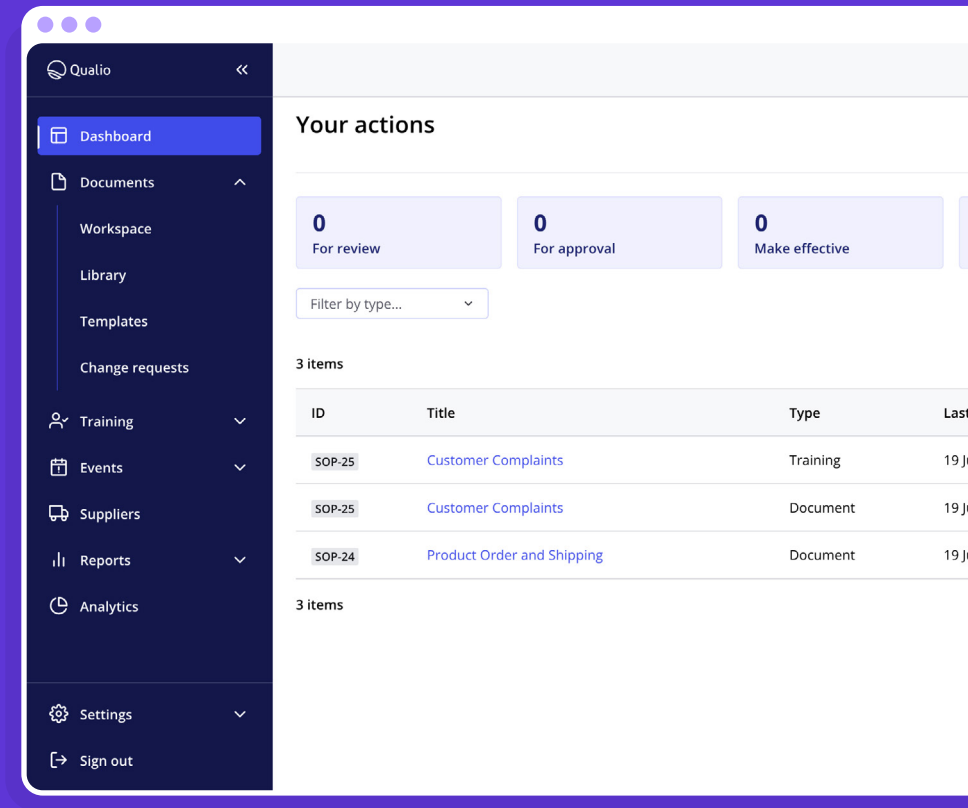
Qualio

QUALIO PRODUCT GUIDE

Qualio

The leading eQMS for growing life science companies



Qualio's eQMS software empowers growing life science organizations to do their vital work with a stronger, faster, more quality-centric approach. Our software is built and continuously improved with three key objectives at the core:

To be the easiest, most intuitive eQMS on the market

To seamlessly connect your internal and external stakeholders to your quality work

To empower your growth with flexible, collaborative quality content management

Over 650 life science businesses across the globe now use Qualio to optimize and automate their quality management systems.

Request a demo

Quality management software for modern life science challenges

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

Watch interview snippet

BECKINAM NOWATZKE

Quality & Regulatory Lead
Synthego

Qualio helps me sleep better at night. Having that structure for everyone to work within is essential for us to really succeed in getting onto the market and staying compliant.

Watch interview snippet

HEATHER UNDERWOOD

CEO
EvoEndo

Quality management software for modern life science challenges

When I first saw Qualio I said, "oh, I can set up any process flow that matches us, instead of having to adapt!" The flexibility has just been mindboggling.

Watch interview snippet

MICHAEL HOLCOMB

Quality Assurance Director
TriMed

The cost of our Qualio licenses is insignificant compared to what we've saved by improving our processes.

Watch interview snippet

PETER BRUESEHOFF

Director of QA
Watchmaker Genomics

Our customers report...

>90% reduction in quality admin time

30% faster quality processes

Up to 3 quality personnel FTE spends mitigated

140% increase in speed to market

5x faster external audits

More collaborative quality cultures built on controlled information

Simplified compliance with FDA and EU requirements, ISO standards, GxP and more

6 interacting areas for holistic quality management

This datasheet is designed to show you and your colleagues how Qualio gives your business robust, best-in-class and totally digital quality processes.

We'll run through the 6 interacting areas of Qualio, from Documents to Analytics, to show you what our software can do.

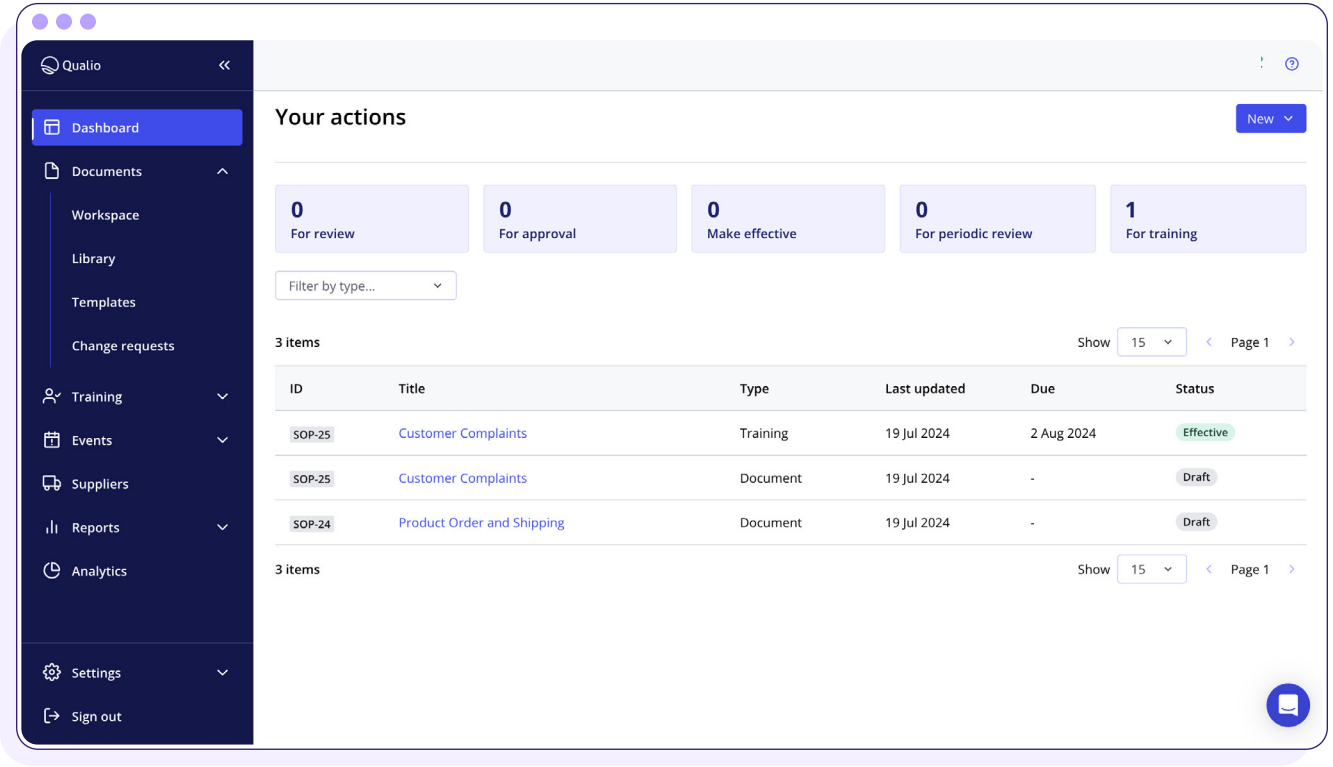
To see Qualio in more detail, including a walkthrough of the system in action, just visit the last page to book a demonstration with us!

1 Document management for a bedrock of controlled information

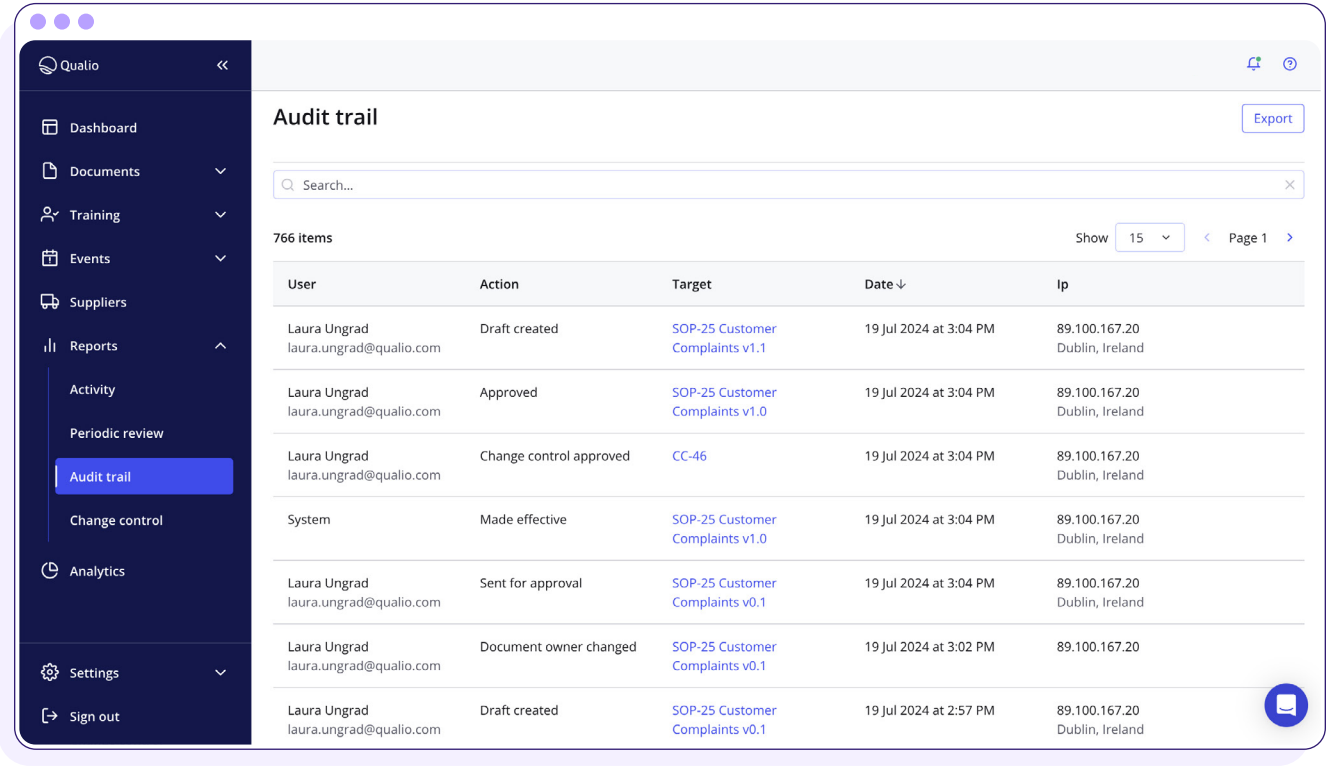
Control your entire document stack with a centralized digital repository that knits your company's quality culture together.

