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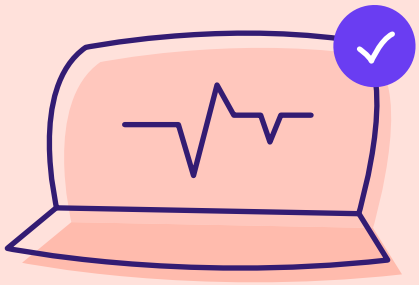

Design controls for medical device companies:

6 principles for success

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Designing a new medical device is an exhilarating experience. But if you get caught up in the excitement and fail to properly document your steps, major headaches could be on the horizon.
The Food and Drug Administration's (FDA) Center for Devices and Radiological Health issued more warning letters in the first eight months of 2021 than in all of 2020. Quality concerns impacted 43.6 million medical device units or 71.8% of recalled units in the first quarter of 2021, according to a U.S. product recall index report.
Suffice it to say that warning letters and recalls are outcomes medical device or software as a medical device (SaMD) companies need to avoid — which is precisely where adhering to regulatory design controls from the outset saves the day.

Kelly Stanton
Director of Quality, Qualio

What are design controls?

Since 1990, the FDA has required manufacturers of all class II and class III devices, and certain class I devices, to enact design controls, which represent a systematic approach to managing the end-to-end design of medical devices and SaMD solutions. Design controls are a set of procedures used to ensure that the design, development and production processes for medical devices meet regulatory requirements.

Organizations use these controls to ensure their design processes ultimately deliver products that work as intended and meet specific user needs in a compliant manner — and that design inputs and outputs are appropriate, with associated procedures thoroughly documented.

In the world of medical devices and SaMD solutions, design controls help organizations accomplish five critical objectives:

1. Delivering quality products
2. Ensuring user safety
3. Maintaining regulatory compliance
4. Keeping costs down
5. Accelerating time to market

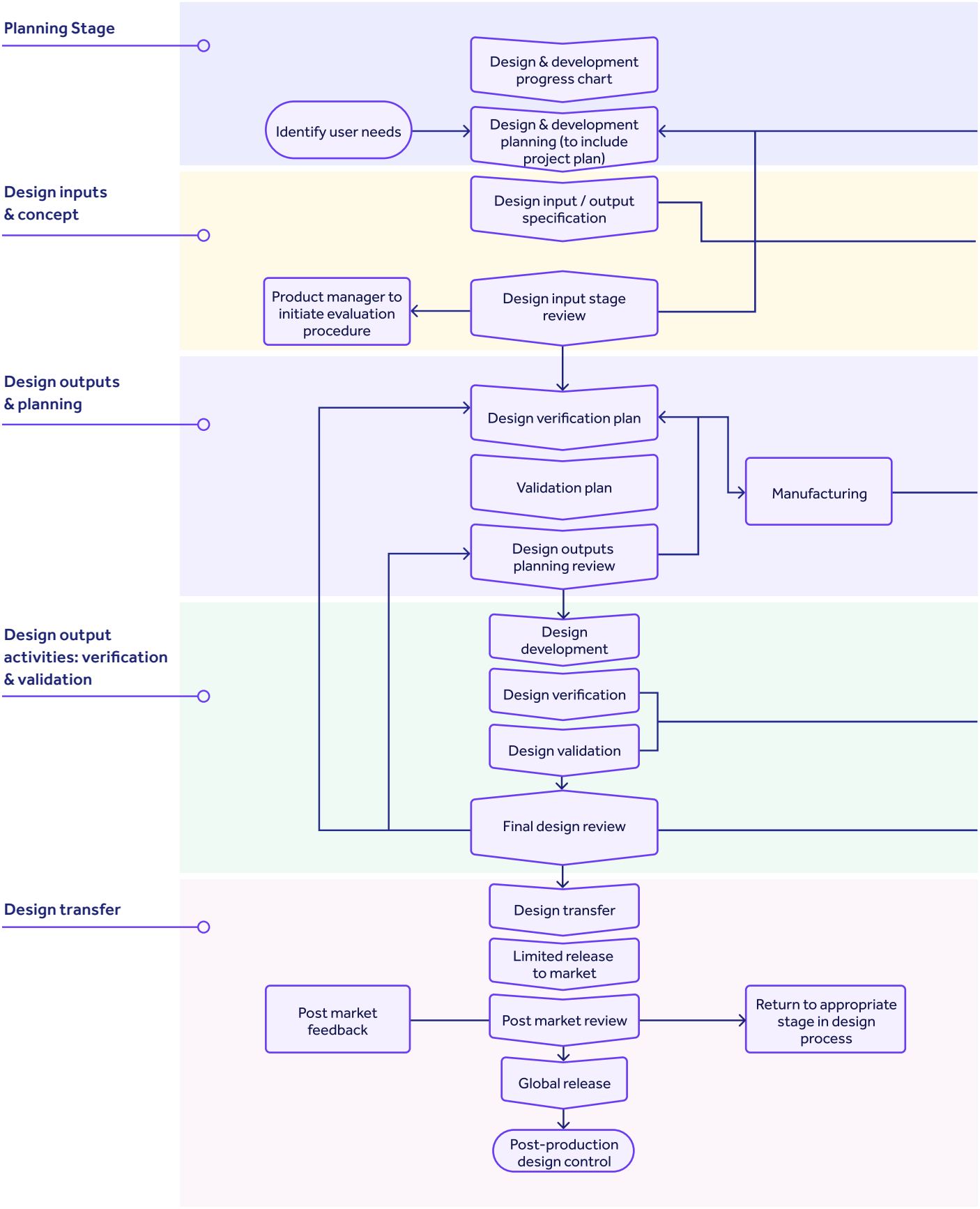
Medical device and SaMD organizations want to bring high-quality, compliant products to market quickly and cost-effectively, and design controls help ensure that happens.

