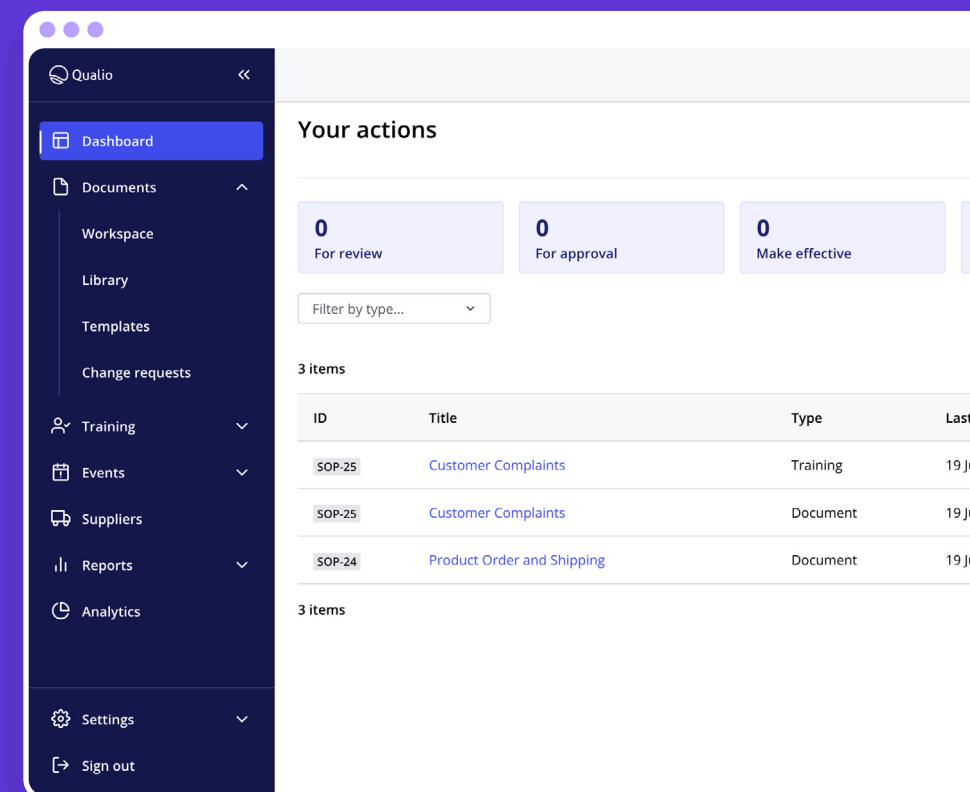




# Qualio

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.

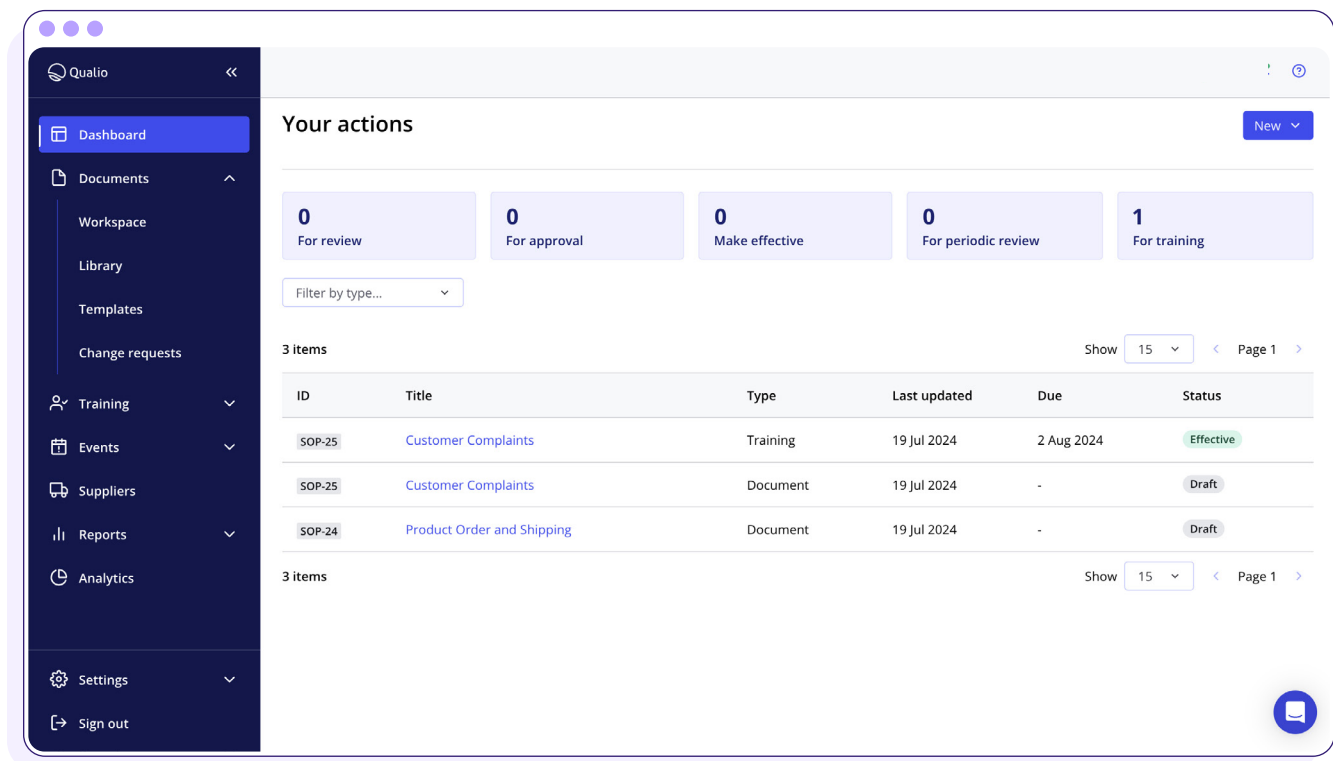
To see Qualio in more detail, including a walkthrough of the system in action, just visit the last page to book a demonstration with us!