Use Qualio Documents for:

> Creating, storing and managing SOPs, policies, records, Medical Device Files (MDFs) and more.



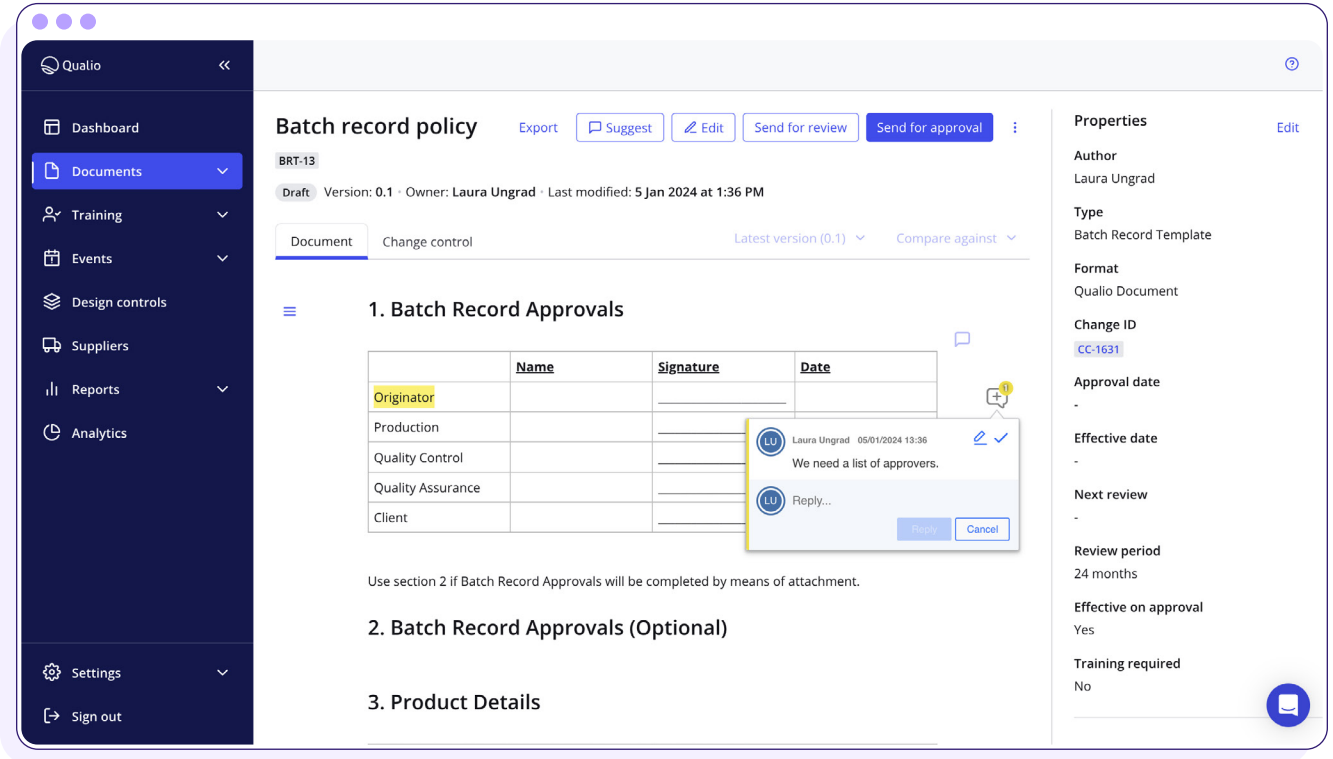
1 Document management for a bedrock of controlled information



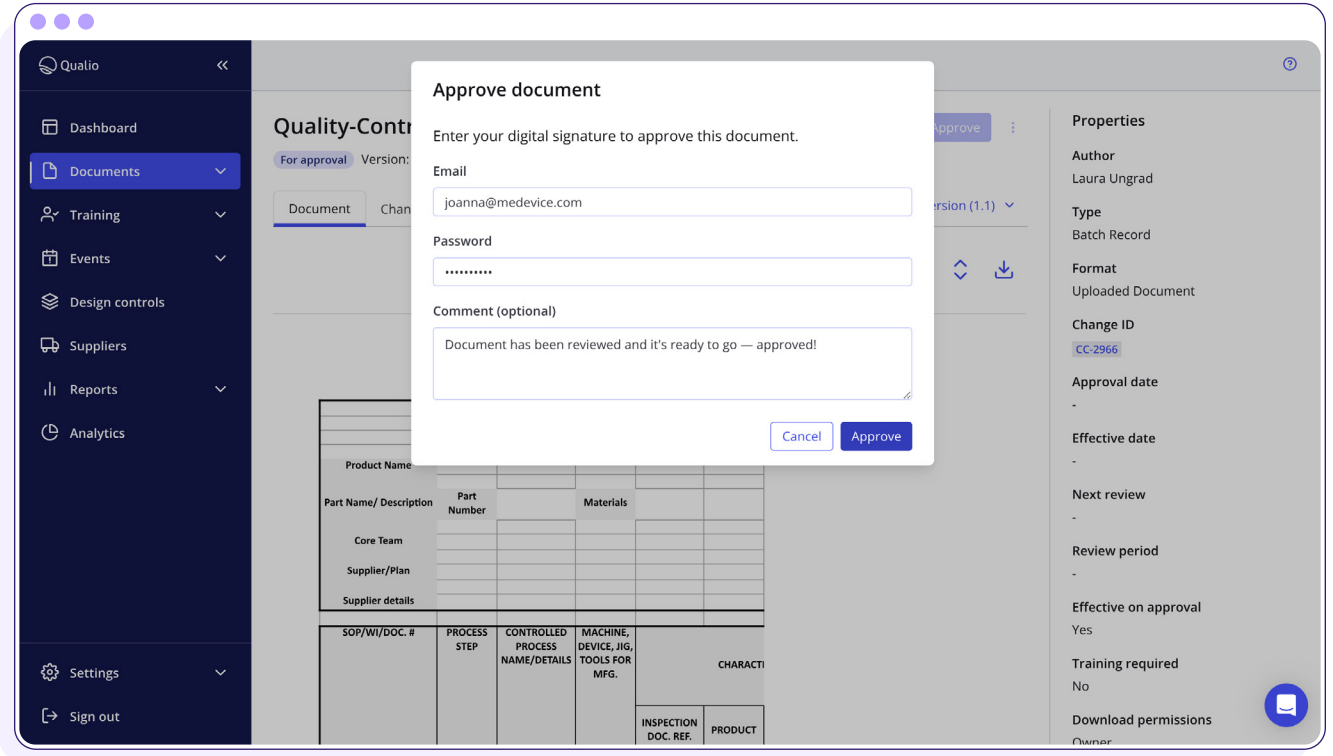
Incorruptible version control and audit trailing.

1 Document management for a bedrock of controlled information

Complete in-app document lifecycle management, from drafting and collaboration to approval, distribution and review.

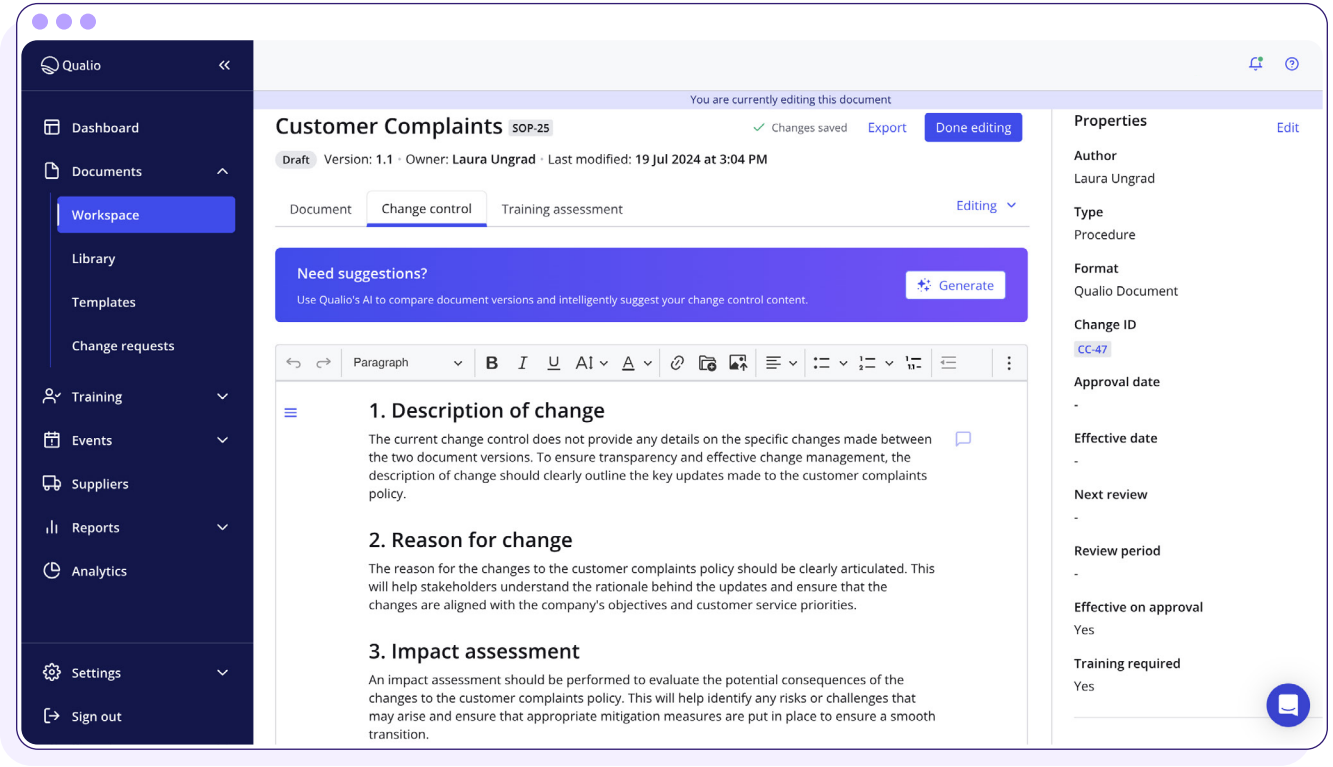


1 Document management for a bedrock of controlled information



Compliance with FDA and EU e-signature requirements.

