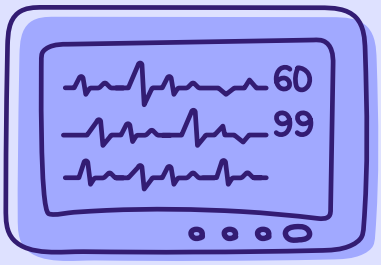
Qualio



How to prepare for ISO 13485 certification

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Have you spent countless stressful hours preparing for ISO 13485 certification?

Feeling daunted by the process?

Don't worry. You aren't alone.

ISO 13485 is the internationally recognized quality management benchmark for medical device manufacturers.

Certification guarantees the trust of your regulators, stakeholders and future customers while quickening your route to market.

There's no denying that it's a complex process which needs to be done right.

But with some expert guidance and the right toolset, there's absolutely no reason your company can't unlock and embed lasting ISO 13485 compliance.

The Qualio quality team has assembled this certification guide to help you.

From top tips and busting myths to 9 key steps and typical mistakes to avoid, this guide contains everything your team needs to kickstart and complete a successful ISO 13485 accreditation journey and to get your medical device to market before your competitors.

And as ever, if you have any queries or questions about your quality and compliance don't hesitate to reach out to us.

Kelly Stanton
Director of Quality, Qualio

What is ISO 13485 certification?

ISO 13485 is an internationally agreed upon set of standard QMS requirements for any company involved in the design, production, installation, servicing and manufacturing of medical devices.

The International Organization for Standardization (or ISO) is an international non-governmental organization of industry leaders who share their knowledge and expertise to provide solutions for global challenges.

Consumers and the life science supply chain have come to trust ISO, and they'll often refuse to purchase medical device products from companies that lack ISO 13485 certification.

Most medical device companies seek certification for either ISO 13485, the general quality management system standard ISO 9001, or both. This guide breaks down the core requirements you'll need to consider as you embark on your ISO 13485 certification journey.

11 benefits of ISO 13485:2016 accreditation

01. Bringing quality and continuous improvement into the heart of your medical device organization

02. Aligned patient-centric business

03. Leadership commitment

04. Opportunity *and* risk management

05. Governance tool

06. Leaner, more profitable route to market

07. An integrated approach through Annex SL

08. Trusted medical device end product

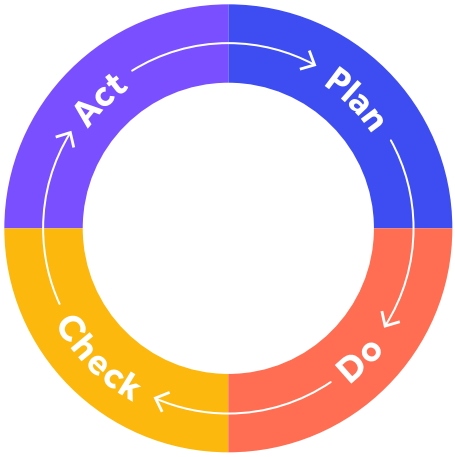
09. Consistent patient focus throughout development and manufacturing

10. Consistent foundation for the future

11. Meet the needs of all interested parties

Some key components of ISO 13485 compliance

The QMS



Adoption of a quality management system to:

1. Consistently provide medical devices that meet patient needs and applicable statutory and regulatory requirements
2. Demonstrate conformity to specified QMS requirements
3. Address both risks and opportunities associated with your context, objectives and strategic direction to maximize patient and product safety
4. Follow a process approach based on Deming's Plan Do Check Act model

Risk management and design controls

Risk-based thinking throughout the product design and development process, including:

1. Identifying and mitigating potential patient health and safety risks
2. Control and quality assurance of all design elements, individually and in totality
3. FMEA processes
4. Potential linkage with ISO 14971, the medical device risk management standard

Traceability of processes, components and materials

The ability to identify and trace medical device products and product components post-market release, in the event of recall.

Design and manufacturing focus

Clearly documented manufacturing quality control processes, including key documentation like the Design History File (DHF).

Analysis and improvement

As we'll see, Clause 8 focuses on ensuring, maintaining, demonstrating and continuously improving the quality and integrity of the QMS and the medical devices it produces.

Learn more!

› 5 key elements of the ISO 13485 standard

› The essential parts of an ISO 13485 medical device QMS

Clause-by-clause breakdown

1. Scope

The scope sets out the intended outcomes of the modern medical device quality management system, including the significance of the process approach and continuous improvement.

2. Normative References

Provides details of the reference standards or publications relevant to the particular standard, including ISO 9001:2015.

