



9 ways to improve quality in medical device product development

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Medical device product developers and manufacturers are constantly under scrutiny by regulatory organizations.

If your goal is producing viable products, you need to make sure you're complying with a number of requirements. While it may seem daunting to comply with standards and regulatory bodies like the FDA, ISO, and IEC, these requirements play a critical role in ensuring the highest and strictest standards when it comes to life-saving products.

Ultimately, these regulations seek to achieve and maintain quality. The underlying element of all activity during the development, production, manufacturing, delivery and ongoing support of medical devices is that the product adheres to quality guidelines.

That way, devices you create will deliver on their promises to healthcare providers and patients.

The Qualio quality team has assembled 9 top tips, based on our extensive experience with medical device manufacturers, to help you chart a robust and quality-centric pathway to market.



Kelly Stanton

Director of Quality, Qualio

Why quality management matters

While quality is critical when it comes to bringing medical devices to market, many developers don't always recognize the importance of building quality workflows into the processes that product creation and delivery require.

Quality management is a set of practices designed to make sure that products are developed, produced, delivered, and maintained without harming people or the environment. These activities involve identifying risks related to poor quality (whether they arise from product design, production, or distribution), developing methods for measuring those risks, deciding how those risks can be managed effectively, and systematically reducing them where possible.

Quality management gives companies the opportunity to develop methods of minimizing risks, such as focusing on design and production processes or evaluating distribution chains. By implementing quality guidelines in all phases throughout development, testing, validation, and post-market surveillance, you can provide customers with products they can trust, every time.

RESOURCES

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Common issues for medical device products

The last thing any company wants to hear is that their product poses a risk. By addressing issues upfront before more serious problems arise, you can develop methods for measuring risks, deciding how those risks can be managed effectively, and systematically reducing them where possible.

Typically, a product is unable to pass regulatory oversight because of one or more of these issues:

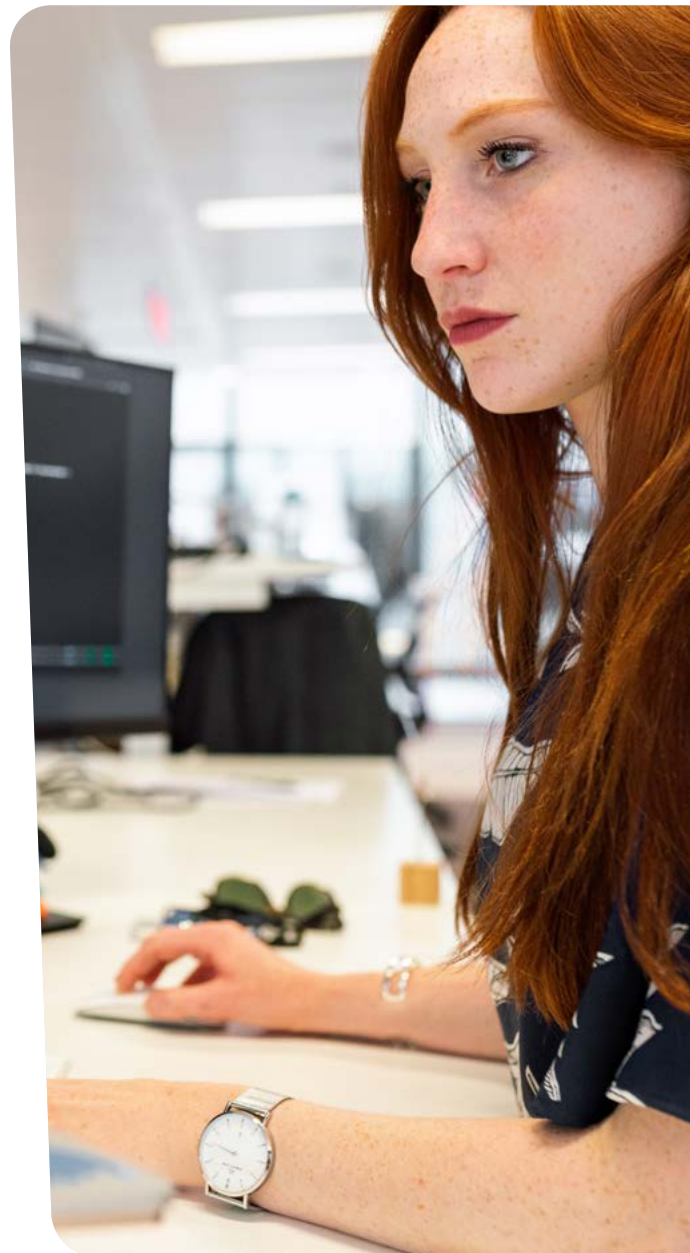
- Product development procedures have not been established correctly.
- Product development procedures, once established, have not been maintained.
- Records are not kept adequately and/or do not furnish enough data about product quality.
- There is a lack of design control management.
- Quality audits have not been established or are not carried out.
- There is not an effective corrective and preventive action (CAPA) process.
- Product controls are not firmly established and/or not followed.
- Compliance with regulatory requirements is not verifiable, stored, or validated.