# 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.

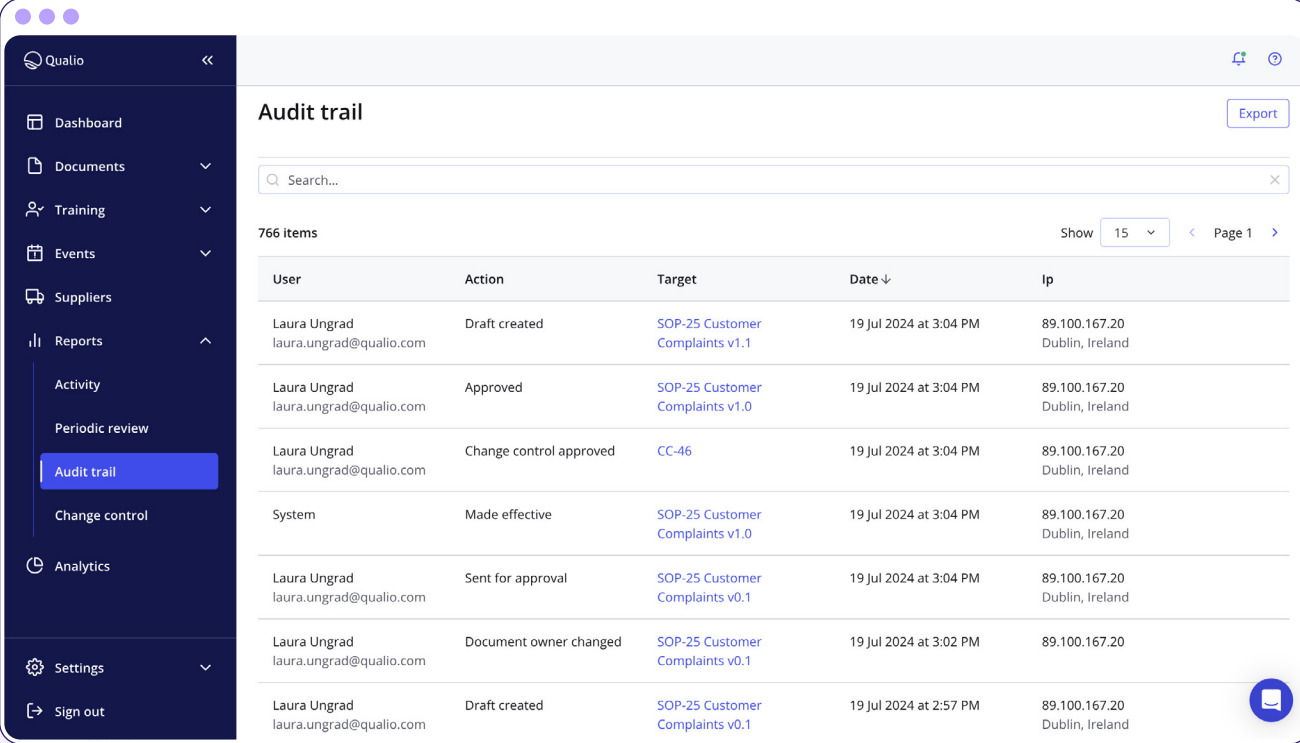
Use Qualio Documents for:

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.



The screenshot displays the Qualio 'Audit trail' interface. On the left is a dark sidebar with navigation options: Dashboard, Documents, Training, Events, Suppliers, Reports (expanded), Activity, Periodic review, Audit trail (selected), Change control, Analytics, Settings, and Sign out. The main panel is titled 'Audit trail' and includes a search bar, a count of '766 items', and a 'Show 15' dropdown. Below this is a table with columns: User, Action, Target, Date, and Ip. The table lists several events, including document creation, approval, change control, and system updates, all dated July 19, 2024.

User	Action	Target	Date ↓	Ip
Laura Ungrad laura.ungrad@qualio.com	Draft created	<a href="#">SOP-25 Customer Complaints v1.1</a>	19 Jul 2024 at 3:04 PM	89.100.167.20 Dublin, Ireland
Laura Ungrad laura.ungrad@qualio.com	Approved	<a href="#">SOP-25 Customer Complaints v1.0</a>	19 Jul 2024 at 3:04 PM	89.100.167.20 Dublin, Ireland
Laura Ungrad laura.ungrad@qualio.com	Change control approved	<a href="#">CC-46</a>	19 Jul 2024 at 3:04 PM	89.100.167.20 Dublin, Ireland
System	Made effective	<a href="#">SOP-25 Customer Complaints v1.0</a>	19 Jul 2024 at 3:04 PM	89.100.167.20 Dublin, Ireland
Laura Ungrad laura.ungrad@qualio.com	Sent for approval	<a href="#">SOP-25 Customer Complaints v0.1</a>	19 Jul 2024 at 3:04 PM	89.100.167.20 Dublin, Ireland
Laura Ungrad laura.ungrad@qualio.com	Document owner changed	<a href="#">SOP-25 Customer Complaints v0.1</a>	19 Jul 2024 at 3:02 PM	89.100.167.20
Laura Ungrad laura.ungrad@qualio.com	Draft created	<a href="#">SOP-25 Customer Complaints v0.1</a>	19 Jul 2024 at 2:57 PM	89.100.167.20 Dublin, Ireland



# 1 Document management for a bedrock of controlled information

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

The screenshot displays the Qualio web application interface. On the left is a dark sidebar with navigation links: Dashboard, Documents (selected), Training, Events, Design controls, Suppliers, Reports, Analytics, Settings, and Sign out. The main content area is titled 'Batch record policy' and includes buttons for Export, Suggest, Edit, Send for review, and Send for approval. Below the title, it shows 'BRT-13' and 'Draft' status, with version 0.1, owner Laura Ungrad, and a last modified date of 5 Jan 2024 at 1:36 PM. A 'Document' tab is active, showing 'Change control' and 'Latest version (0.1)'.

The main section is titled '1. Batch Record Approvals' and contains a table with columns: Name, Signature, and Date. The table has rows for Originator, Production, Quality Control, Quality Assurance, and Client. A modal dialog is open over the table, showing a comment from Laura Ungrad dated 05/01/2024 13:36: 'We need a list of approvers.' with a 'Reply...' button and a 'Cancel' button.