› 21 CFR 820.30 Subpart C

› FDA Design Control Guidance for Medical Device Manufacturers

› FDA Design Control Decision Flow Chart

Medical device design and development pathway



In some cases, design controls might feel like a burden or an unnecessary hassle — particularly when they involve a ton of manual work and intervention.

Either way, these controls have a positive impact on your business. And you also benefit from improving documentation, which enables you to maintain a clear view of each stage of the design process. As an added bonus, this also makes the inevitable audit easier.

Getting the most out of design controls

Successfully developing a new medical device starts with establishing a quality system. This system outlines specific processes and procedures your organization will follow throughout the product development lifecycle.

Design controls are a vital part of the quality system that you create, implement, and manage. To kickstart your own medical device development process and get the outcomes you're aiming for, follow these six best practices.

1. Don't wait to start design control

The first question many companies have is: when do design controls start? Regulation doesn't explicitly name when design controls are required to begin. However, the FDA provides the following direction:

Design controls: When to start?

- Where research ends and design begins
- After Feasibility/"Proof of Concept"
- When you plan to bring your device to market
- Prior to start of any Investigation Device Exemption (21 CFR 812)
- Premarket Mechanism of change/ revision

> *The general principle is to start design controls after feasibility and when you've decided to commercialize the product.*

Some may argue that starting design controls early will subject their product to greater regulatory burden and cost, but that's not the case. The reality is that for many companies, starting design controls sooner rather than later can actually save money and time down the road.

Design controls are not vastly more burdensome than following sound engineering practices. A process with well-defined stakeholders, responsibilities and goals is a far better experience for teams than a disjointed approach, regardless of the stage of the product.

Understanding design controls means embracing the discipline needed to successfully develop a compliant medical device or SaMD solution. Beginning design controls early should be driven by the company's goals to develop a safe and successful product rather than regulatory pressure. The mindset you exhibit toward implementing design controls is just as important as following the regulatory guidance.

