Dynamic Blog

The Critical Role of a Medical Device Quality Management System

Designing and manufacturing are two distinct stages in the production process. In an ideal world, they would align perfectly; unfortunately, that isn't always the case. Having a medical device quality management system (QMS) is critical to ensure that what you're manufacturing meets the standards outlined in your design. Two essential components of a good QMS are quality assurance and quality control. Let's dig into each of these.

What Is a Medical Device Quality Management System?

To put it simply, a medical device QMS is a structured system of procedures that governs all aspects of the manufacturing process. QMS key stages include design, supplier management, complaint handling, documenting clinical data, product labeling, and risk management. A good QMS is a thorough QMS, and it touches everything.

Although a QMS is infinitely customizable, medical device manufacturers have a rather detailed set of instructions to help them get started. If a device is manufactured or sold in the United States, it must meet the US FDA's Quality System Regulation (QSR) requirements, which is also known by its US regulation number (21 CFR Part 820). Devices manufactured or sold in Canada, Europe, Japan, Australia, and other international markets align with the ISO 13485 standards. Fortunately, these two sets of requirements are very similar.

Since the QSR and ISO 13485 govern device quality, these standards should form the basis for your quality management system. Additionally, consider whether your customers have additional requirements; choose the highest standard at any given point and align your processes with it.

What Is the Difference Between Quality Assurance and Quality Control?

Each stage in a QMS can be classified as part of either quality assurance or quality control, and sometimes both. The differences between these two terms are similar to the contrast between product design and the manufacturing process.

Quality assurance procedures assure someone that quality is being achieved. This can meet internal requirements, demonstrating to each level of management that design standards are being achieved. Frequently, these are designed to satisfy external parties, such as customers, regulators, certifiers, government agencies, and other third parties. Documentation is generally a QA procedure, and the quality standards you aim for are determined by both your internal standards and external requirements.

Quality control procedures are those steps that are used to control the quality of a manufacturing process. If quality assurance is similar to the design process, where plans, documentation, and approval happens, quality control is similar to manufacturing: the actual steps taken to create the device. QA identifies the standard that needs to be met and outlines how you will internally measure those requirements; QC is the steps taken to measure and evaluate devices against those standards.

How to Enable the Best Medical Device QMS Outcomes

You likely already have manufacturing and inspection systems in place, so start there. Map out each step in the process and identify the ending point—what marks the device as ready to move on from that stage? It's commonly a particular manufacturing milestone (e.g., a component was added, a part was molded) but could also include internal documentation.

Simultaneously, dig into the FDA's QSR (21 CFR Part 820) and ISO 13485 to identify all of the compliance and documentation standards you need to meet. Once your industrial process is mapped, go through the QSR/ISO compliance checklist you just created and find where it makes the most sense for each standard to be evaluated and documented. It's much easier to integrate these steps into a process than going back and trying to accomplish everything at the end.

Start a trial period and pay close attention to how your new system is working. Expect efficiency to dip in the short-term; anytime you change processes in a tightly controlled manufacturing system, it will take a while to adjust. You'll also see areas where your new approach should be adapted: perhaps one QSR document should be moved to a different step, or another individual should be responsible for generating those records. Don't be afraid to adjust here.

Finally, establish a solid audit process to ensure that all QSR requirements are being met consistently and the documentation you're producing aligns with what the FDA needs to approve your device. Part of this should include a regular review of the steps outlined above: have the standards changed, and if so, how does your process need to adjust? Continually look for new ways to improve.

Having an established, thorough QMS not only ensures quality, it also decreases costs and increases efficiency in the long run.

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