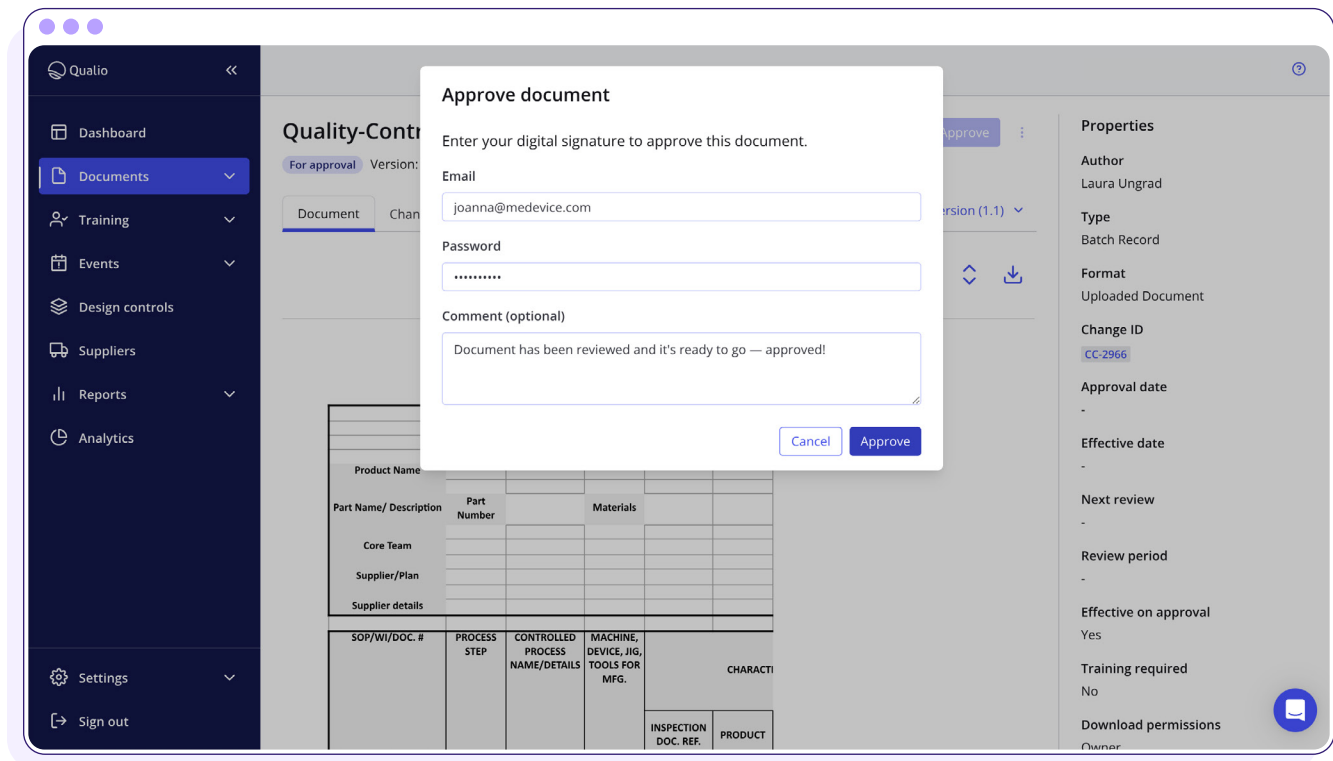
Below the table, it states: 'Use section 2 if Batch Record Approvals will be completed by means of attachment.'

The right sidebar shows 'Properties' for the document, including Author (Laura Ungrad), Type (Batch Record Template), Format (Qualio Document), Change ID (CC-1631), Approval date, Effective date, Next review, Review period (24 months), Effective on approval (Yes), and Training required (No).

Below the main content area, there are sections for '2. Batch Record Approvals (Optional)' and '3. Product Details'.

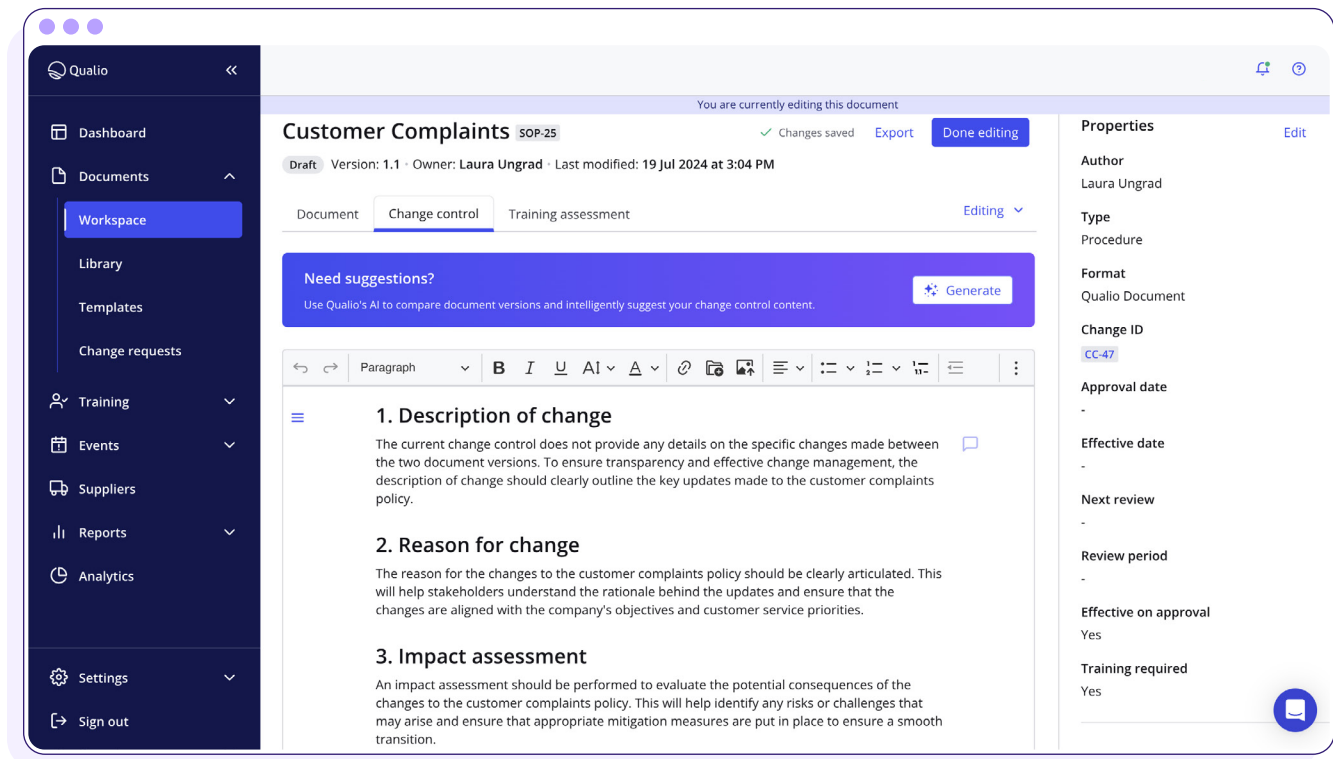
# 1 Document management for a bedrock of controlled information

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.

The screenshot displays the Qualio software interface. On the left is a dark sidebar with a navigation menu including Dashboard, Documents, Workspace, Library, Templates (highlighted), Change requests, Training, Events, Design controls, Suppliers, Reports, Analytics, Settings, and Sign out. The main content area is titled 'Templates' and shows a list of templates with columns for ID and Title. The 'Effective' filter is selected. The list includes templates for DPIAPIA, IAF, IAS, POL, QM, QVAL, SOP, UPL, and WI. The 'IAF' (Internal Audit File) template is selected, showing its status as 'Effective' and version '1'. The template content is displayed in a two-tab view: 'Default Content' and 'Properties'. The 'Default Content' tab shows the '1. Audit Plan' section, which includes a paragraph about the internal audit and a bulleted list of areas to be audited. The 'Properties' tab is currently empty.