2. Master traceability

A traceability matrix gives you the big-picture view of product development from start to finish. It's typical for traceability tasks to take hundreds of hours per project each year. Referring back to your traceability matrix will help you see how far any particular part has been through its life cycle, as well as identify gaps in documentation or actions for regulatory compliance.

While teams can use Google Docs and Excel to track product development, they quickly find out just how cumbersome and time-consuming the task becomes when using these tools.

On the flipside, purpose-built electronic quality management software (eQMS) solutions make traceability tracking a breeze. Using software that was created specifically to meet the unique needs of a medical device company makes this process easier, saving time and keeping you organized.

With the right platform in place, you'll be able to see every step of the product development lifecycle via fully integrated, closed-loop quality processes. Prioritize tools that make it simple to keep all your key stakeholders informed of every action taken on your project, automatically.

3. Maintain flexibility

Flexibility is an essential part of the design process. You're likely to make changes throughout the product development lifecycle in order for your product to be successful. At the same time, you'll also need to be able to adapt to changes quickly without too much hassle.

Whenever any changes occur, teams need to track them in their documentation. Failure to do so leads to mistakes that could result in costly recalls or FDA audits. After all, the last thing you want is to let bad ideas slip into your final design because you didn't take the time to document your progress along the way.

A secure, cloud-based eQMS platform lets you make changes to documents in real time so that you can maintain flexibility.

Your chosen tool should enable you to create, review, and approve documents effortlessly. Look for solutions that offer built-in templates to create documents much faster, bringing even more efficiency to the process.

4. Manage risk

Risk management should be incorporated into your medical device development processes from the beginning. Make sure you review ISO 14971 carefully to ensure that your tactics comply with the guidelines.

Design controls should be integrated with risk management, and you'll need to demonstrate that your medical device is safe for use. To ensure compliance, your design needs to address the needs of its users, meet or exceed performance criteria and applicable standards, and meet requirements around design inputs and outputs.

As you begin searching for an eQMS system, you need to make sure it has a few key features designed to help you stay compliant. Qualio helps you build better products and keeps your business running smoothly by helping you maintain ISO 14971 compliance while managing the enormous volume of associated information.

5. Review meticulously

Design reviews are a crucial part of the development process of your medical device or SaMD solution. On a periodic basis, you need to bring the whole team together to review the progress that has been made to date and see what's working and what could be improved.

Generally, your team needs to review and agree to all the different aspects of your project, including:

- **User needs –** how patients are going to use your medical device and what problems it will solve for them
- **Design inputs –** the action plan you come up with to meet the needs of patients who use your device
- **Design outputs –** all of the device components, material requirements, testing protocols, and inspection procedures needed to manufacture your device
- **Design verification –** proof that your device does what it's supposed to do
- **Design transfer –** the device specifications must be transferred to manufacturing

Design reviews should take place after user needs have been drafted, design inputs and outputs are established, and

the design has passed the verification process — all before going into production.

6. Mark progress proactively

Don't wait too long to document your progress.

> *If your goal is bringing transformative medical devices and SaMD solutions to market, you can't afford to get caught in the trap of procrastination that forces you to play catch-up with design controls.*
> **Kelly Stanton, Director of Quality, Qualio**

You might think it'll be okay to come back and do it later after the work is completed. But how likely are you to actually do that? On the off chance that you do come back to it later, how likely are you to remember every facet of the project? And what happens if you forget altogether?

By maintaining meticulous records and improving the overall quality of your finished product by tracking what works and what doesn't, you can avoid this fate. There's also added value in being proactive in your efforts to document along the way. You're more likely to discover issues sooner and this will save you money and time to launch.

Master design controls for your medical devices and SaMD solutions

Documentation sits at the core of effective quality management. As a medical device or SaMD manufacturer, you need to carefully and thoroughly document quality by creating a quality manual, quality strategy, quality management plan, standard operating procedures, and detailed records of all quality activities.

Qualio's eQMS is the best cloud-based quality management solution for medical device manufacturers. Our software offers unparalleled document management capabilities for fast-growing life science organizations and was built specifically in accordance with CFR 820 and ISO 13485.

