Medical device quality management software

How Qualio arms your business with a complete, compliant medical device QMS

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Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 300 life science and healthcare businesses across the globe use Qualio to centralize, optimize and automate their quality management systems.

Qualio is a scalable and flexible cloud-based system that grows with your business and makes meeting your quality requirements truly simple, from ISO 13485 and ISO 17025 accreditation to FDA and GxP compliance.

Read G2 reviews   **Read Capterra reviews**

Medable   IMBIO   CENTOGENE THE RARE DISEASE COMPANY   Lunaphore technologies

AVECTAS   Biofidelity.   Cardiaccs   PROSCIA

No business faces more regulatory scrutiny or operational risk than medical device organizations.

The smallest quality error can cause serious injury or death for a patient, and catastrophe for your business.

Whether it's for FDA requirements, ISO 13485, ISO 14971, the EU's MDR and IVDR, or the MDSAP, you want complete confidence that your quality management system can get you through a regulatory audit and safely to market.

Qualio is used by hundreds of medical device, SaMD and SiMD businesses worldwide, from the design and production stages to servicing, installation and manufacturing.

Qualio is designed to provide your business with a holistic and end-to-end medical device quality management system which centralizes your data, automates design control activities, gives you control of your product risks, and more.

This guide breaks down the core functionality of our software, and how each component contributes to a robust and airtight medical device QMS driven by quality best practice.

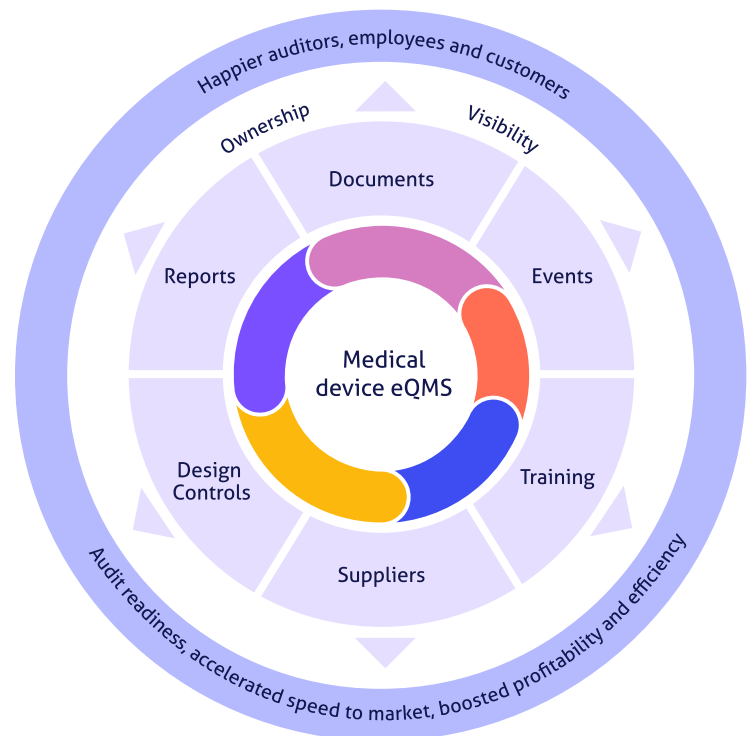**Kelly Stanton**
Director of Quality, Qualio

A holistic medical device quality management software system

Qualio is built around the philosophy that unavoidable quality and compliance tasks needn't be a complex blocker to your product velocity.

Qualio unites your data, people and processes in a single, easy-to-use medical device eQMS framework supported by your entire business.

Qualio customers benefit from:

- Dedicated and integrated system areas for documentation, training, quality event and design control management

- A clean, flat and modern UX that users intuitively understand and love

- Industry-leading 60-day implementation timeframe average

- Simple and painless validation process

- Integration with medical device design/ testing tools like Jira, Azure DevOps and TestRail

- Compliant e-signatures

- Incorruptible audit trailing

- Cloud-based access from anywhere

- Easy document generation and export

- A single source of truth for your medical device product development

Happier auditors, employees and customers

Ownership

Visibility

Documents

Reports

Events

Medical device eQMS

Design Controls

Training

Suppliers

Audit readiness, accelerated speed to market, boosted profitability and efficiency