ID	Title
DPIAPIA	Data Protection Impa
IAF	Internal Audit File
IAS	Internal audit schedu
POL	Policy
QM	Quality Manual
QVAL	Qualio Validation Doc
SOP	Procedure
UPL	Upload Format Type
WI	Work Instruction

### 1. Audit Plan

An internal audit was planned to review the Quality Management System aligning with the requirements of the <mention here the regulation>. The following areas are not within the scope of this audit:

- For example - ISO 13485:2016 7.5.3 / 21 CFR 820.200, Installation. <Mention company name> does not produce products which require installation or participate in activities covered under this requirement.
- ISO 13485:2016 7.5.4 / 21 CFR 820.170, Servicing. <Mention company name> does not produce products which require servicing or records related to this activity under this requirement.
- ISO13485:2016 7.5.9.2. Particular requirements for implantable medical devices. <Mention company name> does not produce implantable medical devices.

Type a summary of areas to be audited. Include the list of regulations and SOPs reviewed in preparation for the audit.

Items reviewed in the preparation for the audit:

<Smartlink all the documents reviewed and also mention the version number>, see example below

IAS-1 Internal Audit Schedule 2024, ver 1.0

QM-1 Quality Manual, ver 1.0

# 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 ›](#)

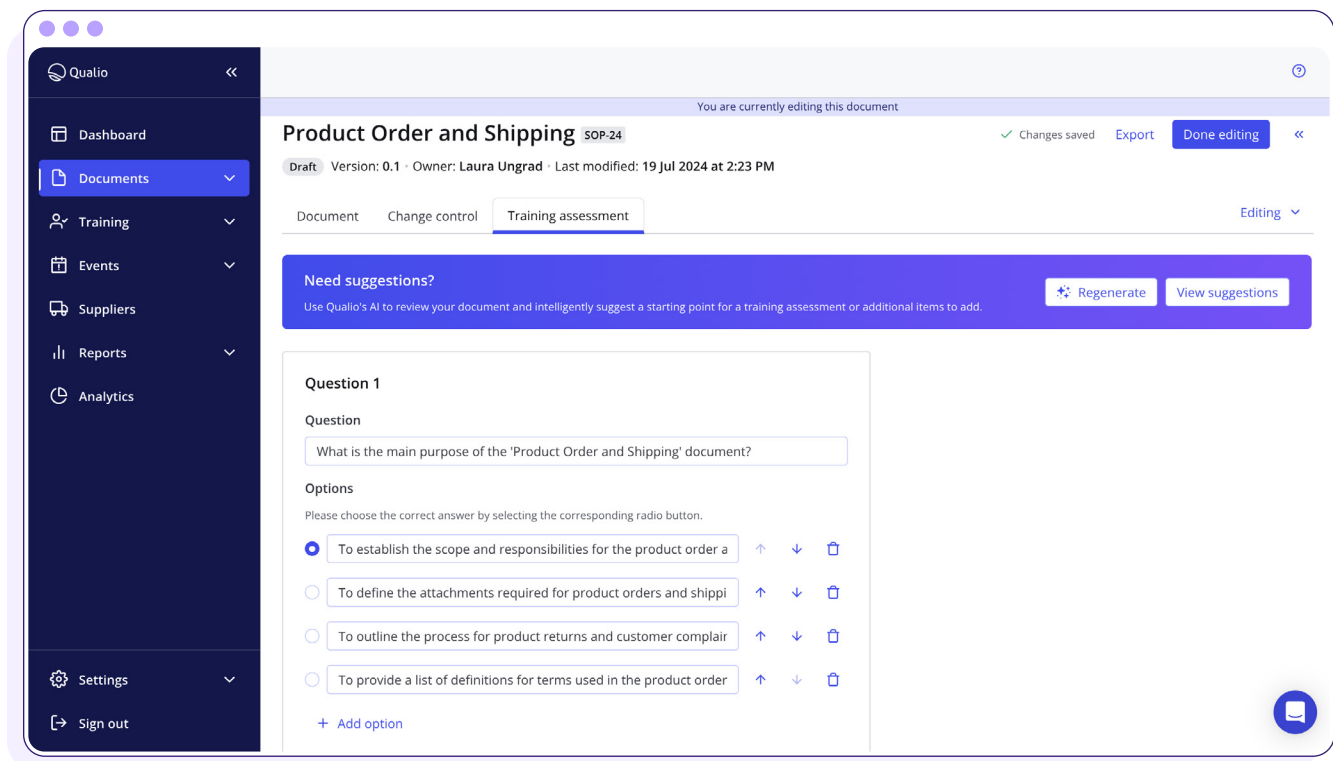
[1-minute document editor overview video ›](#)

## 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.

**Organization training** All time Export

**46%** Training completed **163** Completed **0** Due **188** Overdue

Documents Groups Employees

Search...

143 items Show 15 Page 1

ID	Title	Version ↑	Approved	Next review	Completion	Status
RA-5	<a href="#">Cyclomedica Risk SOP</a>	1.0	17 Jun 2020	16 Jun 2022	100%	Completed
SOP-102	<a href="#">NOVA Biologics Complaint</a>	1.0	2 Jun 2020	2 Jun 2022	100%	Completed
SOP-97	<a href="#">Kymanox Demo Example</a>	1.0	29 May 2020	29 May 2022	100%	Completed
QM-2	<a href="#">Quality Manual</a>	1.0	17 Apr 2020	17 Apr 2022	100%	Completed
FMEA-4	<a href="#">Product FMEA</a>	1.0	19 Apr 2020	19 Apr 2022	100%	Completed
EQR-5	<a href="#">Quick Clot Equipment Part</a>	1.0	2 Apr 2020	2 Apr 2021	10%	Overdue

Qualio Dashboard Documents Training Your training Organization training Training plans Events Design controls Suppliers Reports Analytics Settings Laura Ungrad



## 2 Easy training processes for a confident, compliant team

Building easy e-training pathways your employees will follow.