1 Document management for a bedrock of controlled information

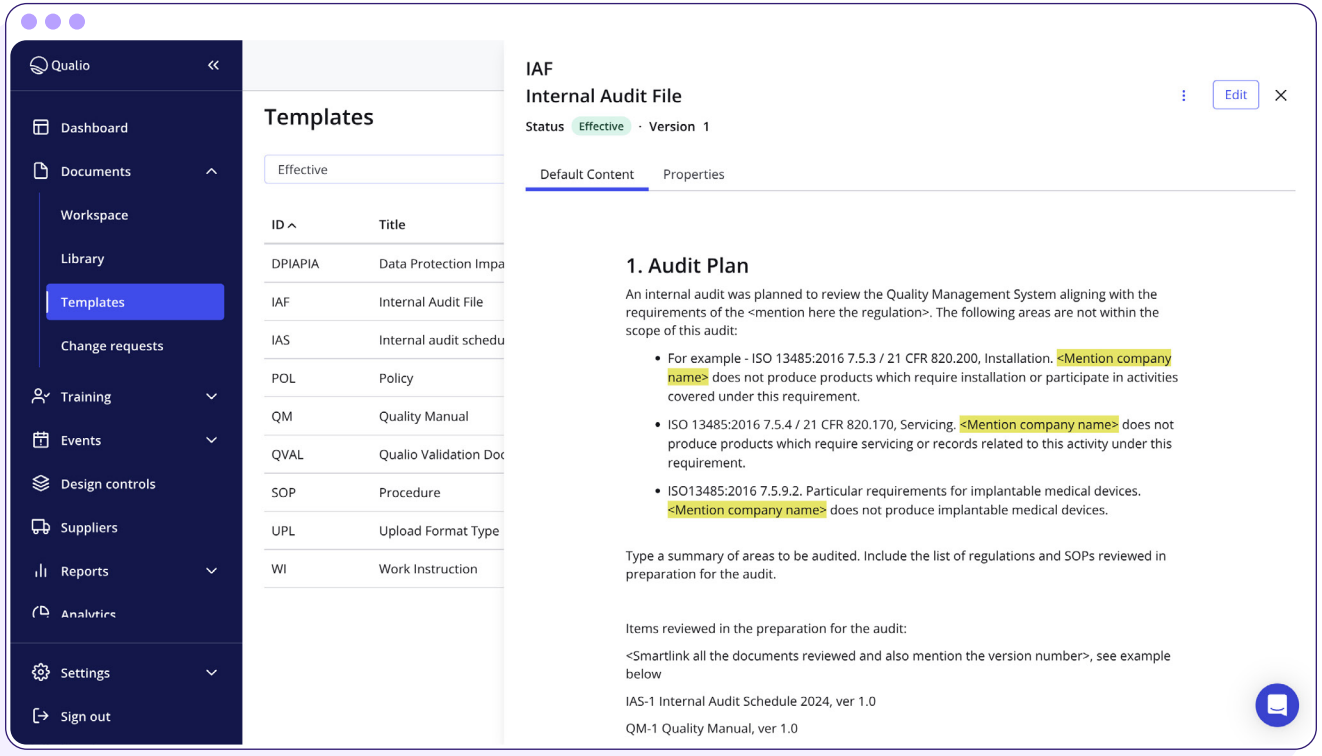


Supercharged, AI-powered document processes, and more!

1 Document management for a bedrock of controlled information

Get to market 6 months faster!

Qualio also provides over 100 pre-built, audit-tested and industry-specific document templates, from quality manuals and management reviews to risk management plans and SOPs, to save you the time-consuming work of building a quality document stack yourself. Simply populate and start using your template set to save yourself up to half a year of work and boost your quality maturity at a stroke.



1 Document management for a bedrock of controlled information

Complete in-app control
In-app document editor and powerful workflows let you seamlessly collaborate on the entire document lifecycle, from resolving comments to routing documents for training, without ever leaving the system

Hybrid document management
Manage your documents how you want to: sync updates from OneDrive, upload documents in their original formats, convert them to editable Qualio documents, or build them from scratch within Qualio

Inter-system connection
Build a central Qualio resource library of reusable core data objects, and apply them across your eQMS, from Documents to Events, for consistent data mapping

Smart linking
Link system documents to each other, to supplier records, to quality events and more with intuitive smart links that build a web of connected quality information

AI support
Apply powerful AI functionality for automatic change summaries as documents are updated, and even document content and language optimization

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

1 Document management for a bedrock of controlled information

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

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

Complete traceability
Drill into document change histories and audit trails for audit purposes

More resources

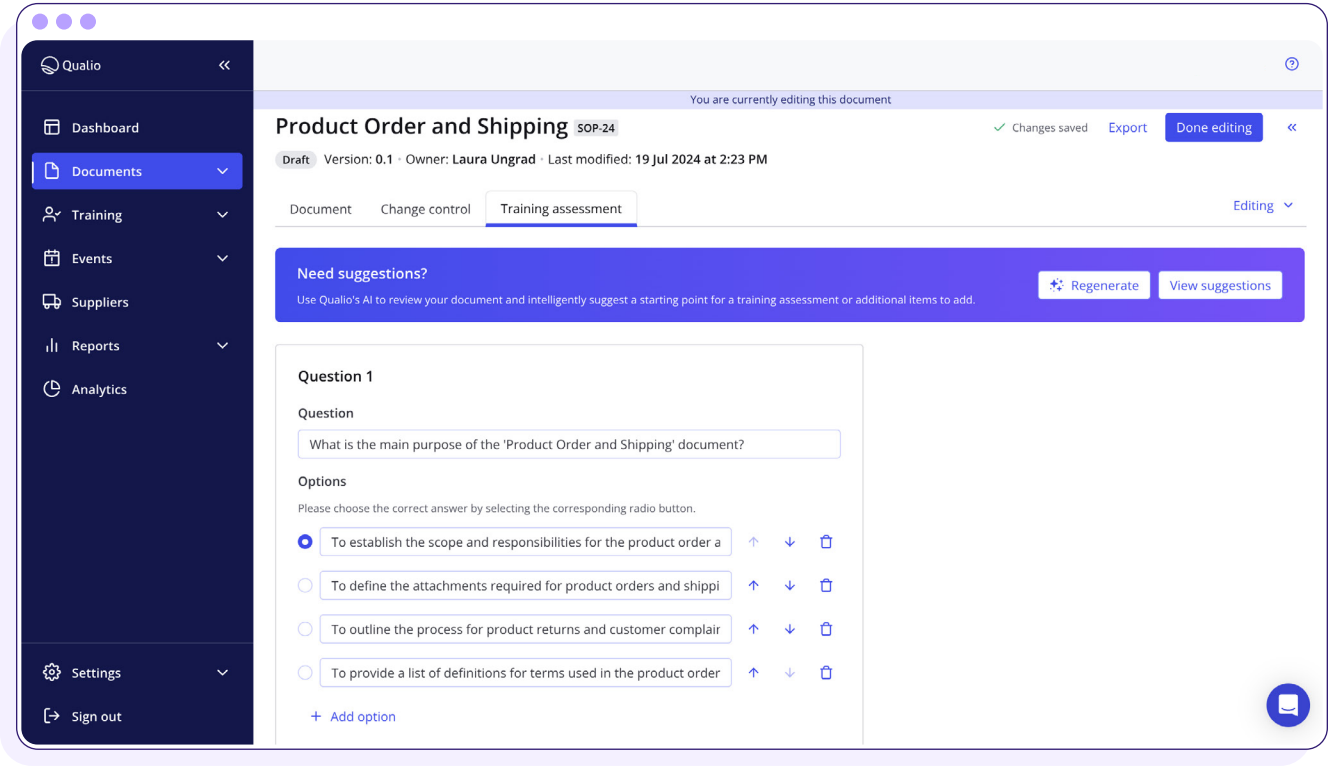
Why your life science business needs electronic document management ›
Document management software datasheet ›
Document management software webpage ›
1-minute document editor overview video ›