With Qualio, quality managers get a single source of truth for all product data, with full traceability across systems and automated output documentation. With less friction between themselves and quality, product development teams can accelerate their efforts and bring products to market even faster.

At the end of the day, designers and engineers want the right tool for the job. While software development teams might

use Jira or Azure DevOps, teams building hardware devices might prefer a solution like Qualio Docs that better fits their needs.

Either way, Qualio connects to the systems these groups use every day via integrations and automatically collates key design elements. This ensures they're following best practices and complying with relevant regulations, saving considerable time and frustration. As a result, engineering teams can work with quality teams efficiently, without creating extra overhead.

Plus, Qualio's new Design Controls dashboard enables users to see what's new, what's changed, and what's in review at a glance — making it that much easier to achieve compliance. Teams can also review design elements in batches or as part of a design review or change control, all in a single click.

› Download our Design controls management datasheet

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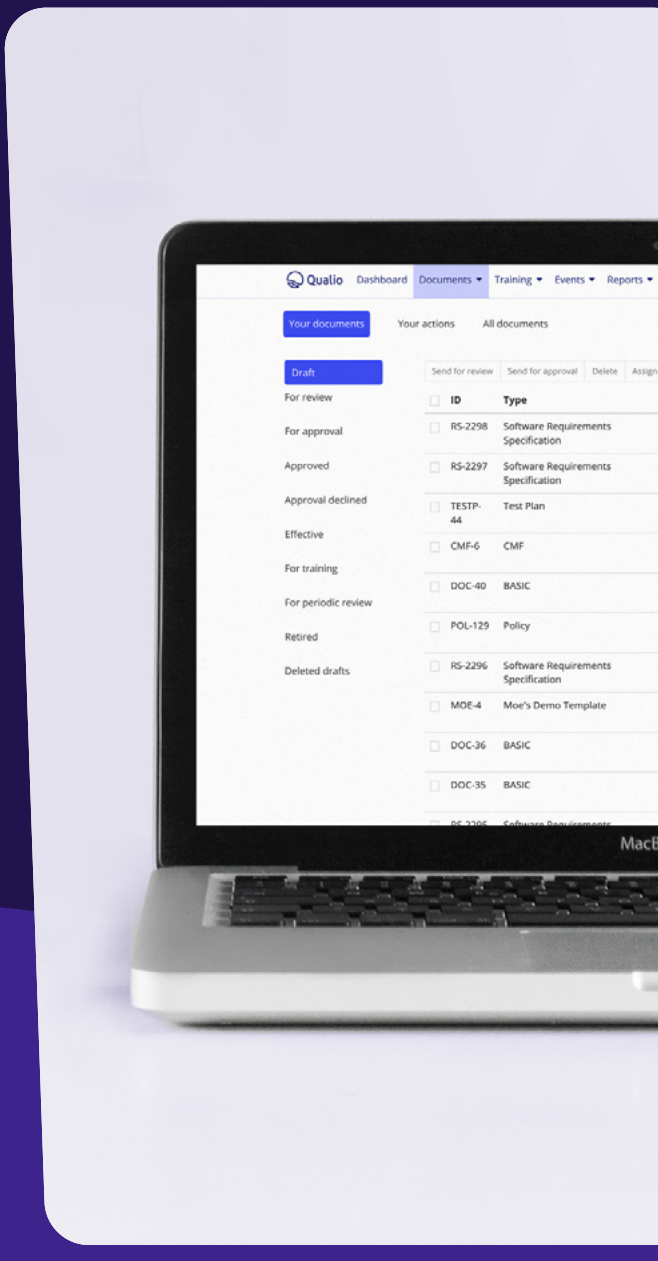
See Qualio in action

Qualio is the highest rated eQMS on the market and ranked as the easiest to use. Want to learn why leading life sciences companies rely on Qualio for a quality-centric route to market?

Request a demo today



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