Qualio

Pharmaceutical quality management software

How Qualio embeds a complete electronic quality management system for pharmaceutical and therapeutic businesses

Table of Contents

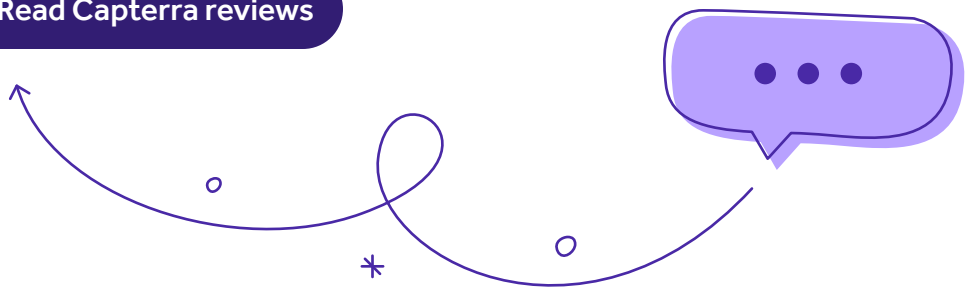
Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 600 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

Pharmaceutical development and manufacture leaves no margin for error.

The regulatory scrutiny and compliance frameworks faced by quality professionals in this space are the tightest on the planet.

You need complete control and visibility of your entire quality landscape if your business is to embed GxP, comply with ICH Q8, 9 and 10, and keep your FDA auditor happy.

Qualio is used by hundreds of pharmaceutical and therapeutic businesses worldwide to embed a complete, compliant electronic quality management system.

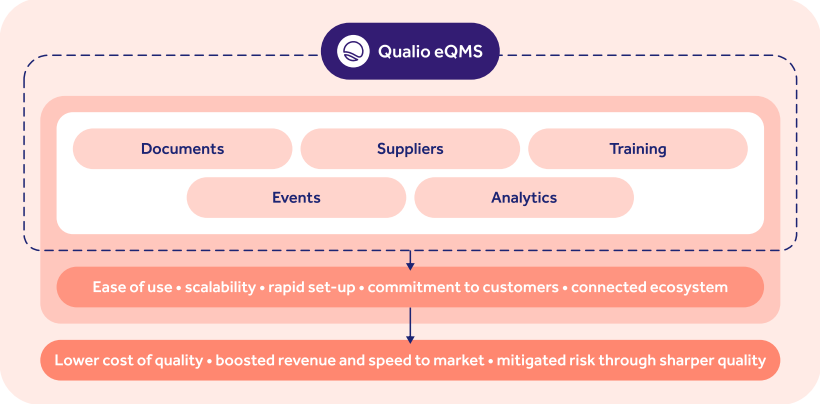
From easing compliance burden and centralizing quality data to simplifying key processes, Qualio is designed to make market-leading pharmaceutical quality management natural and automatic for your business.

This guide breaks down how.

Meg Sinclair
Quality Operations Manager

A holistic pharmaceutical and therapeutic eQMS

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 pharmaceutical and therapeutic eQMS framework supported by your entire business.