"Qualio enabled us to seamlessly work through our ISO 13485:2016 requirements and design errors out of our quality management system. One way Qualio achieves this is to ensure that changes flow through our system and are applied globally."
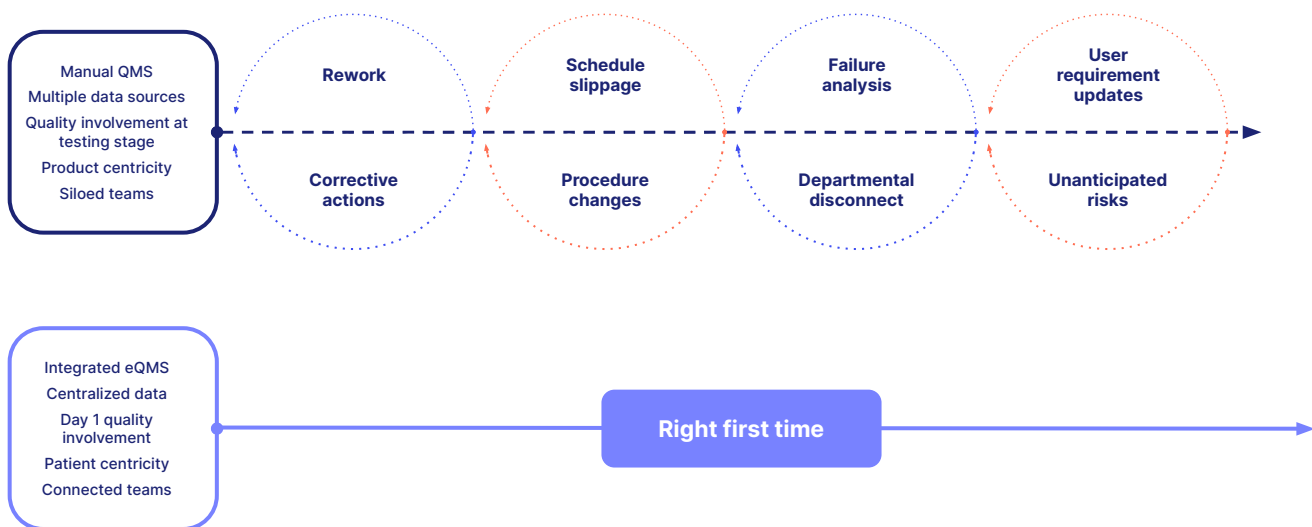
— David H.
  CEO, Cerfatek

ISO 13485:2016 clause number	How Qualio helps
Clause 4: Quality management system	• Formally document a quality management system • Establish, control and retain records and medical device file • Apply risk based thinking • Document validation and revalidation activities for any requirement, procedure, or arrangement.
Clause 5: Management responsibility	• Demonstrate management commitment • Maintain a customer focus • Communicate roles and responsibilities • Manage CAPA, issues, incidents, product monitoring etc.
Clause 6: Resource management	• Determine competence, provide training and evaluate the effectiveness of training • Retain records on maintenance activities • Document work environment health and safety requirements • Plan and document control of contaminated or potentially contaminated products
Clause 7: Production realization	• Plan processes for product realization • Document product requirements • Retain records of the results of the review and actions taken • Plan and control product design and development • Identify, review, verify and validate any changes to the product • Document procedures to ensure product conforms to specified purchasing information • Establish and implement inspection activities

	• Plan, carry out, monitor and control medical device production and service provision • Ensure valid results with measuring equipment is identified. Manage calibration activities
Clause 8: Measurement analysis and improvement	• Plan and implement the quality management system • Gather and monitor information relating to whether the organization has met customer requirements • Monitor and measure medical device characteristics at applicable stages of the product realization process • Document procedures to determine, collect and analyse appropriate data • Take action to eliminate the causes of nonconformities

A new blueprint for medical device success

| Manual QMS
Multiple data sources
Quality involvement at testing stage
Product centricity
Siloed teams | Rework

Corrective actions | Schedule slippage

Procedure changes | Failure analysis

Departmental disconnect | User requirement updates

Unanticipated risks |

| Integrated eQMS
Centralized data
Day 1 quality involvement
Patient centricity
Connected teams | Right first time |

Qualio

Document a quality management system.