2 Easy training processes for a confident, compliant team

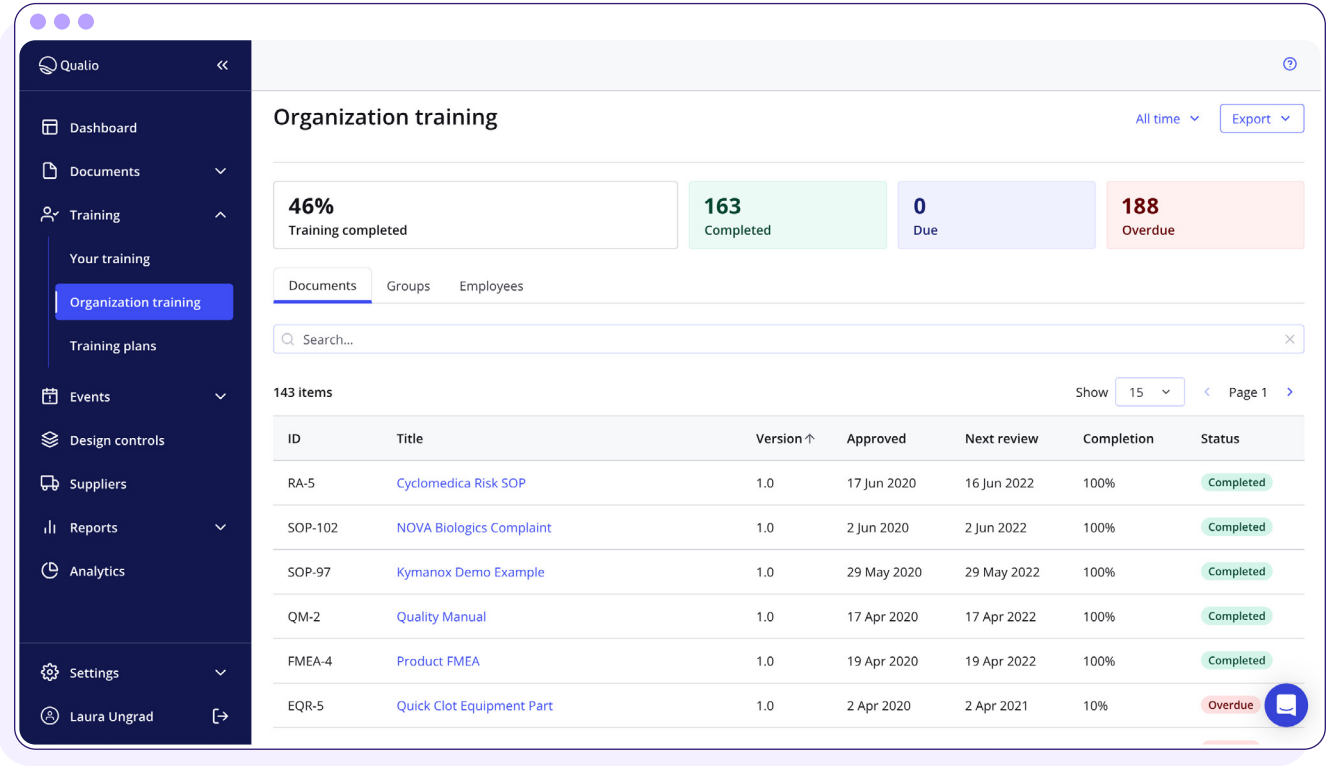
Qualio Training empowers your business with a complete framework for ensuring your workforce is competent, compliant and appropriately trained.

Use Qualio Training for:

> Planning, testing and managing employee competency.

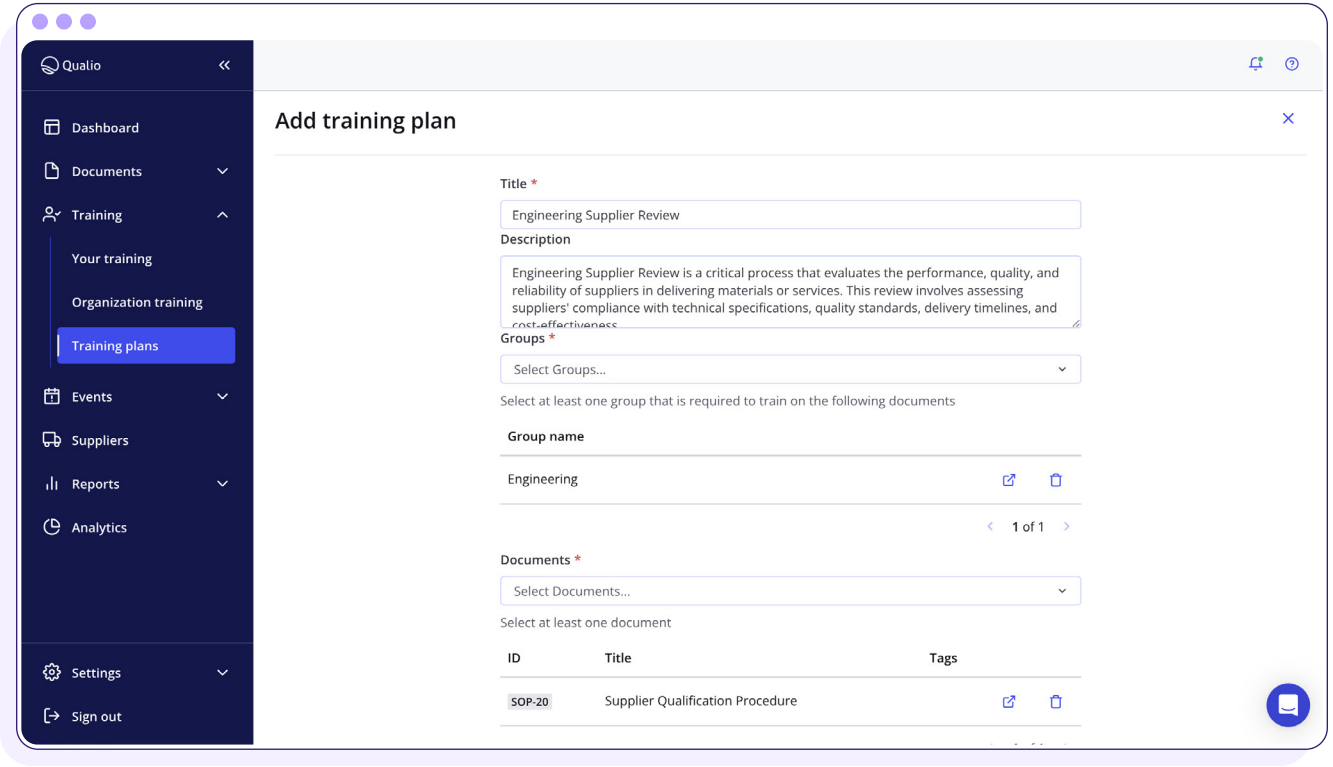


2 Easy training processes for a confident, compliant team



Plugging training gaps, maximizing compliance, and recording training.

2 Easy training processes for a confident, compliant team



Building easy e-training pathways your employees will follow.

2 Easy training processes for a confident, compliant team

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

At-a-glance understanding
View completed and outstanding training for individual documents, groups such as departments and teams, and for individual system users

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

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

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

Accelerated training processes with AI
Apply automatic, AI-generated training assessments as documents are built and updated

More resources

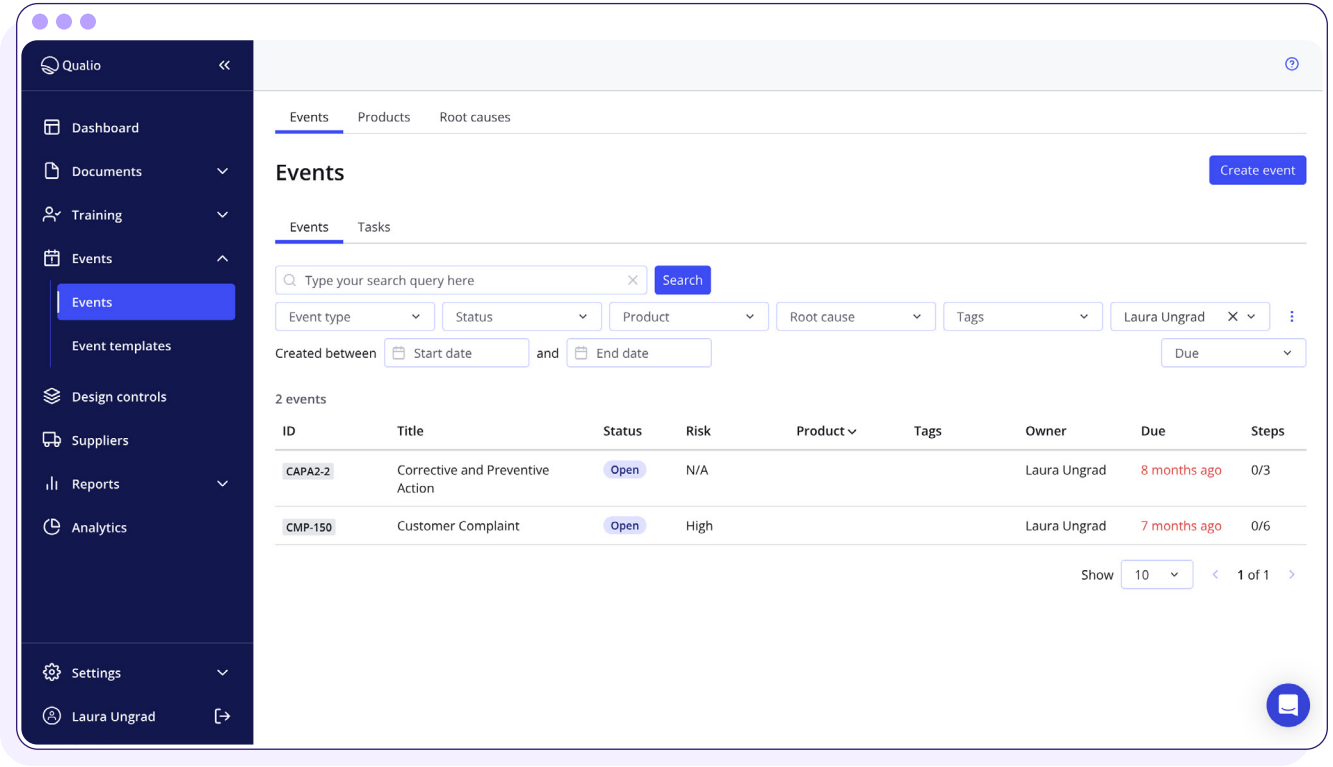
Training management software datasheet ›
Training management software webpage ›
Koneksa training case study ›

3 Event management for continuous quality improvement

Qualio Events allows your business to take consistent, collaborative and fully traceable action to manage quality events like defects, nonconformances, deviations and change controls.