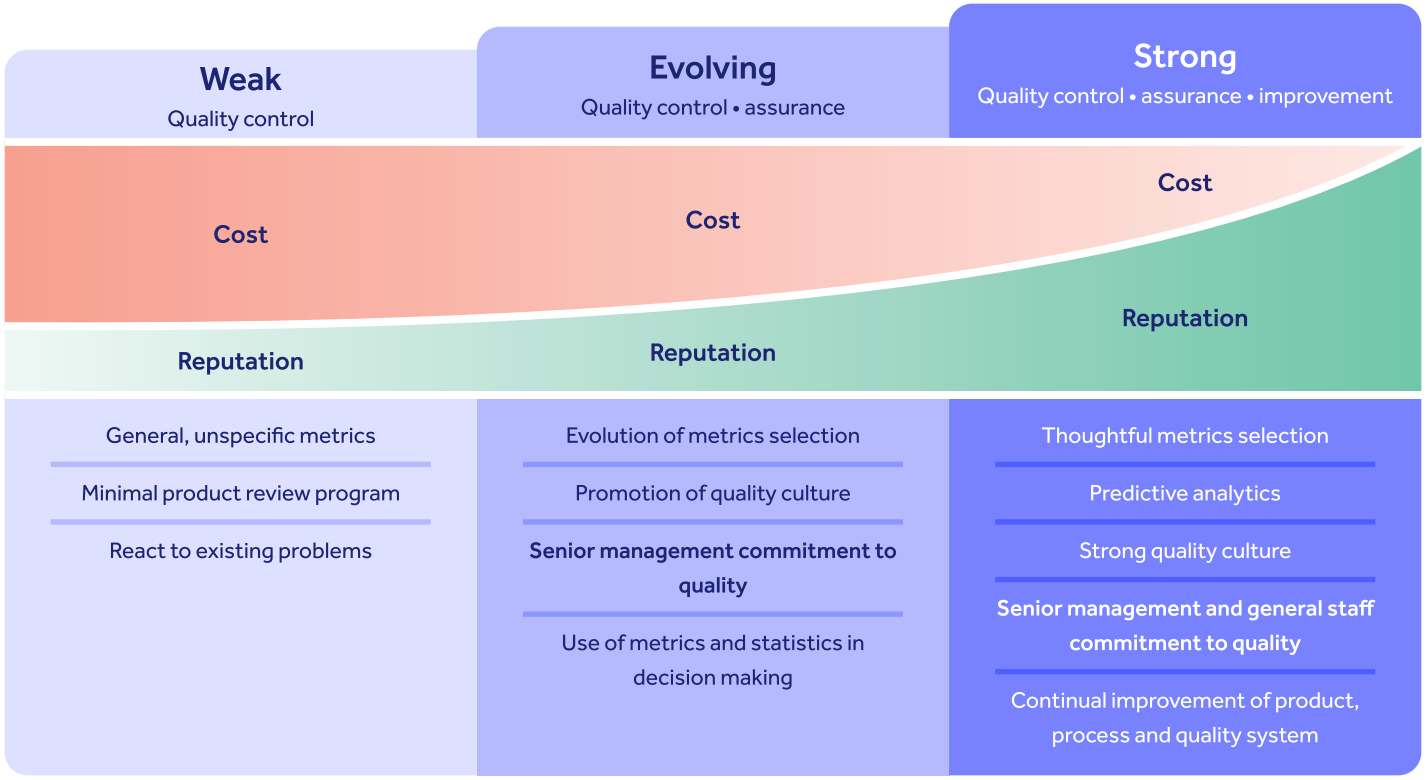
> *"The perfect eQMS for a start-up. Everything, from validation to migration and training, was a positive experience."*
>
> **Drew M.,** Director of Quality, ECM Therapeutics

Qualio customers benefit from:

- Dedicated and integrated system areas for documentation, training, quality event and supplier 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
- Easy document generation and export
- Integration with other business-critical tools like Salesforce
- Compliant e-signatures
- Incorruptible audit trailing
- Cloud-based access from anywhere
- A single source of truth for your product development

ICH Q10 clause number	How Qualio helps
§1: PQS	• Formally document a quality management system • Establish, control and retain records and key documents like a quality manual • Apply risk-based thinking • Document validation and revalidation activities for any requirement, procedure, or arrangement
§2: Management responsibility	• Demonstrate management commitment • Maintain a customer focus • Communicate roles and responsibilities • Give management control and visibility to review all quality processes, from resource management to purchased materials
§3: Continual Improvement of Process Performance & Product Quality	• Manage CAPAs, issues, incidents, product monitoring etc • Manage processes electronically with repeatable template actions to ensure products meet and exceed customer needs • Share and access process and product knowledge from a single source of truth • Establish a state of constant risk control and drive concerted actions to squash defects and deviations
§4: Continual Improvement of the PQS	• Gather and monitor information relating to whether the organization has met customer requirements • Monitor and measure characteristics of the QMS • Document and action procedures to determine,collect and analyze appropriate data • Take action to source and eliminate the causes of non-conformities

Scale the quality maturity curve



The design, organisation and documentation of the pharmaceutical quality system should be well structured and clear to facilitate common understanding and consistent application.

A quality manual or equivalent documentation approach should be established.

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.

— ICH Q10 and ALCOA+
Good Documentation Practice (GDocP) requirements

Document management

Establish pharmaceutical quality policies, procedures, plans and control documentation underpinned by automatic ALCOA+ compliance.

Use Qualio Documents for:

- Building, storing and distributing a digital quality documentation stack, from SOPs to policies and batch records
- 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 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

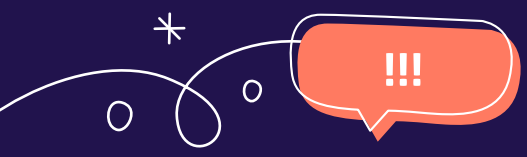
System prompts and reminders keep your document stack fresh and up-to-date

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



Management should provide the appropriate resources and training to achieve the quality objectives.