Document roles and responsibilities.

Document processes needed.

Document procedures for validation of software used in the QMS.

Document a quality manual and quality objectives.

Establish and maintain a file containing documents to demonstrate conformity to the requirements of the standard.

Review and approve documents. Ensure identification of changes and current revision status.

— ISO 13485:2016
Good Documentation Practice (GDocP) requirements

Document management

Establish data management policies, procedures, plans, control documentation and design history files.

Use Qualio Documents for:

- SOPs, technical drawings, Design History File (DHF)
- Validation master plan (VMP)
- Incorruptible version control and audit trails
- Workflows for document drafting, approval, distribution and review
- Compliance with FDA and EU e-signature requirements

AXIOM real-time metrics®

"Qualio gives me everything in one place. I can connect or link documents to other documents and keep the traceability of any changes made or decisions made."
— Dragan V.
Software Engineer, Axiom

More on Qualio Documents

1. [Why your life science business needs electronic document management](#)
2. [Document management software datasheet](#)
3. [Document management software webpage](#)

Collaborate with workflows

Assign roles and responsibilities for documents and route them around your business for viewing, training and acknowledgement

Automatic version control

Outdated and superseded documents are automatically replaced by new versions, ensuring employees access only the latest and greatest

Permission control

Enforce bespoke permissions to ensure documents are only accessible by those who need to see them

Proactive review

System prompts and reminders keep your document stack fresh and up-to-date

Complete traceability

Drill into document change histories and audit trails for audit purposes

Reports & metrics

Build reports at the touch of a button to understand your document environment and compliance status

"

Ensure competent people performing work affecting product quality.

Document the process needed for establishing competence, providing training and ensuring awareness of personnel.

Determine the necessary competence.

Provide training.

Evaluate the effectiveness of the training.

Ensure that personnel are aware of the relevance and the importance of their activities.

Retain records of education, training, skill and experience.

— **ISO 13485:2016 requirements,**
Clause 6.2: People

Training management

Qualio Training empowers your business with a complete framework for ensuring your workforce is competent, compliant and appropriately trained.

Use Qualio Training for:

- Planning, testing and managing employee competency
- Recording training
- Plugging training gaps and maximizing compliance
- Building easy e-training pathways your employees will follow

koneksa

"People are doing their training now. And I think that the reason for that is just that it's simple to do. And it's more of an enjoyable situation than it was in the past."
— Stan S.

Director of Quality Assurance, Koneksa

More on Qualio Training

1. Training management software datasheet
2. Training management software webpage
3. Koneksa training case study

Single source of training truth

All training records are stored in a centralized database that's easily accessible and searchable

Prove compliance

Set quizzes and mandate FDA-compliant completion e-signatures for demonstrable compliance and understanding

At-a-glance understanding

View completed and outstanding training for individual documents, groups such as departments and teams, and for individual system users

Flexible training mandates

Choose bespoke training requirements for every document template in your Qualio system, including if training is required and if new document versions require retraining

Increased engagement

Employees receive system reminders and access a clean and simple training area that doesn't stifle engagement

Reporting

Enjoy real-time access to training reports, easily exportable and shareable directly from the system

Apply suitable methods for monitoring.

Demonstrate the ability of the processes to achieve planned results.

Take correction and corrective action when planned results are not achieved.

— ISO 13485:2016, Clause 8.2.5 requirements: monitoring and measurement of processes

Event management

Qualio Events allows your business to take consistent, appropriate and fully traceable actions as quality events like defects and NCRs arise.

Use Qualio Events for:

- Managing CAPAs, product issues, and any other quality event
- Driving actions to completion with templated workflow steps
- Understanding and fixing the real root cause
- Assigning clear roles and responsibilities for responding to quality events

"Qualio is a superb eQMS solution for medical devices."

— Andrew R.