The screenshot shows the Qualio web application interface for adding a new training plan. On the left is a dark blue sidebar with navigation links: Dashboard, Documents, Training (expanded), Your training, Organization training, Training plans (highlighted), Events, Suppliers, Reports, Analytics, Settings, and Sign out. The main content area is titled 'Add training plan' and contains the following fields:

- Title \***: A text input field containing 'Engineering Supplier Review'.
- Description**: A text area containing 'Engineering Supplier Review is a critical process that evaluates the performance, quality, and reliability of suppliers in delivering materials or services. This review involves assessing suppliers' compliance with technical specifications, quality standards, delivery timelines, and cost-effectiveness.'
- Groups \***: A dropdown menu showing 'Select Groups...'. Below it, a note says 'Select at least one group that is required to train on the following documents'.
- Group name**: A table with one row containing 'Engineering' and two action icons (edit and delete).
- Documents \***: A dropdown menu showing 'Select Documents...'. Below it, a note says 'Select at least one document'.
- Table**: A table with columns ID, Title, and Tags. It contains one row: ID 'SOP-20', Title 'Supplier Qualification Procedure', and two action icons (edit and delete).

At the bottom right of the interface is a blue circular chat icon.

## 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 ›](#)

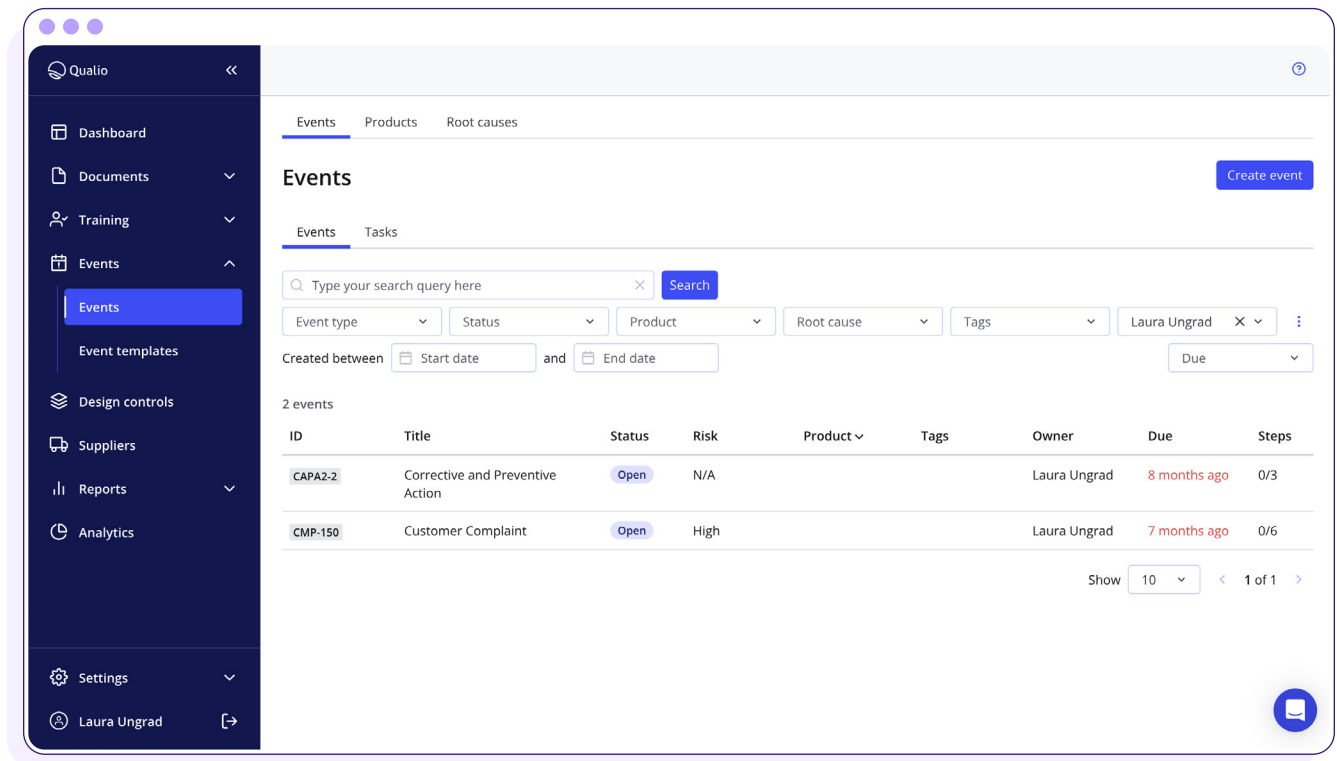
[Koneksa training case study ›](#)

# 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.

The screenshot shows the 'Edit event template' interface in the Qualio application. The left sidebar contains a navigation menu with options: Dashboard, Documents, Training, Events, Event templates (highlighted), Design controls, Suppliers, Reports, and Analytics. The main content area is titled 'Edit event template' and includes a 'Batch Record' sub-header. Below this, the 'Event properties' section contains several input fields: 'Name' (with a red asterisk) containing 'Batch Record', 'Prefix' (containing 'BRT' with a note 'A prefix will be automatically added to every event created.'), 'Time limit (days)' (with a red asterisk, containing '28' and a note 'Each event must be resolved in given number of days. This is a default value and may be changed during event creation.'), and 'Validation step time delay (days)' (with a red asterisk, containing '0' and a note 'Determines how many days must pass before being able to complete approval of final step.'). At the bottom, there is a section for 'Show fields that you want users to collect for this type of event, or hide them if they're not relevant. You can also select if a field is required or not. Required fields will be checked for completion upon closing the event.' This section includes a table with columns 'Field title', 'Description', 'Visible', and 'Required'. The user 'Laura Ungrad' is logged in, and a help icon is visible in the bottom right corner.

Field title	Description	Visible	Required
-------------	-------------	---------	----------

# 3 Event management for continuous quality improvement

Assigning clear roles and responsibilities for responding to quality events

The screenshot displays the Qualio web application interface for managing quality events. The left sidebar contains navigation links: Dashboard, Documents, Training, Events (highlighted), Design controls, Suppliers, Reports, and Analytics. The main content area shows a 'Customer Complaint' event page. At the top, there's a 'Back' link and event details: CMP-150, Status: Open, Due: 24 Dec 2023, Last modified: 2 Aug 2024 at 2:13 PM, and an 'Export event' button. Below this, the 'Preliminary Report' section is active, showing a table with columns: Content status (Draft), Version (0.1), Author (Laura Ungrad), and Last modified (2 Aug 2024 at 2:12 PM). It also lists Approvers and Reviewers, with Alex Pavlović assigned as a reviewer. The 'Investigate' section below it is currently empty. On the right, the 'Properties' sidebar provides additional event details: Status (Open), Due (24 Dec 2023 at 5:37 PM), Last modified (2 Aug 2024 at 2:13 PM), Owner (Laura Ungrad), Created (26 Oct 2023 at 6:37 PM by Laura Ungrad), and Related events/documents.

