

Life science quality management software

How Qualio gives life science companies
an industry-leading eQMS platform

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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 400 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



“

Life science companies face the strictest regulatory scrutiny and highest levels of operational risk on the planet.

Scaling and bringing your life-saving products to market in this environment can be a daunting challenge.

We built Qualio to solve that challenge in three ways:

- 1. By increasing your revenue through boosted velocity to market*
- 2. By slicing your cost of quality*
- 3. By mitigating your risk with sharper, leaner, more compliant digital processes*

Qualio is used by hundreds of medical device, pharmaceutical, biopharmaceutical, SaMD and contract research and manufacturing organizations worldwide, from design and manufacture to post-market surveillance.

This datasheet provides a high-level walkthrough tour of our eQMS software system and the powerful benefits our customers enjoy.



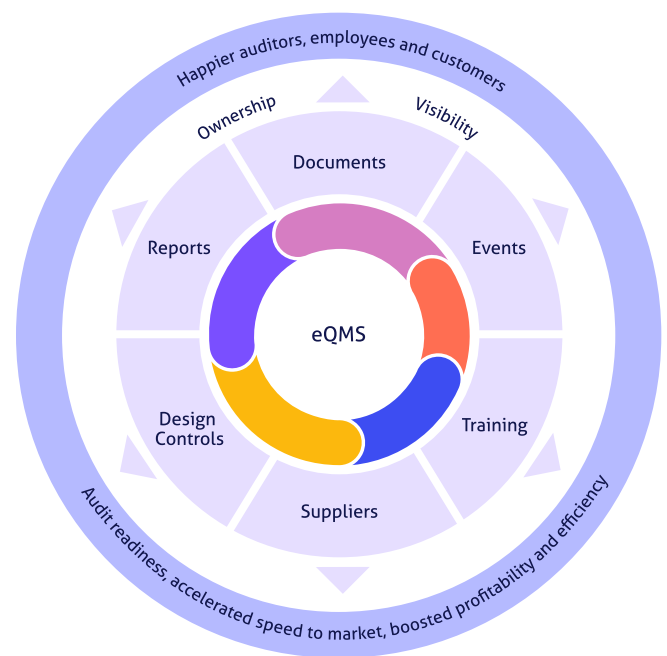
Kelly Stanton
Director of Quality, Qualio

A holistic electronic 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 eQMS framework supported by your entire business.

Qualio customers benefit from:

- Dedicated and integrated system areas for documentation, training, event and supplier management – plus design control management for medical device companies
- 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 your core business tools, from Salesforce to Jira
- Cloud-based access from anywhere
- Easy document generation and export
- A single source of truth for your product development
- Compliant e-signatures
- Incorruptible audit trailing



"When I recommend Qualio, one of the first things I say is: you're going to be able to get this thing in-house, validated, implemented and live in a short amount of time with limited resources. That's unique in this industry."