3. Terms & Definitions

Details terms and definitions applicable to the standard, including definitions of:

- Active Implantable Medical Device
- Active Medical Device
- Advisory Notice
- Customer Complaint
- Implantable Medical Device
- Labeling
- Medical Device
- Sterile Medical Device

4. General requirements

Lays out the broad requirements for a properly documented ISO 13485 QMS, including:

- Quality manual with clear QMS scope
- Documentation control procedures
- Required forms, records and SOPs

5. Management responsibility

Concerns the role of 'top management': the group of people who direct and control your organization at the highest level. Customer and patient satisfaction and safety should be overseen and maintained by top management with:

- Clear responsibilities
- Frequent management reviews
- A clear quality policy with objectives

6. Resource management

Requirements for how resources are managed and applied to meet your quality objectives, including personnel, equipment and training.

7. Product realization

Maps out requirements for the end-to-end medical device product realization process, including:

- Production and manufacture
- Capturing and actioning feedback
- Planning
- Design
- Purchasing
- Traceability

8. Measurement, analysis and improvement

Breaks down how to monitor and analyze your processes with a view to continuous refinement and improvement. Core considerations include:

- Auditing
- CAPAs
- Non-conformance control
- Measuring and maximizing customer satisfaction and patient/product safety

9 top tips for ISO 13485 compliance from real quality managers

1. Ensure the quality team understands and is integrated with every core process and function in the business, not just those directly connected to product manufacture

2. ISO 13485 auditors love to see real-time evidence of quality actions as they unfold. Ensure your system is flexible enough to allow this

3. When choosing an eQMS to lighten your ISO 13485 compliance burden, find one with suitable and appropriate validation processes

4. Look to other heavily regulated industries, like aerospace and automotive, for QMS ideas

5. A tiny oversight can have massive consequences. Conduct thorough and frequent auditing against processes, procedures – and of course, the standard itself

6. Boost the level of compliance your customers can expect and differentiate from the competition by investing in appropriate quality management tools

7. Ensure all staff ensure the core goals and aims of the ISO 13485 QMS

8. Keep everything as simple and easy to follow as possible

9. Build a single source of truth for processes, systems and policies that will withstand any future growth, merger or acquisition

Busting 4 persistent ISO 13485 myths

Myth #1: ISO 13485 is only for medical device manufacturers.

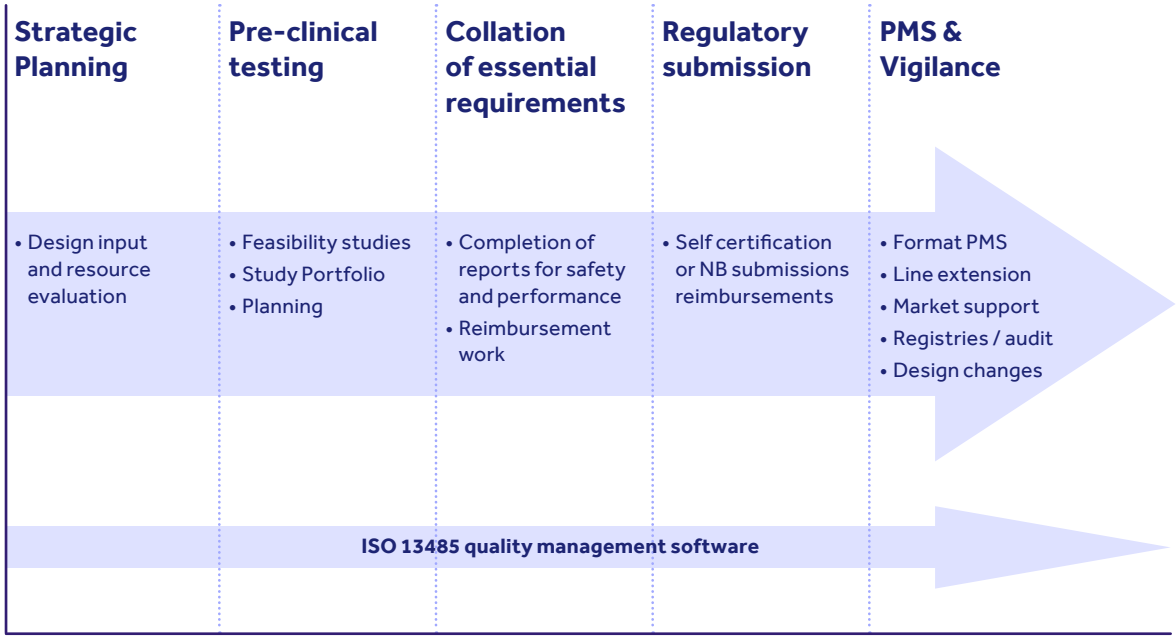
Truth: If you're involved in the design, production, servicing, installation or manufacturing of medical devices, ISO 13485 compliance is key.