Why you need a quality management system

Successful medical device companies have one major thing in common: They use an effective quality management system (QMS) that allows them to catalog, review, and act upon every aspect of the product life-cycle. A QMS generates quality reports, helps with compliance, and allows for easier management of design control. Using a QMS allows you to focus on your core competencies. It also provides you with a complete, quality-driven way to measure the success of your product.

The QMS is a comprehensive collection of processes designed to ensure that product quality remains at or above desired levels for customers. With a robust QMS in place, you can improve your medical device product development in the following nine areas — much to the delight of regulators, patients, shareholders, and other investors.



9 ways to improve quality

1. Review process

It might sound fairly basic. But medical device manufacturers need to have a single review process that drives all product activity.

The review process is a company's most important quality measure. It should take into account all aspects of product development and delivery and ensure that requirements are established and met prior to allowing a product to move forward.

At the core is the issue of quality. Sign-offs are not nearly as important as the need to define and adhere to creating a quality product. Quality assurance needs to be checked and validated at each step in the process.

The results of the review process need to be documented to serve as the reference point for how quality decisions are made within the organization. These documents should not only describe what happens during the review process, but also explain why it happened. It won't be too helpful if you just jot down a checklist of tasks with no explanation about why they were done or what was found during each activity.

One thing to keep in mind: this document should be easy for anyone at your company to understand and use. That way, they can make decisions based on quality principles instead of simply checking boxes.

2. Program requirements

Medical device manufacturers need to understand and define the critical steps in product development.

This includes all activities from the defining of a requirement through validation, including reviews for each step. In some cases, additional review programs are needed to track particular aspects of design or production. Standardization is key here; without it, there will always be questions.

Program requirements often change due to the evolving needs of manufacturers and regulatory bodies. These changes can include new requirements that must be met or revisions that need to be made in order to maintain compliance with current standards. As such, it's important for all parties involved in a program — engineers, managers, quality assurance personnel — to stay abreast of these changes.

3. Quality checkpoints

It is not enough to simply have a process. You also need to implement the necessary checks and balances.

Quality points should be identified in your QMS and then implemented as per checkpoint protocol: design review, prototype validation, or verification of requirements fulfillment, for example. This will ensure important steps that may get overlooked are being completed.

Consider validating your process to ensure it is working as intended and meeting standards. Validation could be in the form of tests, inspection, or verification testing. Either way, it will give you feedback on how well your processes are operating and allow for adjustments if needed.

4. Audit procedures

While establishing audit procedures is a good starting point, it isn't quite enough. The more important part of this step is using the audit process as a way to identify where quality is not being met and rectify it immediately. This alone can help medical device manufacturers speed the process of bringing their products to market faster.

In our experience, there is a direct correlation between the time quality issues are detected and the speed at which a product passes regulatory scrutiny and is brought to market. The quicker you can detect and address a quality issue, the better for your company.

5. Feedback loops

Quality is not a goal. It's a guiding north star that is never fully achieved.

Every action in the product life cycle requires a new review to ensure the appropriate level of quality is maintained. One of the best ways to make certain that a quality issue has been caught as early as possible is to create an environment where employees feel comfortable reporting any mistakes or anomalies they find in their work product. The longer the feedback loop, the more opportunities for delays and potential problems. If you've got slow-moving feedback loops, it's time to adjust your quality processes and find ways to tighten them.

A QMS can help your team establish and adhere to a regular loop of feedback among stakeholders and decision-makers. This allows for fast action and enables you to quickly address problems that might otherwise impede product development. Feedback loops in your QMS should include discussions about process improvement and should not be limited to information sharing alone.

"Quality is not a goal. It's a guiding north star that is never fully achieved."

— **Kelly Stanton**

Director of Quality

6. Content management

Standards bodies and regulatory agencies will want to review everything related to product development. If any documentation is missing — or perceived as missing because it is poorly organized — it will raise a red flag that could cause an unnecessary delay of development.