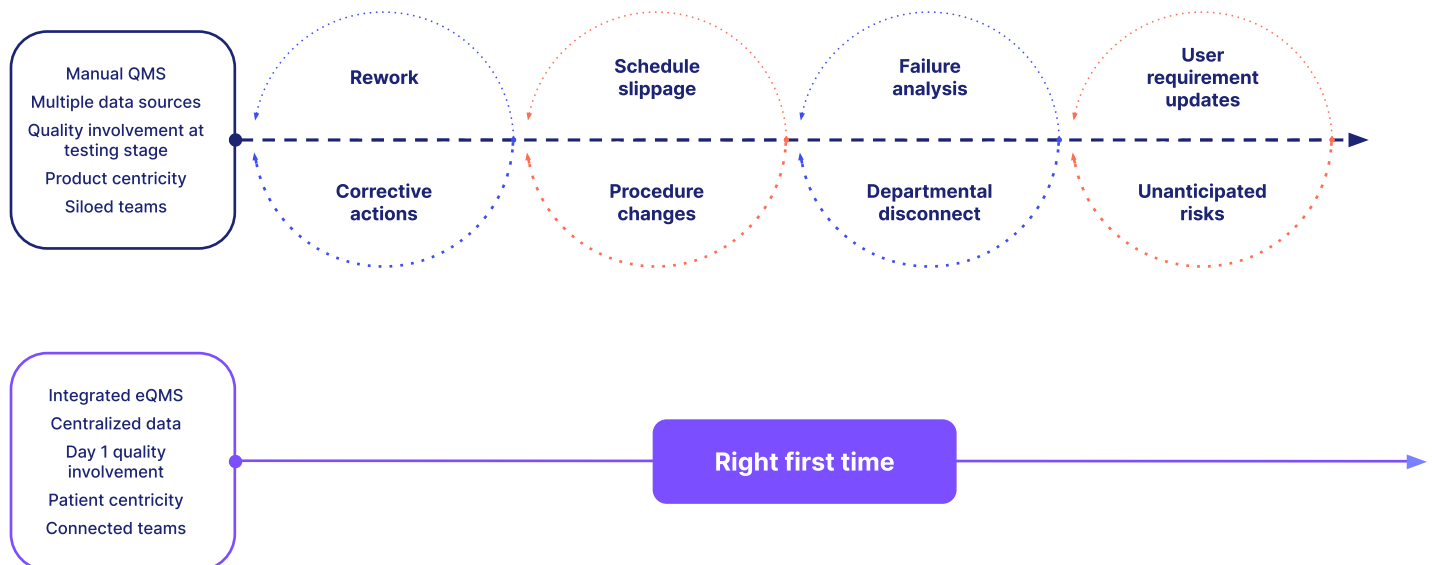
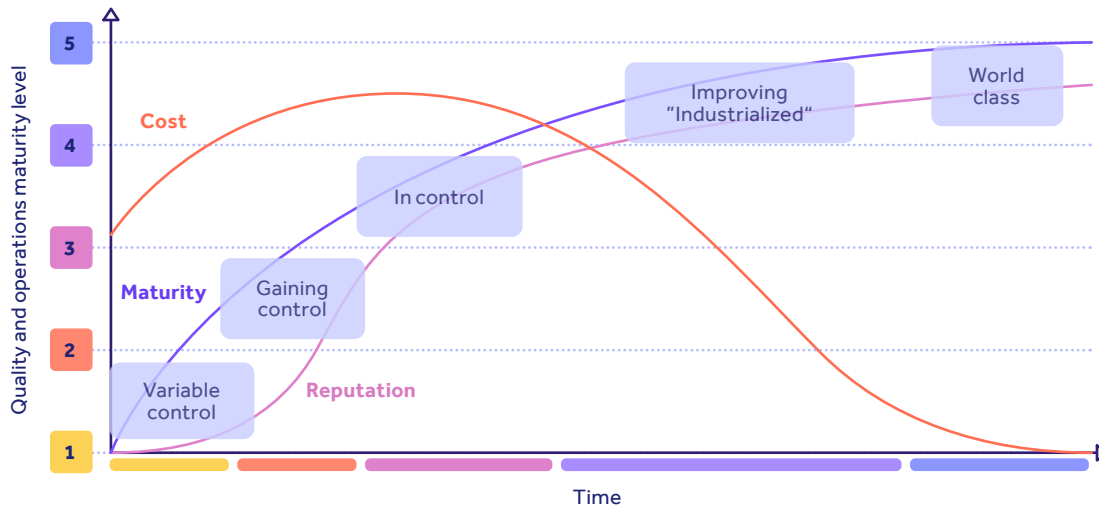
— Becki N.

Quality & Regulatory Lead, Synthego

Build a stronger, smarter electronic quality approach

The journey to world class

Quality maturity curve





Document a quality management system.

Document roles and responsibilities.

Document a quality manual and quality objectives.

Change is an inherent part of the development process and should be documented.

A pre-defined approach should be used to manage activities such as retention of documentation.

Documentation should be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, available.

— **ISO 13485, ICH Q10 and ALCOA+**

Good Documentation Practice (GDocP) requirements

Document management

Control your entire document stack in a centralized, compliant digital repository. 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

"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

- › [Why your life science business needs electronic document management](#)
- › [Document management software datasheet](#)
- › [Document management software webpage](#)

Collaborate with workflows

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

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

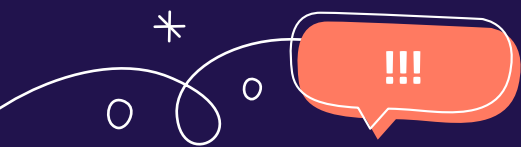
System prompts and reminders keep your document stack fresh and up-to-date

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.

The management review system should identify appropriate actions, such as provision, training and/or realignment of resources, capture and dissemination of knowledge.

Each individual... shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

— **ISO 13485, ICH Q10 and FDA 21 CFR 58.29**

Training and competence requirements

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

"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

- › [Training management software datasheet](#)
- › [Training management software webpage](#)
- › [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

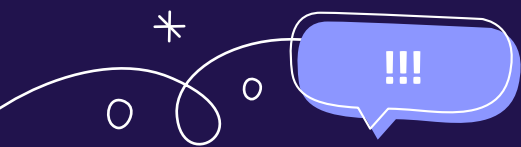
Choose bespoke training requirements for every document template in your Qualio system, including if training is required and if new document versions require retraining

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.

The company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring.

— **ISO 13485 and ICH Q10**

Monitoring and measurement of process requirements

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 keeps us in a constant state of audit readiness."