Myth #2: You need a Target Product Profile (TPP) for ISO 13485 compliance.

Truth: A TPP isn't mandatory, but may be a useful addition to your medical device QMS. Consider writing one during the development stage and begin with the end in mind, taking into account unmet needs and value, suitable comparators, the adequacy of CPT coverage, and any claim requirements.

Myth #3: Paper-based quality systems are suitable for long-term ISO 13485 compliance.

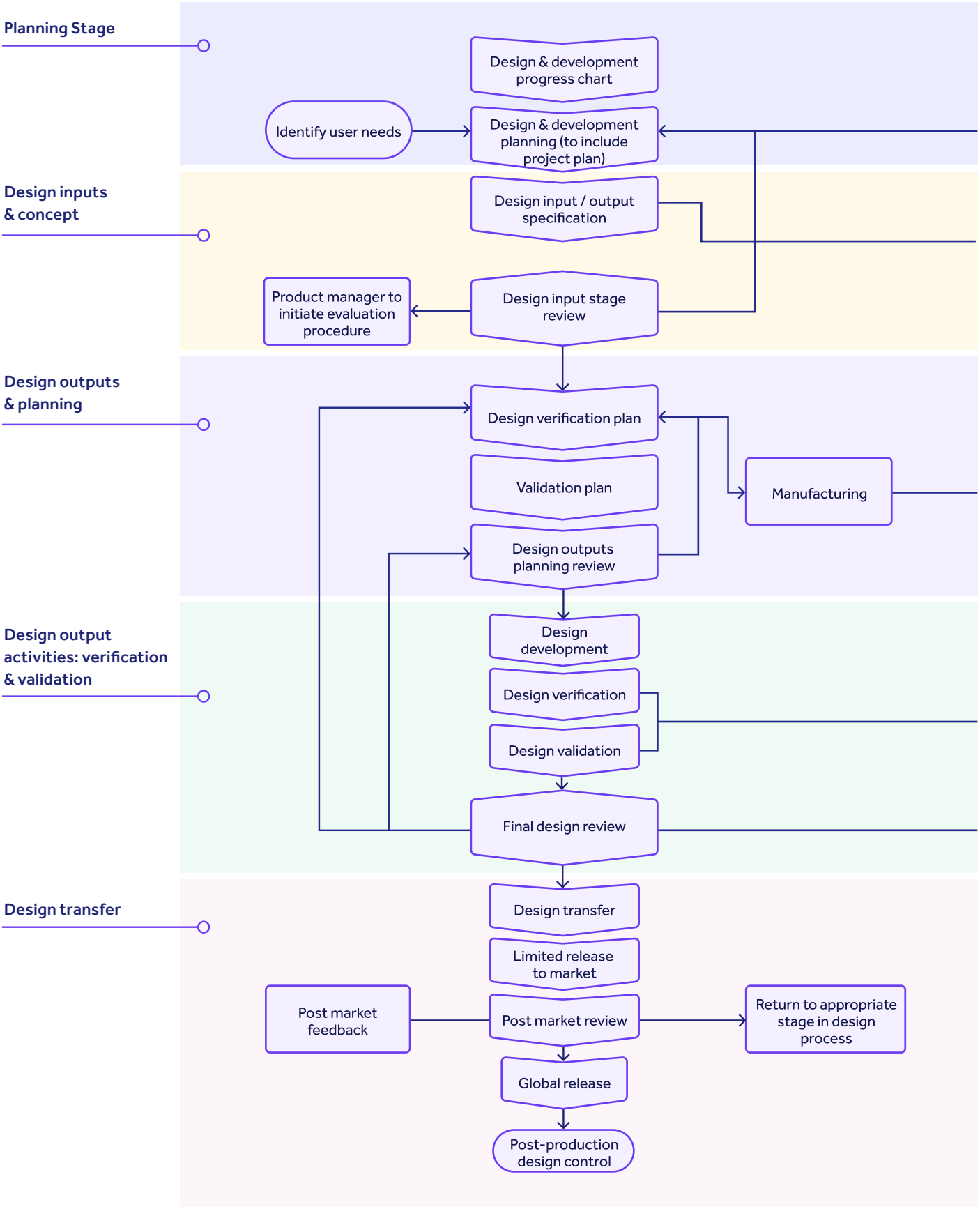
Truth: You can get by with a paper-based system in the short term if your company is very small. But if you have any growth ambitions, long-term go-to-market plans, or desire to maintain a baseline of compliance without undue effort, a paper-based system is unsuitable. More and more medical device companies are realizing this and turning to electronic quality software as a result.



