7 Critical Factors for Predictable Quality in Medical Device Manufacturing

By Matt Knutson
Vice President of Manufacturing Operations

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In their mission to create innovative products that enhance and save lives, medical device manufacturers today are challenged with several opposing priorities, including:

- As products must be safe, reliable and accurate, regulatory approval requires adhering to stringent standards and implementing proven processes to adhere to stringent standards.
- Stakeholders are pushing for lower costs and better value.
- A crowded market adds more cost pressure and requires speed.

From a business standpoint, noncompliance can result in costly approval and product launch delays, customer returns, potential field corrective actions or recalls, reputational damage, and worse.

Predictable quality is essential – and requires a very high level of diverse engineering expertise, electronic integration of quality and business systems, and proven experience in the medical device sector.

Predictable quality does not happen by accident or luck. It comes from a culture, knowledge, experience, and track record of performance to produce products and provide services that meet requirements.

Here are seven critical elements for achieving predictable quality:

1. Meeting established standards

Medical device manufacturers must follow Good Manufacturing Practices (GMP), and comply with the International Standards Organization ISO 13485 Medical Device Standard, which establishes requirements for a quality management system specific to the medical devices industry. They also will be able to demonstrate their compliance history and have a comprehensive internal auditing process.

In addition, keep in mind, contract medical device manufacturers undergo audits by customers and regulatory authorities, such as ISO, the U.S. Food and Drug Administration (FDA) and other Notified Bodies. When working with one, ask about the results of such audits and any proactive or required actions taken as a result.

2. Mitigating risk through design for manufacturability

Design for manufacturability (DFM) is one of the most important elements in designing, developing and manufacturing a new product at scale and one of the most important risk mitigation processes. Through comparative analysis of product characteristics, DFM helps developers engineer out potential issues, align product requirements with manufacturing capabilities, and ultimately optimize a product for repeatability and consistency in serial production. A strong DFM process considers the materials used, requested tolerances, part geometry, process control limitations, etc., throughout the design and development process.

3. Objectively validating processes for quality

Process validation is essential, as it ensures medical devices are manufactured to produce the outcome for which they are designed and intended to serve. To reach this end goal, manufacturers must have adequate skilled resources in the necessary disciplines to design, develop, qualify and release to production a robust process meeting all requirements. Typically, a strong project team includes engineers with diverse backgrounds in mechanical, manufacturing, chemical, process, and quality engineering. For automated processes, software validation practices help ensure the data being generated is valid for your submissions and lot acceptance purposes.

4. Monitoring controlled environments

Manufacturing medical devices in controlled environments is a critical element within a Quality Management System. Monitoring programs for particulate, surface and airborne bioburden should be reviewed and documented regularly, not just done annually during certification time. In addition, clean room personnel should follow best-practice gowning procedures when exiting and entering the cleanrooms.

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5. Strategies for sampling plans and process controls

A one-size-fits-all quality management process will not work for medical devices and components. Sampling plans need to be based on a valid statistical rationale. Production monitoring levels should be based on the performance observed during process validation at the limits of the qualified process, and should continue to perform at the observed levels during qualification. Process control plans/inspections should be part-specific, and dimensional outputs need to meet key capability requirements. Critical processes should be monitored using an integrated approach where the process inputs and outputs can easily be correlated, so if issues arise, rapid root-cause analysis and correction/corrective action can be taken.

6. Accurately storing data and records

Using rigorous inspection equipment and inspection software validation processes, critical activity data and records should be kept accurately and electronically – including so they can be easily and reliably queried, filtered and exported to support a regulatory inspection or unannounced audit.

Furthermore, most companies understand complete and accurate device history records (DHRs) are necessary to ensure compliance and all device master record (DMR) requirements have been satisfactorily met. However, sub-components used in the finished assemblies must also be methodically reviewed to ensure no issues will be detected, whether early in the production process or downstream after they have been consumed into medical devices. A thorough component history record (CHR) review process is essential to prevent such unpleasant surprises. Too often the sub-components don't garner the same attention as the finished device, despite the sub-components' criticality.

Importantly, understanding that regulators expect records within minutes, manufacturing records should be electronic for real-time and fast access, because your state of compliance could depend on it.

7. Properly managing suppliers

Regulatory attention is increasingly focused on ensuring sufficient supplier controls throughout the supply chain. Strong suppliers employ a risk-based approach to supplier classification, qualification and ongoing monitoring processes. How well they manage their supplier base is a good indication of their overall maturity. Look for contractors that have taken the necessary deep dive into supplier capabilities and potential risks to your supply chain.

In addition, the supplier should be able to provide you with the documentation package that allows you to confidently go dock-to-stock on your finished medical device. This includes creating a customizable Certificate of Compliance (CofC) to suit your company's specific requirements, as well as using a validated, system-generated CofC with the ability to integrate supplied data tables, data summary documents, and/or raw data.

With a robust quality management system, you can shorten your time to market, your business risk and ultimately reduce the risk to patients. When work is done with predictable quality, the following is true:

- Timelines are met
- Quality targets are met
- Systems are structured to meet or exceed requirements
- Compliance history is solid
- Enterprise resource planning system is a fully integrated electronic system

By doing your homework upfront, you can avoid painful and costly compliance issues and earn big dividends in the long run.

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About the author

Matt Knutson is vice president of manufacturing operations, where he is responsible for production, manufacturing engineering and automation, quality, maintenance and facilities. He has held various positions in the custom injection molding and medical contract manufacturing industries over the last 25 years, including manufacturing engineering, quality management, and executive management.

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