# 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.

The screenshot shows the Qualio Design Controls interface for a project titled 'Tertiary Infusion Smart Pump'. The left sidebar contains a navigation menu with options: Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, and Analytics. The main content area has tabs for Open Issues, Dashboard, Requirements, Risks, Documents, and Reviews. Below the tabs, there are filters for 'All', 'Orphaned 11', and 'Missing links 15'. A table lists design controls with columns for Code, Title, Last updated, Status, and Design Control. The table contains 12 rows of data.

Code	Title	Last updated	Status	Design Control
DIR-6	Drug Administration Accuracy and Duration	Jul 16 2021	For approval	CHANGED
DIR-13	Externals Durability	Aug 9 2021	Draft	CHANGED
DIR-19	5v rechargeable battery	Apr 30 2021	Draft	CHANGED
DIR-20	EMI Shielding	Jul 1 2021	Draft	CHANGED
DIR-22	Example DI 11/16 Webinar	Nov 16 2021	Draft	In Review
DIVER-11	Alarms and Notifications	Jul 2 2021	Draft	Approved
DOR-1	Smart Pump Peristaltic Motor Assy	Nov 29 2021	Draft	In Review
DOR-12	Webinar example 11/16	Nov 16 2021	Draft	In Review

# 4 Design control management for safe, effective medical devices

Applying ISO 14971 and FMEA methodology to product risks.

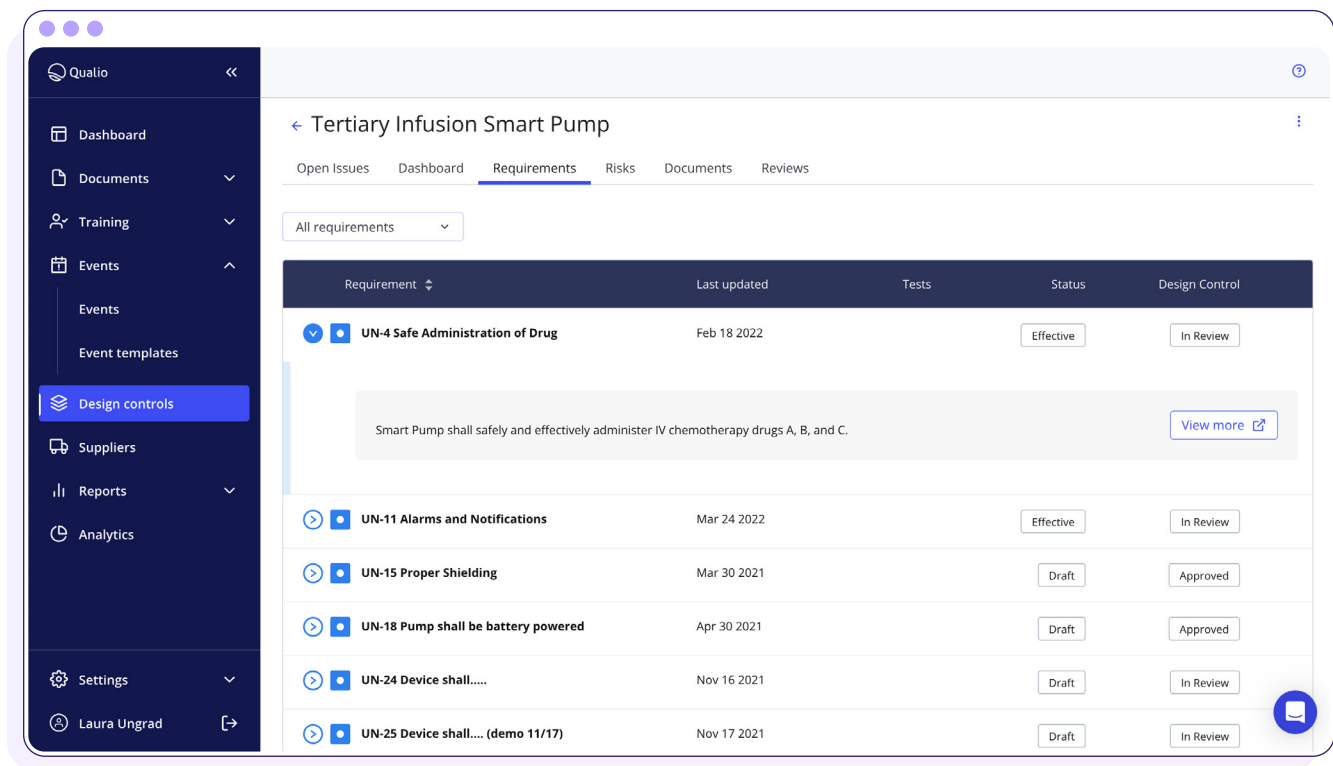
ID	Hazard	Hazardous Situation	Harm	Initial	Final	Last Modified	Design Control
RK-14	Mechanical, Interfacing...	Crack in the tubing causing loss of damage	Underdose: ineffective...	High	Medium	Dec 17, 2021	In progress
RSK-1	Mechanical, Interfacing...	Crack in the tubing causing loss of dosage	Underdose: ineffective...	Medium	Low	Mar 29, 2023	Approved
RSK-2	Mechanical, Electrical	Over-administration >5% over target	Overdose: serious injury...	Low		Apr 28, 2021	Approved
RSK-3	Mechanical, Electrical	Under-administration >5% under target	Underdose: ineffective...	Low		May 05, 2021	Approved
RSK-4	Mechanical	Patient may not be able to receive therapy	Delay in therapy	Low		Apr 28, 2021	Approved
RSK-5	Cybersecurity, Electrical	Unintended parties access PHI	PHI violation to patient/clinic	Low		Apr 28, 2021	Approved
RSK-6	Electrical	User received electrostatic shock	Electric shock - serious injury...	Low		Apr 28, 2021	Approved