Use Qualio Events for:

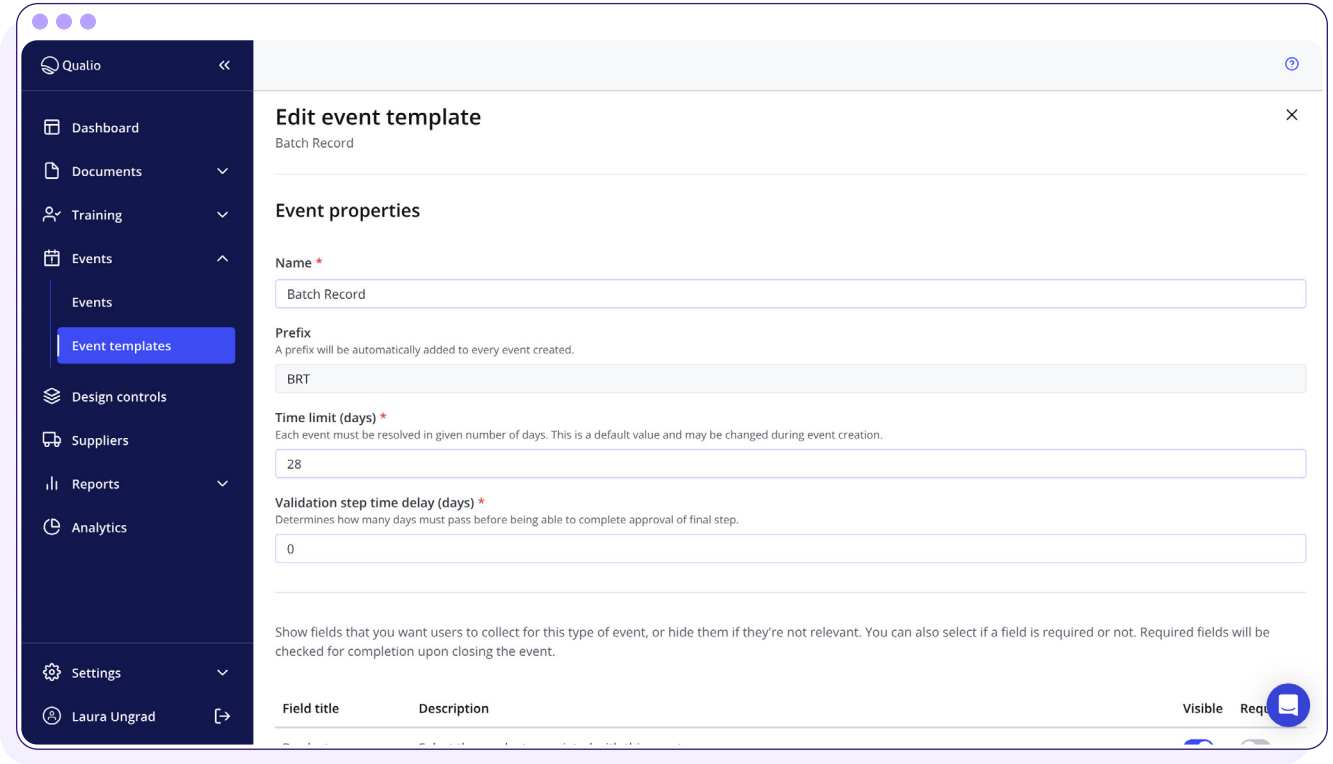
> Managing CAPAs, product issues, and any other quality event.



3 Event management for continuous quality improvement

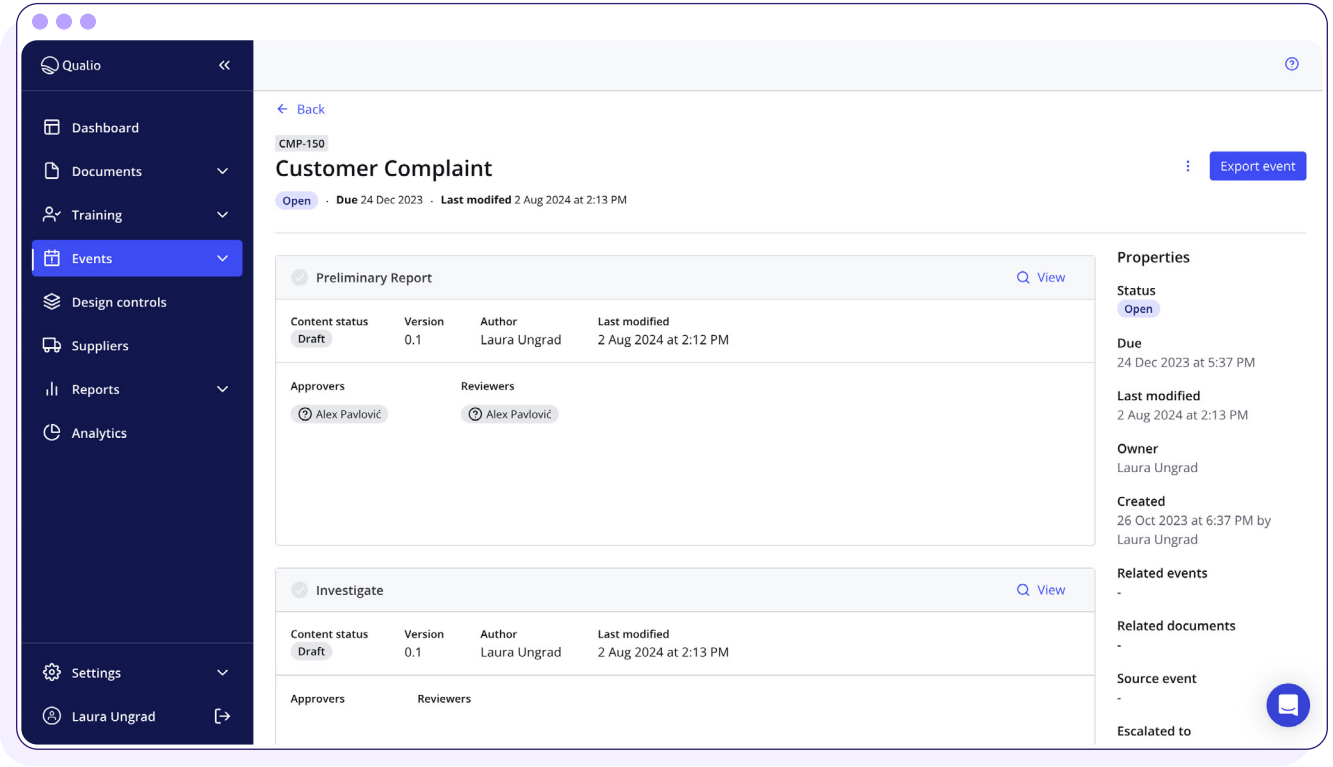
Driving actions to completion with templated workflow steps.

Understanding and fixing the real root cause.



3 Event management for continuous quality improvement

Assigning clear roles and responsibilities for responding to quality events



3 Event management for continuous quality improvement

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

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

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

Get the info you need
Fully flexible event templates let you build your own fields, apply forms and action steps, and use your own terminology to ensure information is captured how you want it to be

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

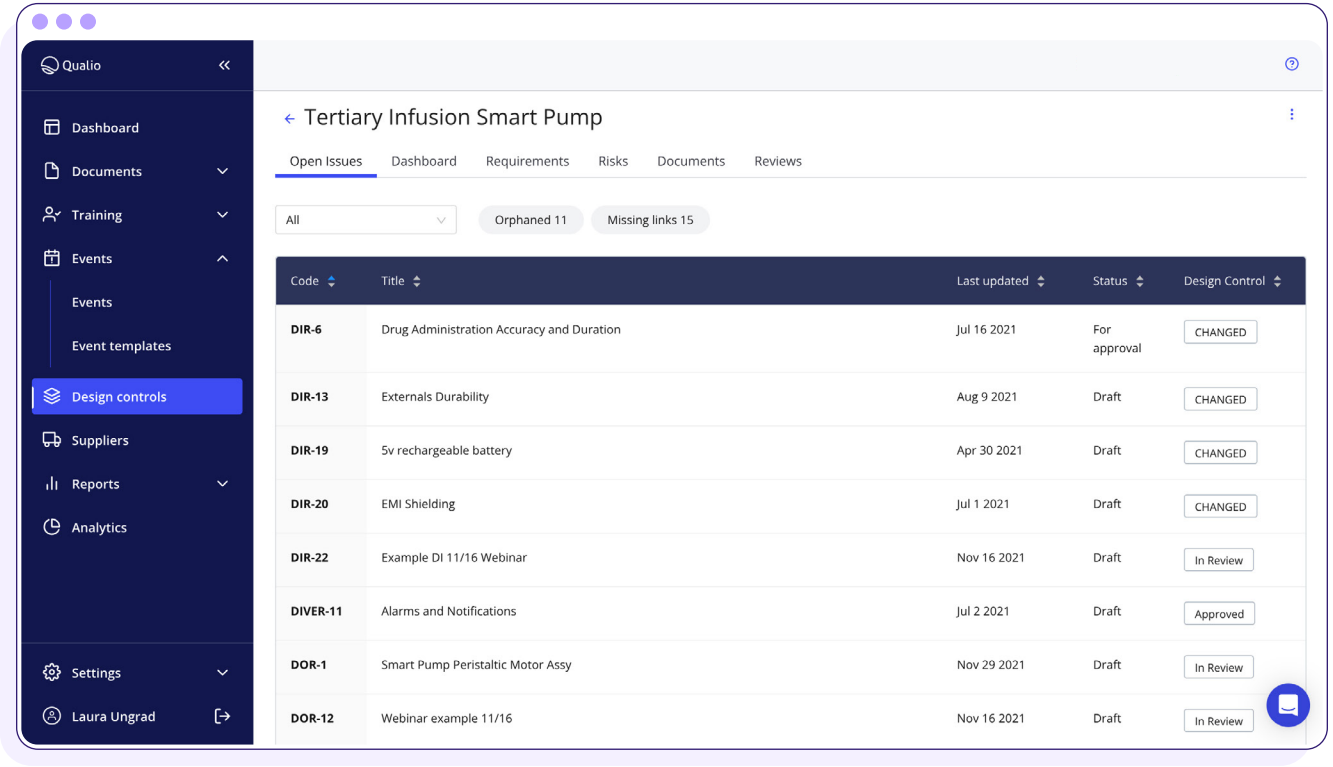
Templated workflows for consistency
Build bespoke event templates and workflows that connect your colleagues to ordered action steps, ensuring the right action is taken by the right person at the right time

