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Data Driven Process Development in Medical Device Manufacturing— A Medtech Makers Q&A

Data can be a valuable tool to help ensure accuracy in manufacturing of components for medical devices.

By Sean Fenske - Editor-in-Chief

The use of data has been growing in the medical device and healthcare sectors. More data can lead to better leveraging of artificial intelligence to help with care aspects from diagnostics to surgery. Knowing what data is useful, however, is critically important. Too much data can overwhelm doctors and nurses, while an overflow of data from apps can intimidate patients.

The same is true of the medical device manufacturing process. Data can be an invaluable asset in fabrication processes such as molding and machining to ensure quality and monitor equipment status. It's important for engineers to collect and use the correct data though.

In the following Q&A, Raghu Vadlamudi, chief research and technology director at Donatelle, offers insights on how manufacturers can use data acquired from their manufacturing processes to ensure accuracy and eliminate errors. They can also use it to ensure machine uptime is kept to a maximum and unexpected equipment stoppages are significantly reduced.

Sean Fenske: Why is it useful to collect data during the manufacturing of medical devices?

Raghu Vadlamudi: The most common method to monitor

manufacturing processes of medical devices is to inspect the product and ensure it meets requirements. Collecting product inspection data helps to avoid shipping bad product, but it increases product costs. Collecting and monitoring manufacturing process data helps identify trends that occur over time due to variation in materials, set-up, and wear and tear of the equipment (which are inherent to the process), as well as troubleshooting if variations occur.

Fenske: How is the data captured?

Vadlamudi: Data is typically captured by using the pressure and temperature sensors, along with force sensors. Recent advances in technology facilitated the use of ultrasonic transducers and accelerometers. In addition to instrumenting the tools and equipment with sensors, data acquisition systems are needed to capture the signal and condition, and then present the data in a useful format that's helpful in decision making. The sensors send the data in the form of electrical signals to the data acquisition systems, and the signals are converted into a format that can be read and interpreted.

Fenske: How can the data collected be used to alter and

improve manufacturing processes?

Vadlamudi: Usually, the process data is collected and reviewed during the characterization of the process. This data can be used to identify the limits of the process that can produce conforming products. Once the limits are identified, the data collected during the performance qualification runs can be shown as evidence the process was run within the acceptable limits. The data collected during the subsequent production runs show evidence the validation state is maintained over time.

Fenske: Can the data be used to ensure quality rather than through an inspection method?

Vadlamudi: Manufacturers in the medical device industry need to be compliant with the FDA's Quality System Regulation (QSR). Per QSR, special processes such as injection molding and any automated processes need to be validated prior to the start of production runs. During the validation, process parameters are collected and can be used to accept or reject based on whether the process parameters are within the acceptable limits or not.

Fenske: Does the data collected have value in an FDA submission or some other use outside of the manufacturing process?

Vadlamudi: Depending on the manufacturing process, the process data collected during process validation activities can be used to convince regulators the device manufacturing has been done per QSR. The data collected can also be used to train personnel in identifying the trends and to troubleshoot. Additionally, the data can be used to implement preventative measures to guard against equipment failures.

Fenske: Can you share any real-world examples of this type of data collection and what the benefits of its use were?

Vadlamudi: Process data is widely collected in manufacturing processes such as injection molding and metal machining. Plastic melt temperature, mold temperatures, and cavity pressures are some of the important process parameters collected and monitored during the injection molding process. Monitoring and maintaining these parameters within the acceptable limits during production will render the manufacturing process capable. Similarly, spindle power consumption in the machining process provides valuable information in maintaining the process stability.

Fenske: Do you have any additional comments you'd like to share based on any of the topics we discussed or something you'd like to tell medical device manufacturers?

Vadlamudi: Medical device manufacturers should take advantage of the advent of the Internet of things to gain better understanding of the process and also maintain the validation state of their manufacturing processes.