# 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 ›](#)

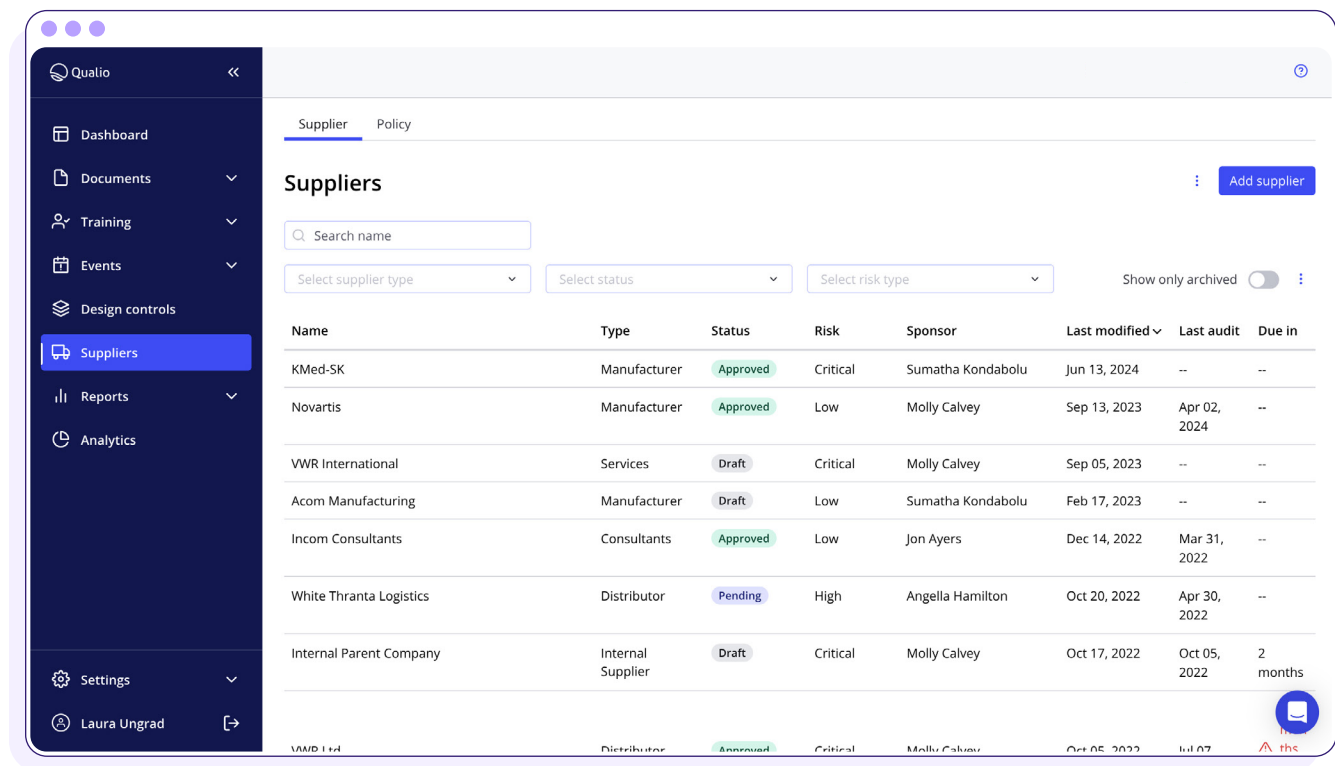
[ISO 13485 toolkit ›](#)

# 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.

The screenshot shows the Qualio web application interface. On the left is a dark blue sidebar with a menu containing: Dashboard, Documents, Training, Events, Design controls, Suppliers (highlighted), Reports, and Analytics. At the bottom of the sidebar are Settings and a user profile for Laura Ungrad. The main content area is titled 'Policy Configuration' and has a sub-header 'Supplier types'. On the left of this section are three expandable categories: 'Supplier types' (selected), 'Risk levels', 'Document types', and 'Audit types'. The 'Supplier types' section contains four entries, each with a text input field and a description: 'Manufacturer' (Is a person or company that produces finished goods from raw materials by using various tools, equipment, and processes, and then sells the goods to consumers.), 'Services' (Describes work that supports a business but does not produce a tangible commodity.), 'Distributor' (A distributor is a person, entity or selling agent who works independently to sell the products of a manufacturer, and is bound by a financial contract.), and 'Consultants'.

# 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.

The screenshot shows the Qualio web application interface. On the left is a dark blue sidebar with a menu containing: Dashboard, Documents, Training, Events, Design controls, Suppliers (highlighted), Reports, and Analytics. At the bottom of the sidebar are Settings, a user profile for Laura Ungrad, and an external link icon. The main content area has a header with 'Supplier' and 'Policy' tabs, and a 'Configuration' button. Below the header, there are tabs for 'Required documents' (active) and 'Audits'. The main section is a table titled 'Supplier Policy' with columns for 'SUPPLIER TYPE' and 'RISK LEVEL' (Critical, High, Medium, Low). The table lists four supplier types: Manufacturer, Services, Distributor, and Consultants, each with a list of required documents for each risk level. A chat icon is visible in the bottom right corner.

SUPPLIER TYPE	RISK LEVEL			
	Critical ⓘ	High ⓘ	Medium ⓘ	Low ⓘ
Manufacturer ⓘ	Quality Agreement Supplier Quality Survey Standard Certification Supplier Evaluation Form	Quality Agreement Standard Certification Supplier Evaluation Form	Quality Agreement Supplier Evaluation Form	GDPR Statement
Services ⓘ	Quality Agreement Supplier Quality Survey Standard Certification Supplier Evaluation Form SOW Agreement	Quality Agreement Standard Certification Supplier Evaluation Form SOW Agreement	Quality Agreement Standard Certification Supplier Evaluation Form SOW Agreement	No documents required
Distributor ⓘ	Quality Agreement Standard Certification Supplier Evaluation Form	Quality Agreement Standard Certification Supplier Evaluation Form	Quality Agreement Supplier Evaluation Form	No documents required
Consultants ⓘ	Quality Agreement Standard Certification Supplier Qualification Form SOW Agreement	Quality Agreement Standard Certification Supplier Qualification Form SOW Agreement	Quality Agreement Supplier Qualification Form SOW Agreement	No documents required

# 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.

The screenshot displays the Qualio 'Policy Configuration' interface. On the left is a dark sidebar with a navigation menu including: Dashboard, Documents, Training, Events, Design controls, Suppliers (highlighted), Reports, and Analytics. At the bottom of the sidebar are links for Settings and a user profile for Laura Ungrad. The main content area is titled 'Policy Configuration' and features a sub-menu on the left with 'Supplier types', 'Risk levels' (selected), 'Document types', and 'Audit types'. The 'Risk levels' section contains three visible configuration cards: 'Critical' with the description 'Highest-risk suppliers with critical impact on the quality or availability of the product.', 'High' with 'Heavy-risk suppliers with direct impact on the product, but for which alternatives are available.', and 'Medium' with 'Moderate-risk suppliers have more of an indirect impact on the product.'. A 'Low' card is partially visible at the bottom. Each card has a text input field for the name and a larger text area for the description, with a trash icon in the top right corner of each card. A help icon is in the top right of the main panel, and a chat icon is in the bottom right.