4 Design control management for safe, effective medical devices

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

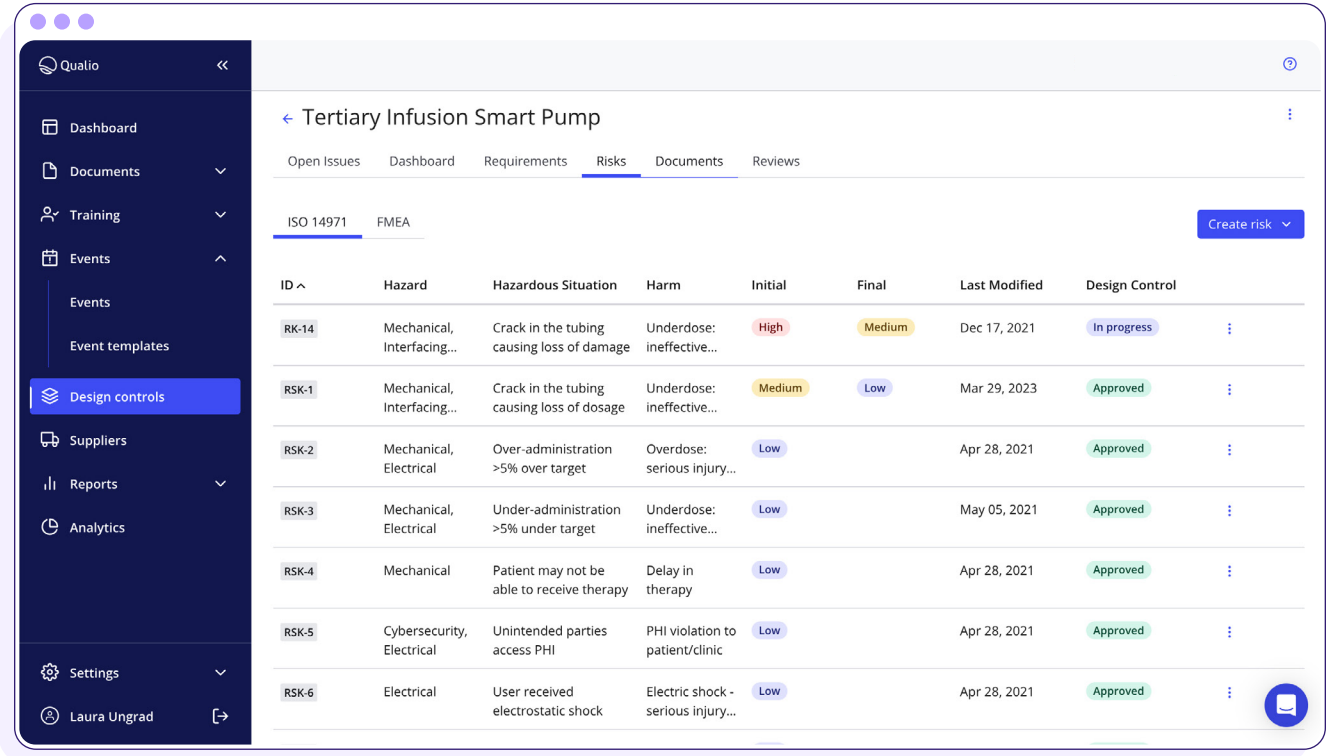
Use Qualio Design Controls for:

> Integrating with your product design tools like Jira and TestRail to automatically pull design elements straight into Qualio.



4 Design control management for safe, effective medical devices

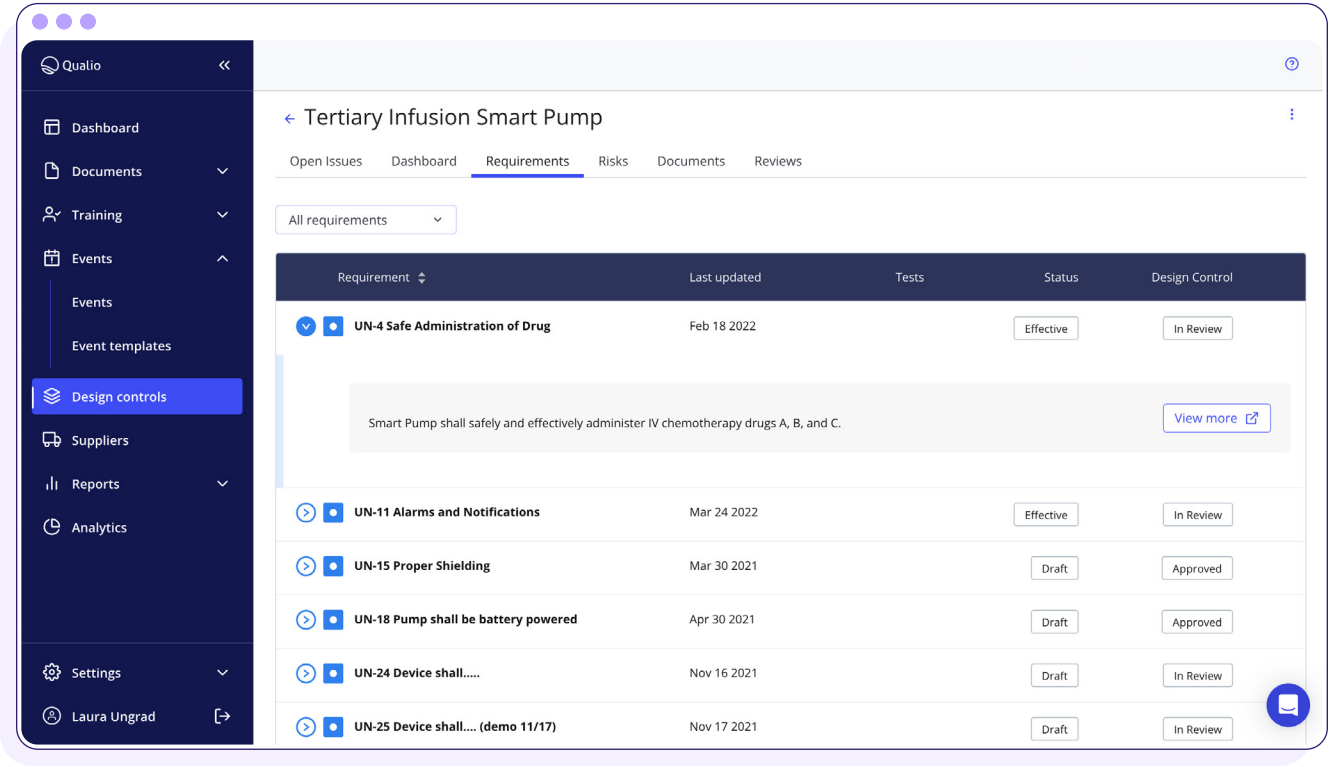
Applying ISO 14971 and FMEA methodology to product risks.



4 Design control management for safe, effective medical devices

Building a centralized and compliant design control document stack.

Collating requirements, inputs, outputs, issues and risks by product.



4 Design control management for safe, effective medical devices

Ordered design controls by product
Categorize your development activity in a single source of truth from user requirements to test data – all arranged by product

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

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

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

More resources

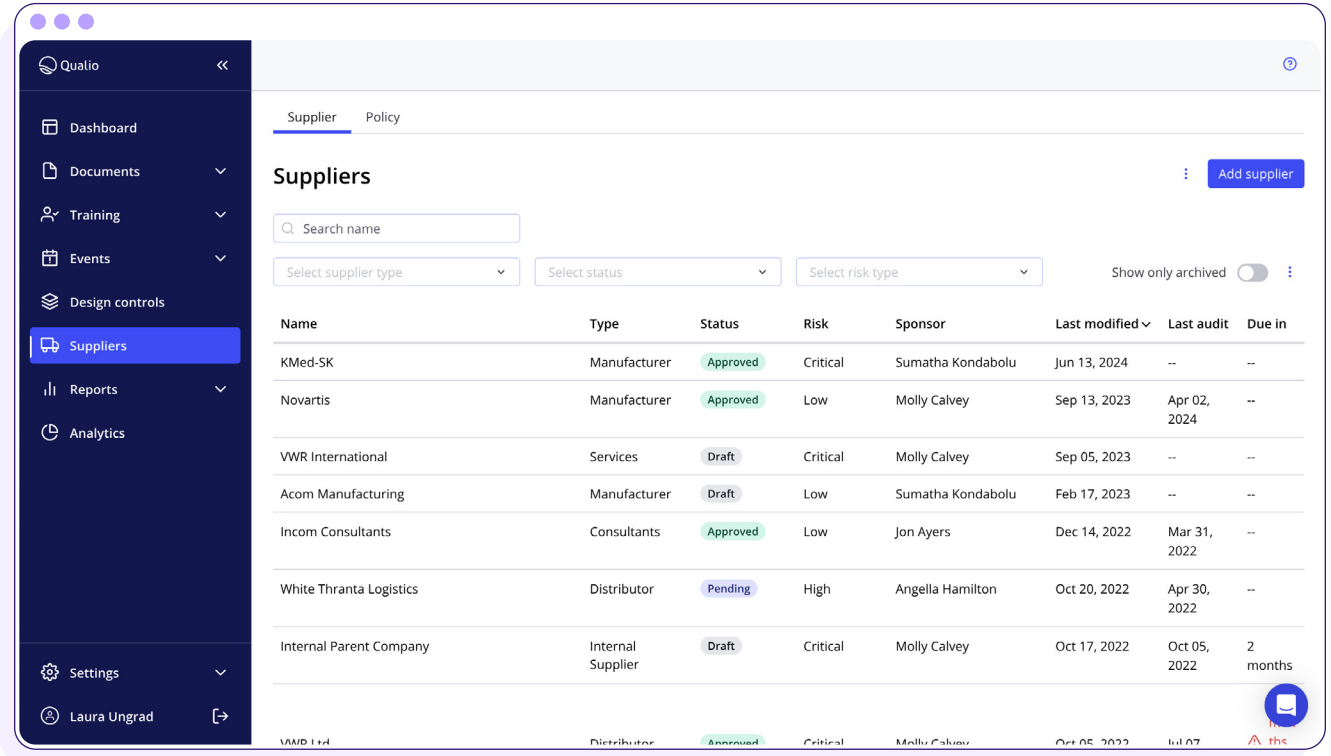
Design controls management software datasheet ›
Design controls software webpage ›
ISO 13485 toolkit ›