Director of Tech & Quality, Medbaye

More on Qualio Events

1. Event management software datasheet
2. CAPA management software webpage
3. 9 ways to improve quality in medical device product development

Quality event database

Store complete records of quality events and responses, including status and completed actions, in a central audit-ready repository

Templated workflows for consistency

Build bespoke event templates and workflows that connect your colleagues to ordered action steps, ensuring the right action is taken by the right person at the right time

Full visibility

Dive into any reported quality event for at-a–glance visibility of status, outstanding steps, root cause and more

Connect to the rest of Qualio

Attach key documents like SOPs and training records to quality events to connect information in a logical, structured way

Rich reporting

Drill into powerful system reports to analyze root causes, view resolved and unresolved issues, uncover product statistics and more

Get the info you need

Fully flexible event templates let you build your own fields and use your own terminology to ensure information is captured how you want it to be

Document the methods to ensure traceability of design and development outputs to design and development inputs.

Documentation of each design and development phase.

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

— ISO 13485:2016 requirements,
Clauses 7 and 8

Design controls management

Qualio Design Controls is a specialized component of our software, specifically designed to give medical device companies streamlined and automated design control compliance.

Use Qualio Design Controls for:

- Integrating with your product design tools like Jira and TestRail to automatically pull design elements straight into Qualio
- Applying ISO 14971 and FMEA methodology to product risks
- Building a centralized and compliant design control document stack
- Collating requirements, inputs, outputs, issues and risks by product

"Qualio stood out for us because it was cloud-based and optimized for medical device companies. Qualio was the right investment."
— Andy L.
    CEO, ArcScan

More on Qualio Design Controls

1. Design controls management software datasheet
2. Design controls software webpage
3. Design controls: 6 principles for success

Ordered design controls by product

Categorize your development activity in a single source of truth from user requirements to test data — all arranged logically by product

Connect your teams

Pull design elements straight from the source systems your development and engineering teams use, like Jira, TestRail and Azure DevOps

Integrated risk management

Record, categorize and treat your product risks with built-in FMEA and ISO 14971 methodology frameworks

Complete design control compliance

Comply with ISO 13485 and FDA 21 CFR 820 by gathering all product development documentation in real time, from inputs to V&V, and viewing and exporting at the touch of a button

Automatic document stack

Qualio Design Controls absorbs your product development data and automatically generates trace matrices, requirements documents and more - as change controls are managed and completed with end-to-end visibility

Set-up and services

Medical device expertise and commitment to partnership

An excellent medical device quality management system can't be achieved with a single tool alone. It requires time, energy, resource and expertise.

Qualio commits to a long-term partnership with our customers, from the exciting infancy days of start-ups to post-market growth and expansion.
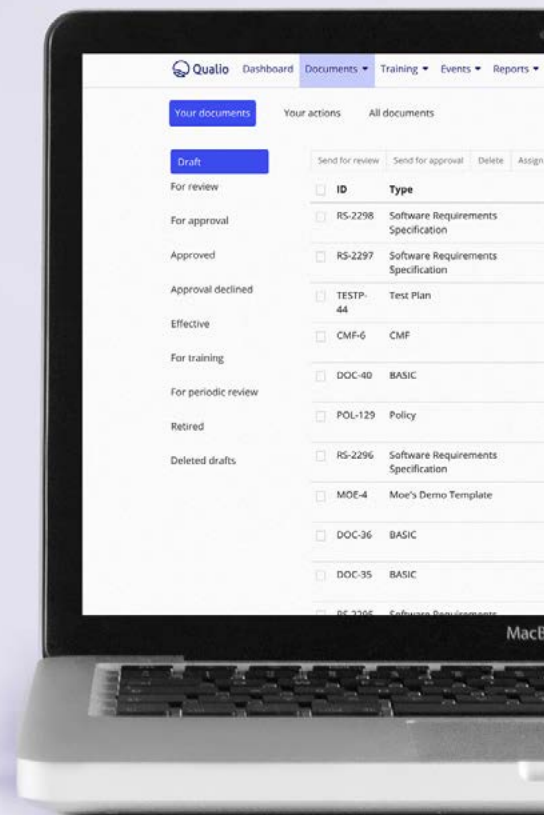
Our services include:

- Simple and painless validation to get your platform up and running
- Training
- Best practice implementation
- Customer success
- Strategy sessions and QA support*
- Market intelligence*
- Gap assessments and internal/supplier audits to get your QMS shipshape*

*Qualio+ and Qualio+ Audit offerings

Qualio

See our medical device quality management software in action

Schedule a demo with us