director. He has more than 25 years of experience in the medical device manufacturing industry managing process development groups, directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Raghu is an ASQ certified Medical Device Auditor, Certified Metal Cutting Professional, Certified Medical Device Compliance Professional, and a Certified Process Validation Professional.

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