5 Supplier management for a healthy, controlled supply chain

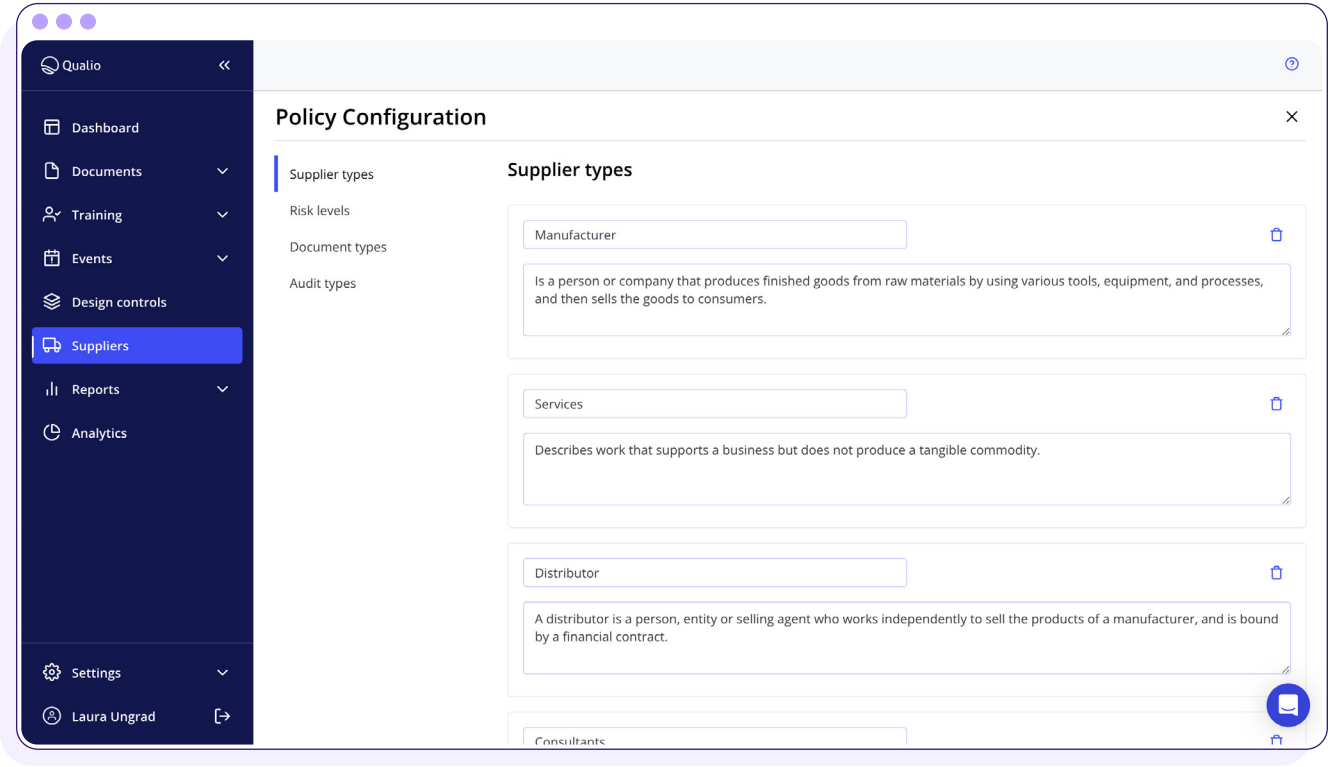
Qualio Suppliers gives your business a consistent, controlled and centralized approach to managing and coordinating supplier activity.

Use Qualio Suppliers to:

> Ditch spreadsheets and duplicated effort by harmonizing all supplier compliance information in a single source of truth.



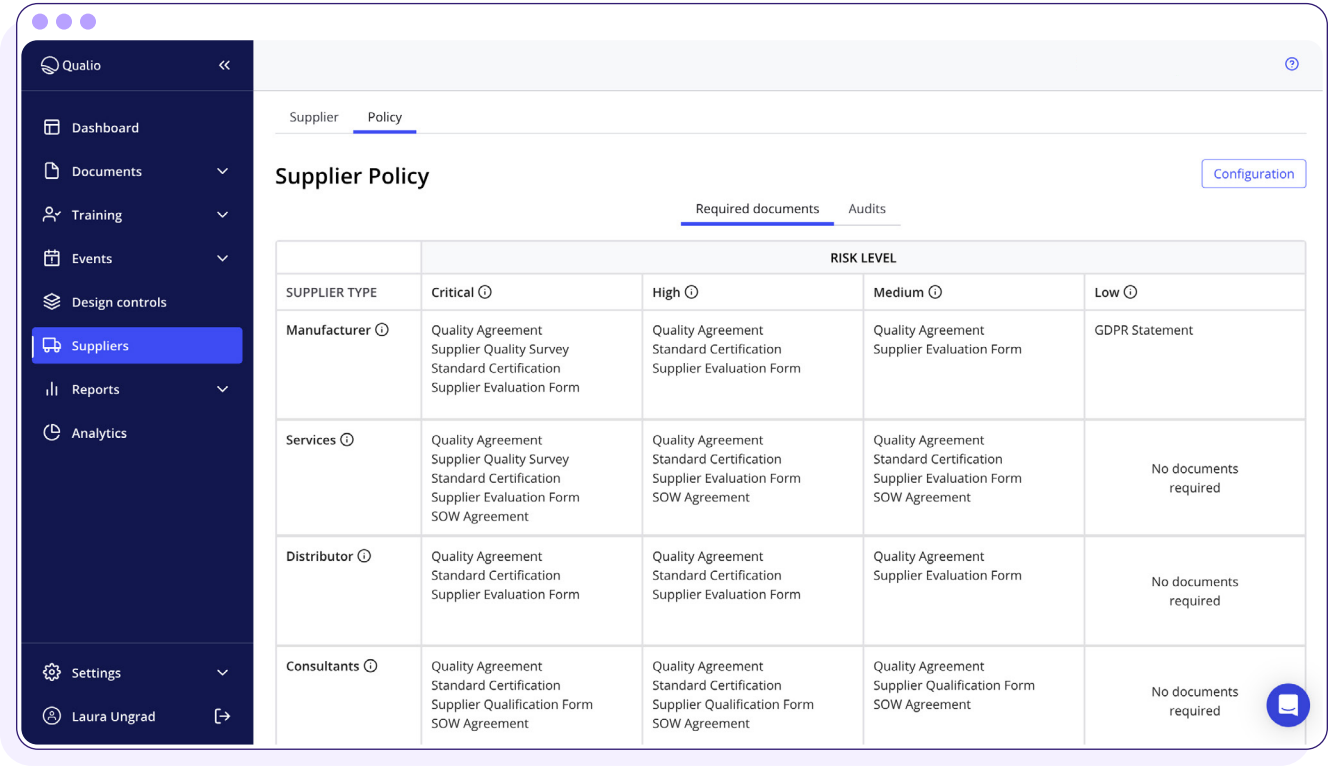
5 Supplier management for a healthy, controlled supply chain



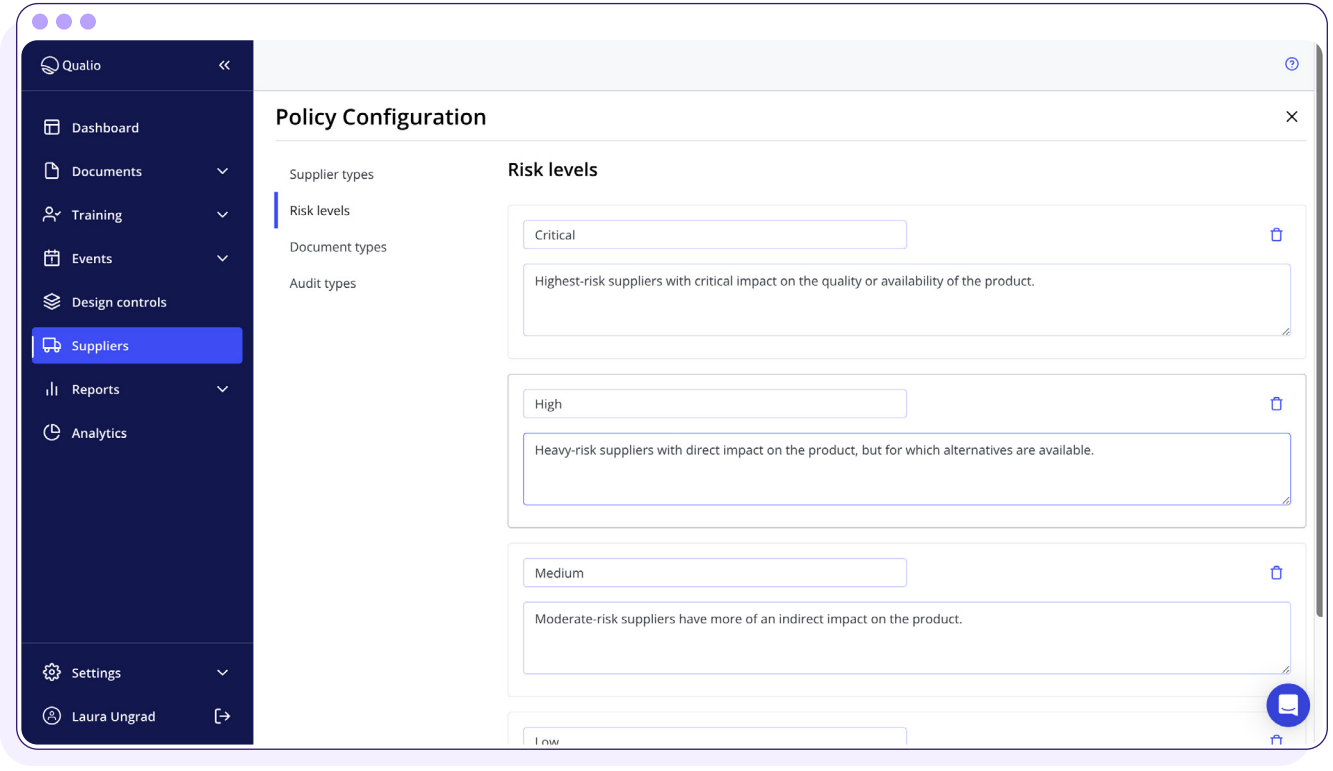
Configure bespoke policies for manufacturers, service providers, distributors, consultants and more. Then use them to enforce supplier requirements and ensure compliance.