Myth #4: You can buy pre-validated ISO 13485 QMS software.

Truth: Every piece of software you implement must be validated separately in accordance with the requirements of GAMP 5. But although validation is unavoidable, it needn't be painful. Qualio is a GAMP 5 Category 3 product supported by an industry-leading validation process run entirely by us, not the customer.

Medical device design and development pathway



Top 8 ISO 13485 mistakes to avoid from real auditors!

01. Mixing up the design control and product development processes

02. Not preparing the QMS for when the business scales

03. Over-complicated and disorganized document stack

04. General lack of business-wide alignment

05. Labeling inaccuracies

06. Incomplete audit trails for CAPA, risk and supplier records

07. Lack of training completion traceability

08. Lack of records showing whether internal review meeting actions were executed

9 steps to prepare for ISO 13485 certification

Preparing for ISO 13485 doesn't have to be complicated. Follow these nine steps to help you get your certification faster.

1. Familiarize yourself with the guidelines

Take time to read the guidelines thoroughly and make sure you understand what's required of you to become certified. You can view a preview and purchase the complete document on ISO 13485 from ISO's website here.

2. Meet CAPA standards

Refer to the FDA's inspection guidelines, ISO 13485 8.5.3 (prevention), and ISO 13485 8.5.2 (correction) to ensure your company meets CAPA standards.

Failure to meet CAPA standards is the number one trigger for FDA citations in the medical device industry.

3. Implement complaint procedures

Establish complaint procedures that follow the guidelines laid out in FDA CFR 820.198 and ISO 13485 8.2.2. A lack of standard procedures for handling complaints or failure to provide evidence that they followed procedures is the second most common reason organizations received a 483 observation.

4. Include purchasing controls

Create a written procedure for supply chain management to reduce the risk of noncompliance or supplier risks that could compromise your device quality.

5. Develop MDR procedures

MDR (Medical Device Reporting) should include events and annual reports as detailed under FDA CFR 803.17 and ISO 13485:2016.

Written procedures and systems are critical for compliance with record-keeping guidelines for MDR.

6. Create a process to prepare for the audit

Review the following areas every three months, so you aren't putting internal audits off until the last minute:

- Design
- Purchasing
- Training
- Quality Assurance

7. Focus on upstream quality

Manufacturers use the term "Upstream Quality (UQA)" to refer to a concept that relates to quality from the start. Focusing on UQA means putting effort into planning in the early stages to reduce quality issues later down the line.

8. Prepare to talk to the auditor

Auditors don't fail or pass you right there on the spot. Interactions are generally low-pressure and more conversational.

Avoid giving any information you aren't sure of and be prepared to have a productive conversation.

9. Use an eQMS — not a paper-based system

Electronic quality management systems designed for life sciences companies — like Qualio — are built using the ISO 13485 framework for quality control, operational efficiency, regulatory compliance and the safe manufacture of medical devices.

Unless you want to hire an in-house team of IT staff to run your eQMS, you need software that's simple and easy to use.

The perfect eQMS should provide essential functions such as document control, training, and the ability to expand to other areas — like CAPA — as you get closer to product approval.

And as your company grows, your eQMS needs to grow with you. A robust eQMS should offer essential components for risk management, testing, and other procedures to streamline product submission.

An International Trade Administration study found that 73% of medical device manufacturers have 20 or fewer employees, so utilizing a cloud-based eQMS is critical for effective collaboration among a distributed workforce.

When you implement a robust eQMS like Qualio for your life sciences company, you're instantly one step closer to obtaining – and keeping – ISO 13485 certification.

ISO 13485 vs. ISO 9001

ISO 9001 lays the framework for a quality management system that can be applied no matter what industry you're in or what your product, service, or company size is.

If your company intends to manufacture medical devices, you'll need to seek ISO 13485 certification. ISO 13485 has additional requirements not found in ISO 9001 that are specific to medical device manufacturers.

Let's take a look at the similarities and differences between ISO 9001 and ISO 13485, so you can get a better understanding of where you need to raise the bar on quality as a medical device manufacturer.