Content management best practices

- Organize the data by type and use structure to make it easy for everyone involved in product development or compliance workflows to find what they need when they need it.
- At minimum, you should have these content types: standards and regulatory documents; quality system documentation, including SOPs; work instructions; and other documents.
- Make sure all related items are stored in the same location so the people who need them can find them easily. Create an inventory of what you have to help meet this goal. Content managers will also want to think about organizing content from a functional perspective. This would make it easier to find content that relates to specific aspects of your business.
- Distribute content regularly so people can work with the most up-to-date information.

A key component of your QMS should be content management. This includes storing data and documents, identifying where they are stored for future reference or audits, and organizing content to make it easy to find the right items when needed.

Simply put, content management should be a core part of your QMS — not an afterthought.

7. Corrective action

CAPAs are meant to alleviate poorly designed processes and rectify issues before they completely derail projects. However, too often the items being corrected are not tracked. The most common reason corrective actions are not taken is because they were forgotten or ignored, and there wasn't any documentation to remind management of the issue.

CAPAs are meant to alleviate poorly designed processes and rectify issues before they completely derail projects. However, too often the items being corrected are not tracked. A common reason corrective actions are not taken is because they were forgotten or ignored, and there was no documentation to remind management of the issue. Documenting your CAPA helps you track how quickly you're resolving these issues as well as show other departments in your company that you're taking these issues seriously.

When startups and small organizations who are working toward market approval are evaluating QMS systems, CAPA isn't always prioritized. Since your organization doesn't have an active need for CAPA, you may simply choose to verify that a QMS offers that capability and focus on modules which meet your current use cases. However, data on the most frequent causes of FDA warning letters tells another story.

Your organization can avoid regulatory risk and derive business value from your CAPA system by selecting a robust solution that's fully integrated with your QMS suite. When CAPA processes are automated and linked to surrounding quality systems, you can avoid regulatory risk and take a proactive approach to root cause analysis and preventive/corrective actions.

8. Training management

Training is a critical piece of the medical device product process. Maintaining a unified understanding of the training process and ensuring that everyone on your team understands how it fits in with their day-to-day responsibilities is critical to improving quality.

How can you prioritize training in your culture?

- View training as an ongoing process that's based on the needs of your team and company culture, not something done once or twice per year.
- Educate your leadership team about the importance of training.
- Set measurable goals for training and then measure how well you're meeting those goals.

In many ways, training is all about getting all players on the same page, and a QMS acts as a collaboration and communication tool to help make sure that happens.

9. Reporting & submission

Reporting and submitting quality data can be a time-consuming task.

Developing the right reporting mechanisms helps ensure that teams report quality metrics in an efficient way and on time, so they're not forgotten or overlooked.

A QMS maintains a continuous record of all actions around the medical device product development. When you're required to communicate with the FDA or ISO, it can help to pull necessary data and deliver it for review.

What's more, a QMS helps you manage internal quality audits and other regulatory processes so they're done in a timely manner, with no errors or omissions. That way, your company can identify the right data to report and submit while being confident that it's accurate and compliant.

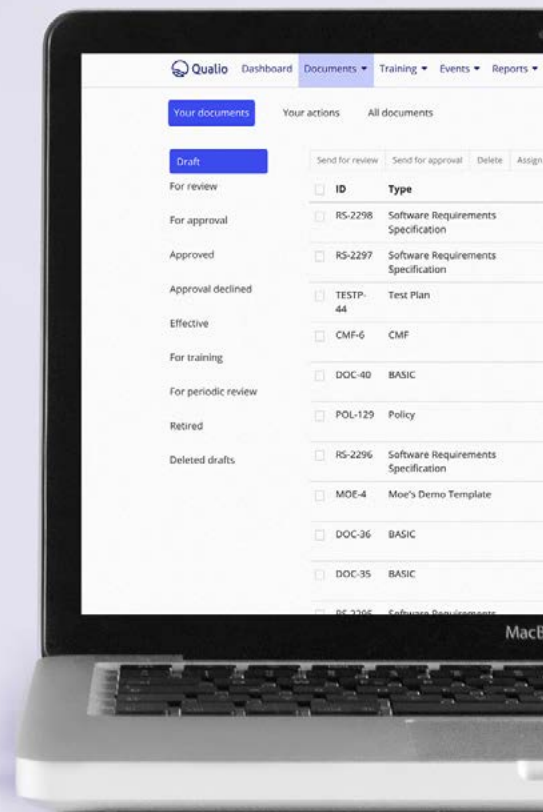


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