5 Supplier management for a healthy, controlled supply chain

Link key documentation like quality agreements, SLAs, GDPR statements and SOC 2 reports to suppliers. Mandate document sets for specific supplier categories.



5 Supplier management for a healthy, controlled supply chain



Build bespoke risk levels, then assess and categorize suppliers accordingly for a full picture of your third-party risk environment.

5 Supplier management for a healthy, controlled supply chain

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

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

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

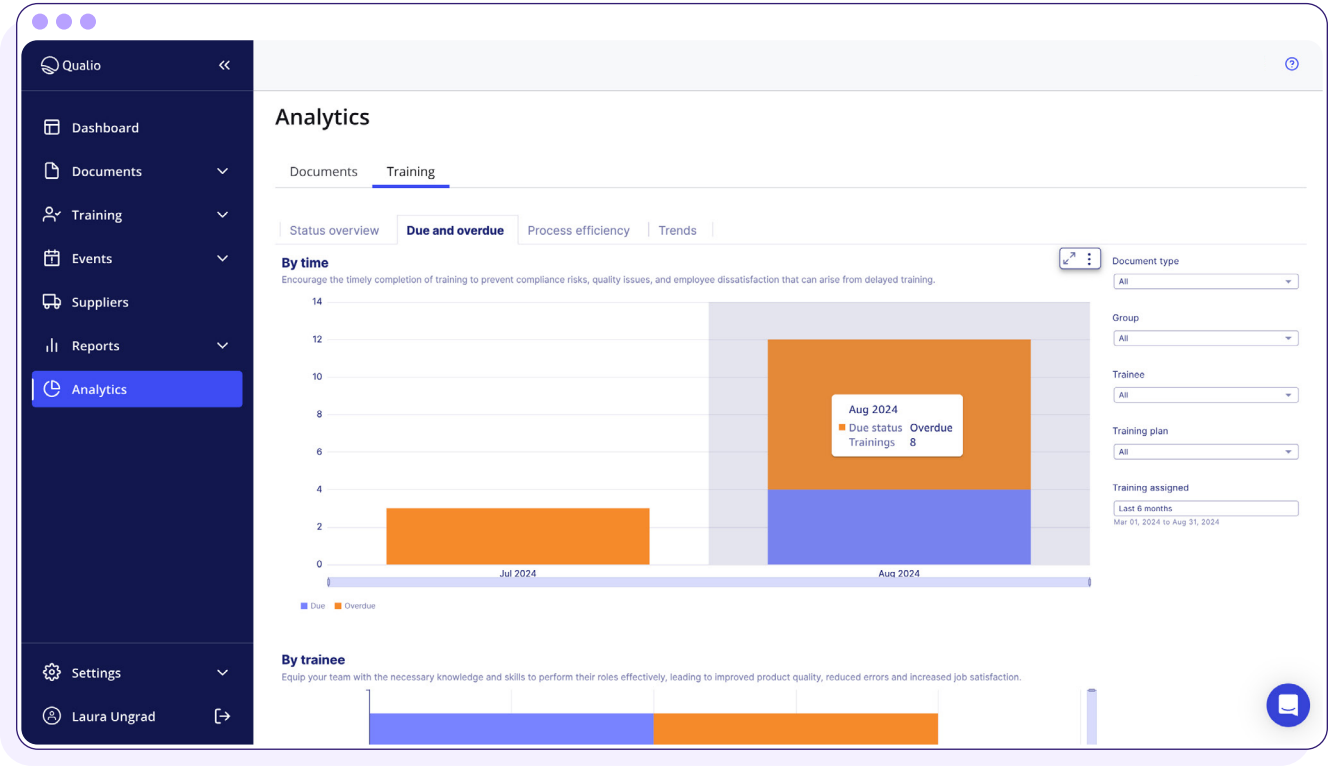
More resources
Supplier management software datasheet ›

6 Detailed analytics for data-driven insights

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

Use Qualio Analytics to:

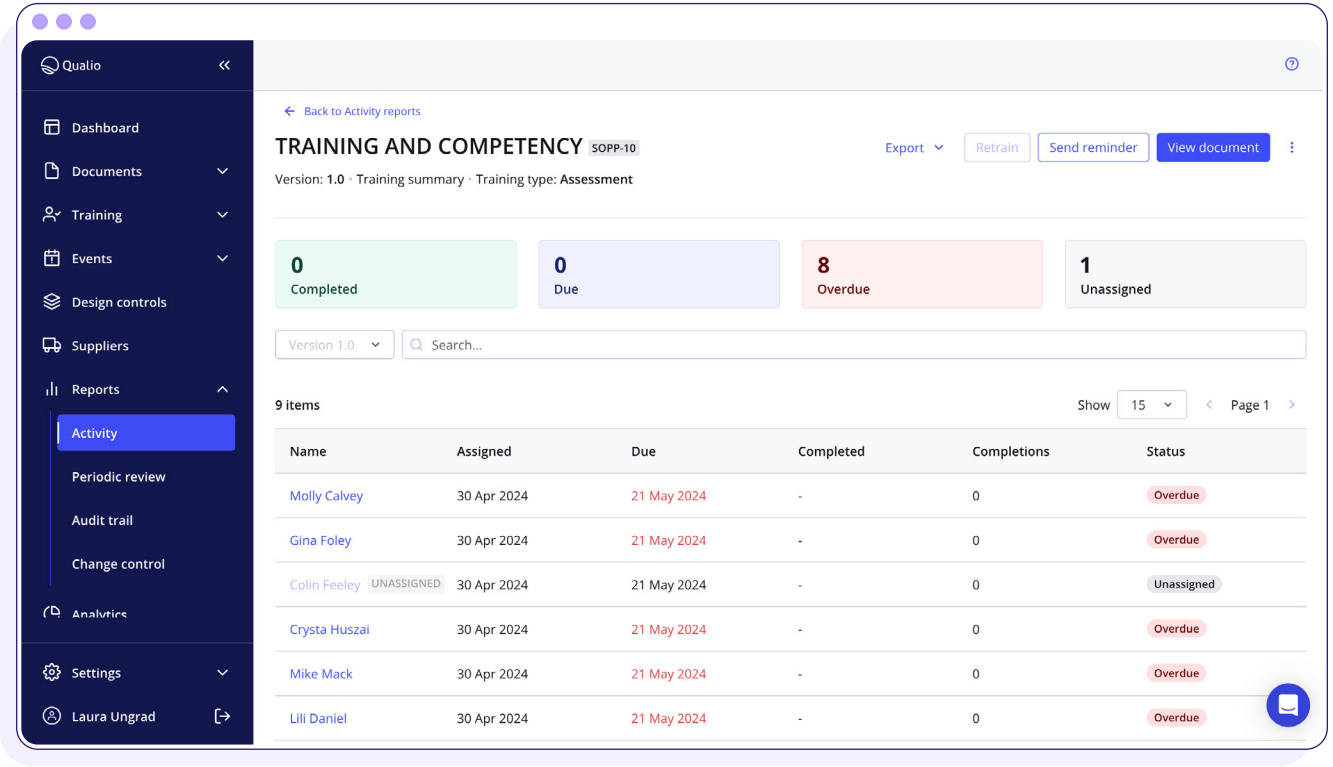
> Understand how your QMS works in real time.
>
> Make your company constantly audit-ready by spotting trends and underlying issues, then tracing actions to completion.



6 Detailed analytics for data-driven insights

Replace murky paper and spreadsheets with data-driven quality decisions.

Export and present QMS insights to colleagues, senior leadership and regulators.



6 Detailed analytics for data-driven insights

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

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

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.

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

More resources
Quality analytics datasheet ›

The ROI of Qualio

Qualio arms your business with a best-in-class digital framework that optimizes your quality and compliance maturity.

The financial impact can be considerable – and our customers report savings in a matter of months.

Get your ROI figure ›

$1 not properly spent on proactive nonconformance prevention =

$10 of extra appraisal costs

$100 of extra remediation costs

Paper-based quality systems in small businesses cost:

20% of employee time lost searching for information

$27K a year in production, usage, storage and maintenance costs

Every day the average life science product is kept from the US market =

$136K in lost revenue

Suboptimal quality processes cost the average med device company:

≈8% of annual revenue

Cost to amend a clinical trial in progress:

$141K Phase II

$535K Phase III

$8m Average cost of a product recall

$400K Average cost of an FDA warning letter

12 reasons to manage your quality with Qualio

Hear from our customers!
Explore our successful customer stories ›

1. Dedicated life science eQMS vendor with over 650 regulated customers
2. Clean and intuitive UX with ease of use at the forefront to maximize engagement
3. Flexible content management to build, import and distribute quality information how you want to
4. Only in-app doc editor in a life science eQMS
5. Secure cloud-based access from anywhere
6. Collaborative, visualized and scalable digital processes knit your organization's culture of quality together
7. Audit trailing, e-signatures and action histories for total compliance
8. Pre-built document templates for instant market readiness
9. Lean, cost-effective quality and compliance without extra headcount
10. Deep analytics to keep on top of your quality landscape
11. Voted the best eQMS for setup, support, usability and implementation on G2
12. AI functionality to automate and accelerate work

Qualio

Take control of your quality and compliance

We'll answer your questions, give you a live tour of Qualio and help you determine if we're a good fit for your organization.

Schedule a demo with us