— **Deb G.**

Director of Quality, Dimension Therapeutics



More on Qualio Events

- › [Event management software datasheet](#)
- › [CAPA management software webpage](#)
- › [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

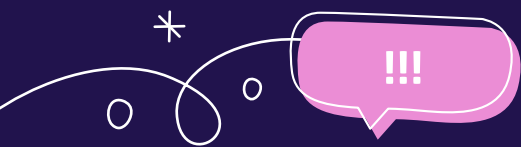
Attach key documents like SOPs and training records to quality events to connect information in a logical, structured way

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.

For each software system of the medical device, the manufacturer shall define and document software system requirements from the system level requirements.

— **ISO 13485 and IEC 62304**

Design control requirements

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

- › [Design controls management software datasheet](#)
- › [Design controls software webpage](#)
- › [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



Develop and maintain procedures to ensure all supplied products and services meet requirements.

The pharmaceutical quality system should include appropriate processes, resources and responsibilities to provide assurance of the quality of outsourced activities and purchased materials.

These processes should incorporate quality risk management and include assessing prior to outsourcing operations or selecting material suppliers, the suitability and competence of the other party to carry out the activity or provide the material using a defined supply chain (e.g., audits, material evaluations, qualification).

— **FDA 21 CFR Part 820.50 and ICH Q10**

Supplier management requirements

Supplier management

Qualio Suppliers gives your business a consistent, controlled and centralized approach to managing and coordinating supplier activity.

Use Qualio Suppliers to:

- Ditch spreadsheets and duplicated effort by harmonizing all supplier compliance information in a single source of truth
- Configure bespoke policies for manufacturers, service providers, distributors, consultants and more – then use them to enforce supplier requirements and ensure compliance
- Link key documentation like quality agreements, SLAs, GDPR statements and SOC 2 reports to suppliers. Mandate document sets for specific supplier categories
- Build bespoke risk levels, then assess and categorize suppliers accordingly for a full picture of your third-party risk environment

"I like the policy configuration part of Suppliers. It supports a more risk-based approach. Before, we required an audit, an agreement, a questionnaire for every single supplier regardless of what they did."

— **Steve F.**

VP Quality Assurance, Capstone Development



More on Qualio Suppliers

› [Supplier management software datasheet](#)

Build and enforce a policy matrix

Categorize suppliers by risk and type, then automatically enforce appropriate document and audit requirements

Centralize your supplier info

Build a single source of truth for suppliers and third parties, with a clean easy-to-use interface list

Access consistent supplier records

Drill into key supplier information with a click, from contact details to internal sponsors

Complete control and approval activity

Add an extra layer of consistency, control and diligence to your supplier management by designating approvers as new suppliers are vetted and onboarded

Manage risks easily

Take appropriate risk-based action for each supplier with prompts and reminders for key activities like audits

Set-up and services

Life science quality expertise and commitment to partnership

An excellent life science 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:

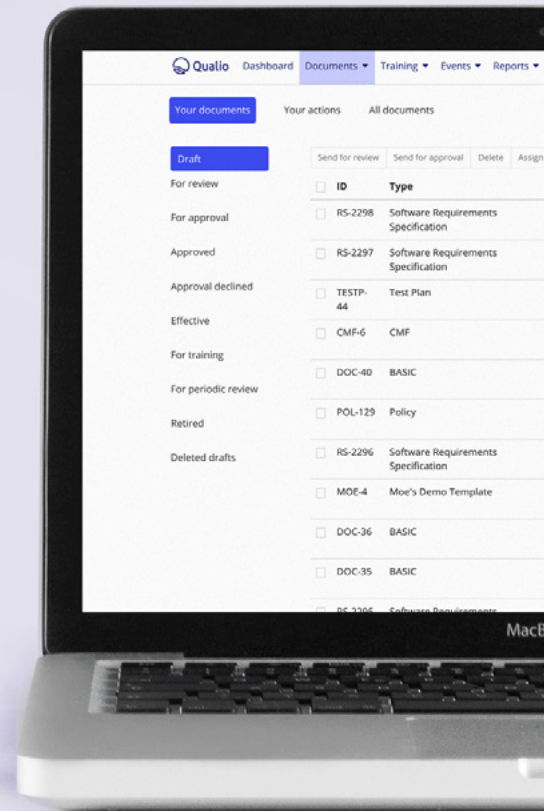
- Simple and painless validation to get your platform up and running
- Training
- Best practice implementation
- Customer success
- Strategy sessions and QA support*
- Market intelligence*
- Gap assessments and internal/supplier audits to get your QMS shipshape*

**Qualio+ and Audit Program offerings*



See our quality management software in action

Schedule a demo with us



Call us today

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