# 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 ›](#)

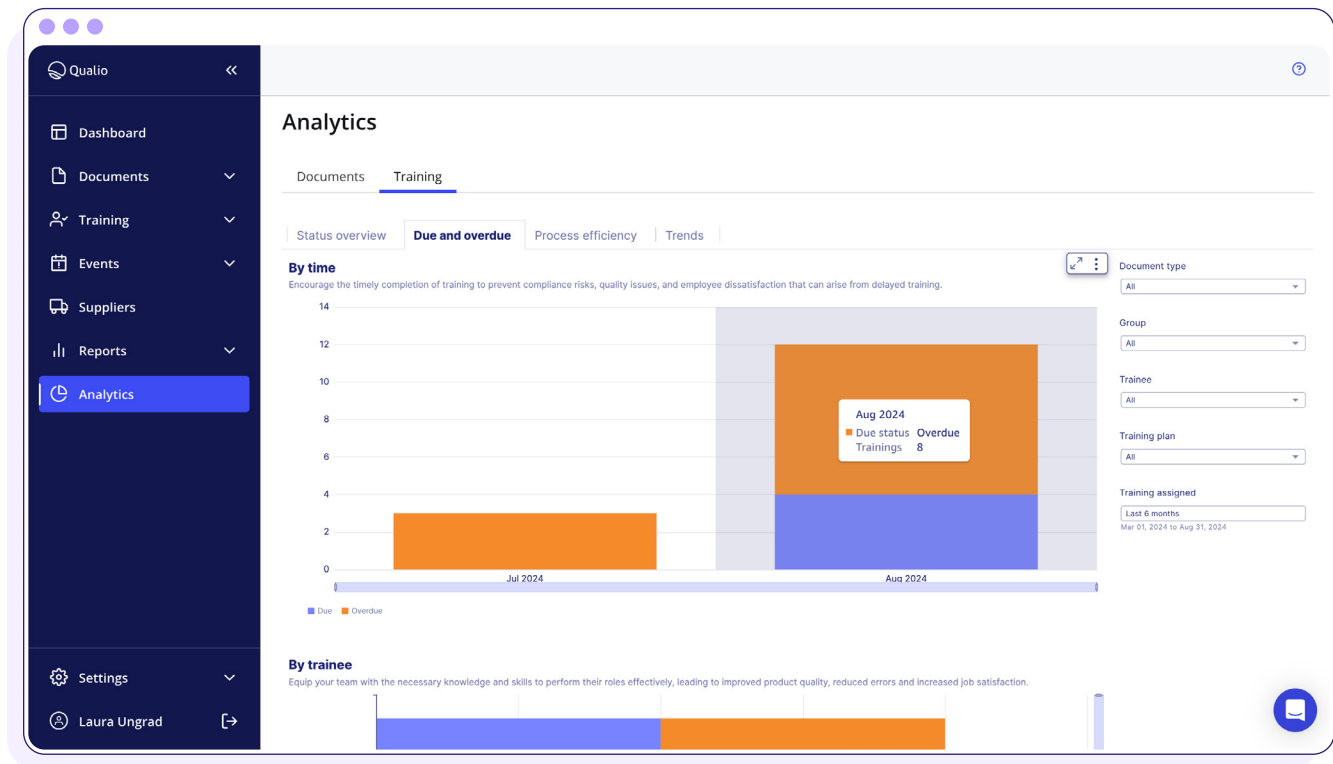
# 6 Detailed analytics for data-driven insights

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.

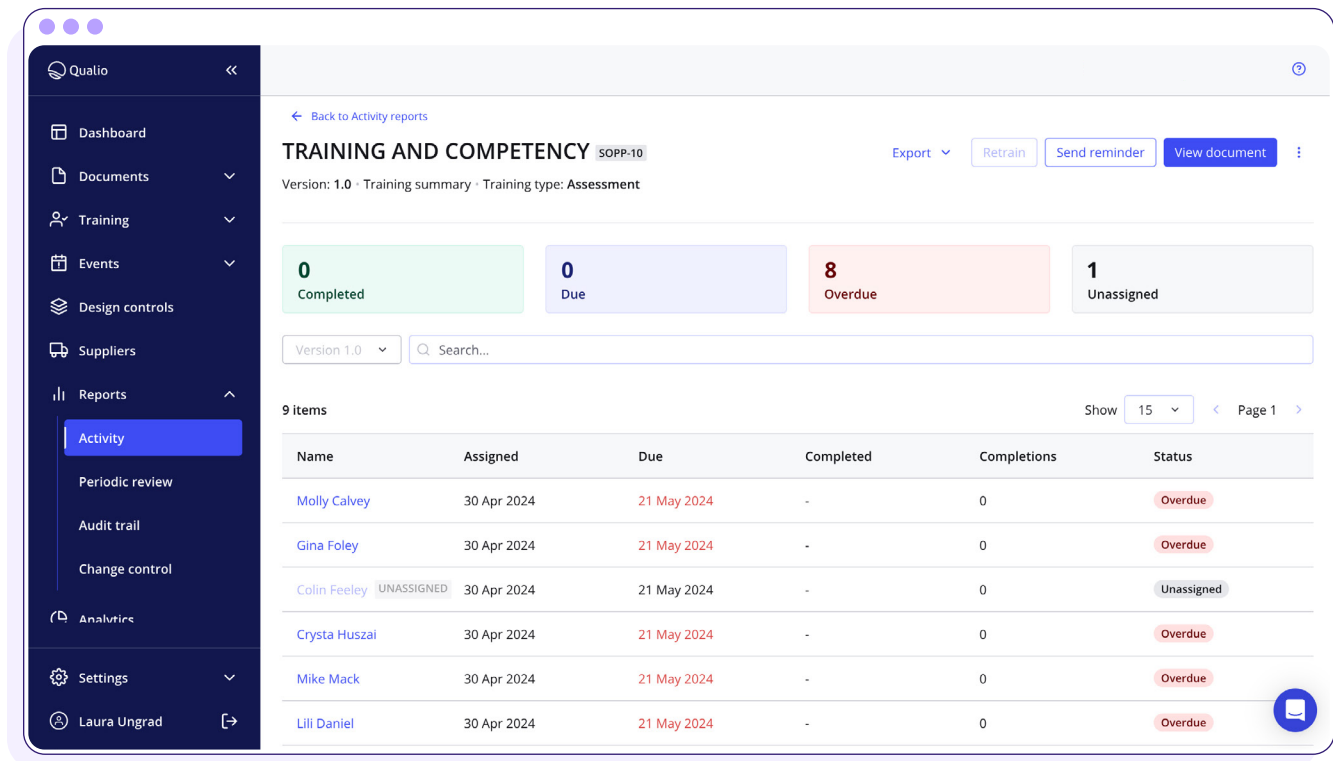




# 6 Detailed analytics for data-driven insights

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



# *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](#)