Similarities between ISO 13485 and ISO 9001

- Each standard helps organizations achieve a quality management system
- Both place a focus on risk mitigation and assessment
- Both utilize the Deming cycle, also known as Plan Do Check Act
- They each place a focus on competency and infrastructure for quality
- Both emphasize understanding the customer for the realization of quality products

Additional requirements for ISO 13485

- Device master record explicitly defining QMS requirements
- Feedback and review system for non-conformance detection

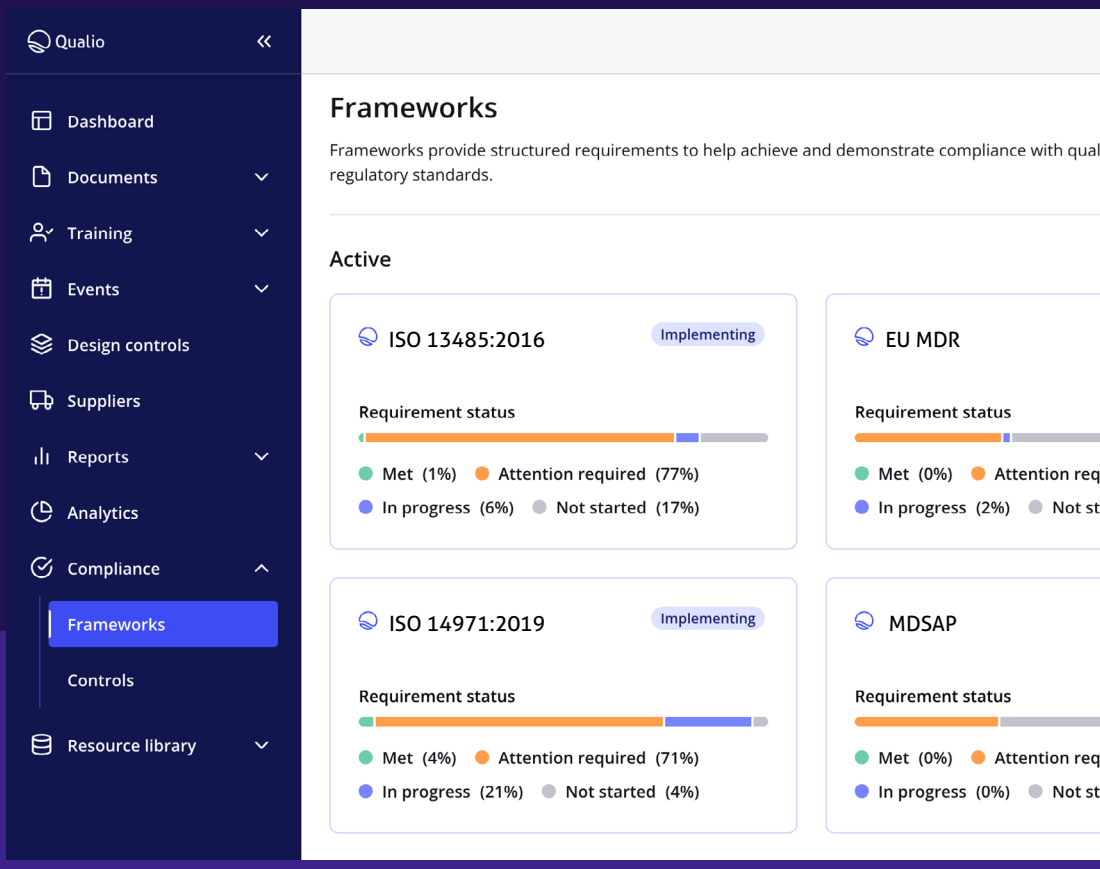
- Product quality control (monitoring and measuring) throughout production process
- Set quality requirements must be met before product release and delivery
- Advisory notices, rework activity, release of non-conforming product (which still meets regulatory requirements) must be documented
- Personnel require access to procedures, requirements and reference materials at the point of work
- Unique and specific records for every approved and verified device batch
- Installation and verification device requirements
- Maintained records of device installation, verification and servicing activities and procedures
- QMS containing product specification documents and quality policy, with a framework for reviews and updates controlled by the management team
- Management must verify QMS goals and compliance
- Documented procedures for shelf life, quality data collection/analysis/retention, maintenance activity, risk/environment management, adverse event flagging, product conformity, identification, returns, maintenance, labeling and packaging

Qualio

Master every ISO 13485 requirement

Our quality and compliance management software gives you everything you need for complete ISO 13485 compliance — from a holistic, digital medtech QMS to AI-powered compliance gap analysis.

Learn more



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