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.

— ICH Q10 and FDA 21 CFR 58.29
Training 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

The pharmaceutical 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.

— ICH Q10

Monitoring and measurement of the PQS and its 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 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

› The perfect quality assurance plan for pharmaceutical companies

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

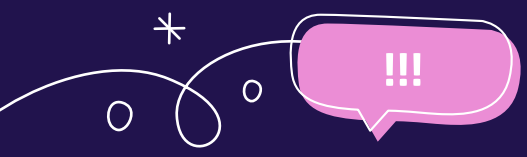
Attach key documents like SOPs and training records to quality events to connect information in a logical, structured way

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



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

More on Qualio Suppliers

› Suppliers software datasheet

› Suppliers software webpage

"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

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

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation... to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

— ISO 9001 Clause 10.3
Continuous improvement expectations

Quality analytics

Qualio Analytics surfaces your document, training and event management activity into digestible visual breakdowns.

Use Qualio Analytics to:

- Understand how your QMS works in real time
- Make your company constantly audit-ready by spotting trends and underlying issues, then tracing actions to completion
- Replace murky paper and spreadsheets with data-driven quality decisions
- Export and present QMS insights to colleagues, senior leadership and regulators

> *"In the past, we had multiple spreadsheets which needed pulling together. It took days. Now I can build management reports the day of the meeting, because I can pull the information right out of Qualio!"*
>
> **— Stan S.**
>
> Director of Quality Assurance, Koneksa

More on Qualio Analytics

› Quality analytics datasheet

Stronger quality and compliance

Open bottlenecks, spot compliance weaknesses and uncover trends - then act accordingly to make your business stronger

Data at your fingertips

Enjoy snapshot visibility of open and closed events, document cycle times, group and individual training performance, overdue tasks and more

Make everyone responsible for quality

See who's up-to-date with their quality tasks, and who isn't.
Pinpoint bottlenecks and open them to ensure CAPAs, deviations and nonconformances are closed out promptly.

Export and share

Prepare for management reviews and regulatory inspections in minutes by exporting visual snapshots of your QMS activity

Cut through the noise

Surface cloud-powered quality data at the touch of a button to plan, review, allocate resources and make the right quality and compliance decisions

Set-up and services

Pharmaceutical expertise and commitment to partnership

An excellent pharmaceutical 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:

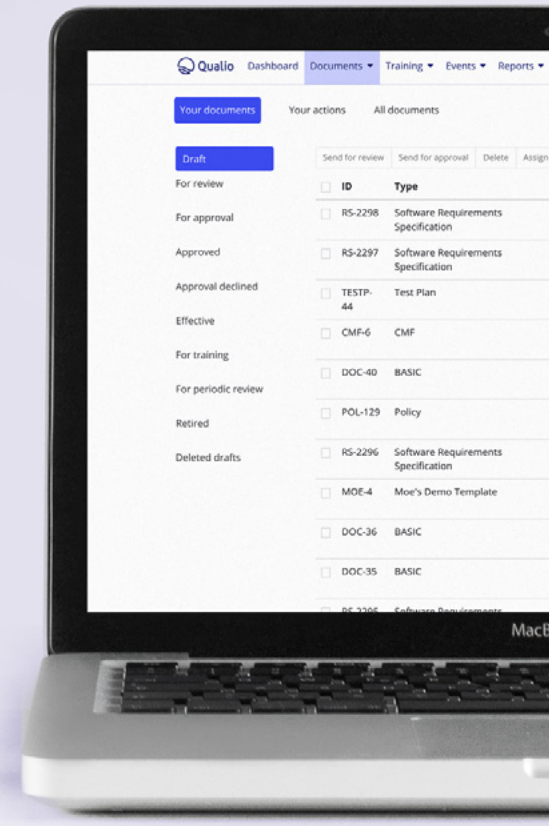
- Simple and painless validation to get your platform up and running
- Training
- Best practice implementation
- Customer success
- Pre-built QMS document templates and migration of your legacy documents*
- Strategy sessions and QA support*
- Market intelligence*
- Gap assessments and internal/supplier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

**Qualio+ offerings*

Qualio

See our pharma quality management software in action

Schedule a demo with us



Call us today
1.855.203.2010 • +353 1 697 1522