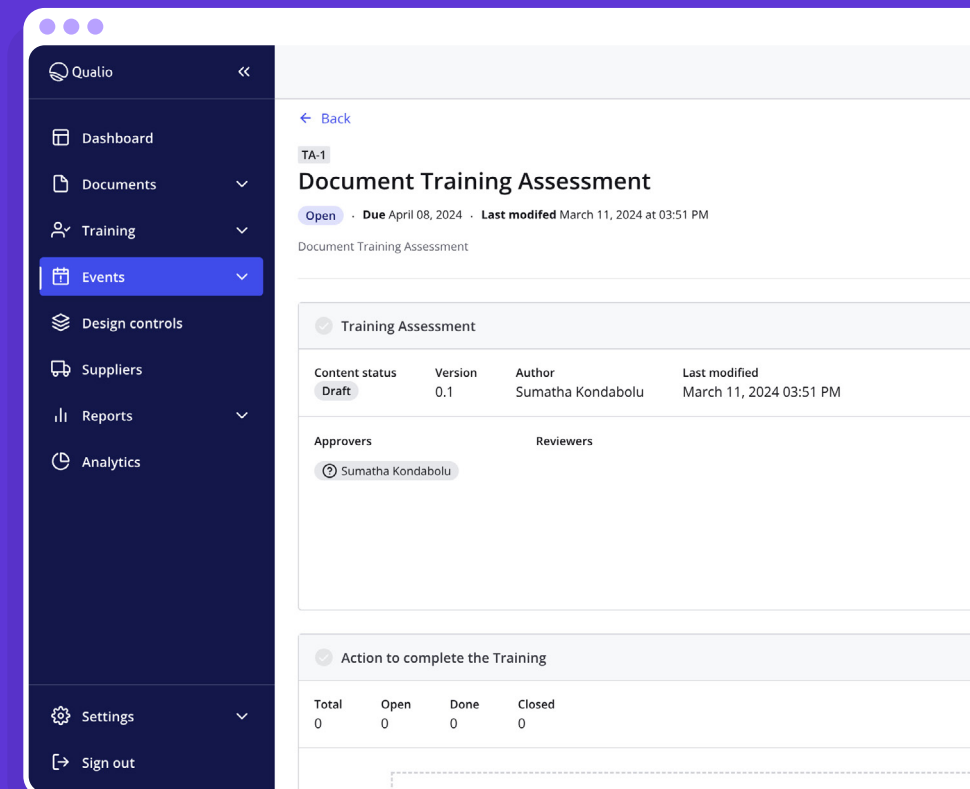


Qualio Events

For connected, best-in-class
quality processes





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 event management software for modern life science challenges



We didn't want to buy something perfectly configured for FDA 21 CFR 820, for example, then pivot in a few years and have a useless solution. So the customizability of Qualio was big.



Watch interview snippet



CALEB WALTERS

Director of Quality
Warehouse Anywhere



We asked ourselves: what would happen if we had a quality fault and we couldn't track it to understand the root cause? Qualio helps us do the important regression analysis to help us learn where the issue was, to look at it right here, and to fix it. It's easy to get upset when something goes wrong. It's easy for it to snowball when you don't know why it went wrong.



Watch interview snippet

PHIL HAYES-ST CLAIR

CEO
Drop Bio Health



Quality event management software for modern life science challenges



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

PETER BRUESEHOFF

Director of QA
Watchmaker Genomics



Watch interview snippet



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.

MICHAEL HOLCOMB

Quality Assurance Director
TriMed



Watch interview snippet

Our customers report...

>90% reduction in quality admin time

33% faster quality event processes

90% increase in operational efficiency and ability to scale

140% increase in go-to-market speed

5x faster external audits



More collaborative quality cultures built on controlled information



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

5 software features to optimize your quality event processes

This datasheet is designed to give you and your colleagues an introduction into how the Events area of Qualio helps your business get robust, best-in-class event management in place.

We've picked out the 5 top things we think you should see.

Want to see more, including a walkthrough of Qualio in action? Visit the last page to book a demonstration at a time that suits you.

1 Templates and workflows for consistent, collaborative action

Quality event management within Qualio, like document management in the Documents area, is structured around consistent, easy-to-use templates underpinned by easy in-system editing and collaboration.

Set a name and prefix, designate a resolution timeframe target and validation period, then build ordered steps for an automated pathway to completion.

The screenshot shows the 'Edit event template' interface in Qualio. 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' header. Below this, the 'Event properties' section contains several input fields: 'Name' (with a red asterisk) containing 'Batch Record', 'Prefix' (with a red asterisk) containing 'BRT', 'Time limit (days)' (with a red asterisk) containing '28', and 'Validation step time delay (days)' (with a red asterisk) containing '0'. A note below these fields states: 'Each event must be resolved in given number of days. This is a default value and may be changed during event creation.' and 'Determines how many days must pass before being able to complete approval of final step.' At the bottom, there is a table with columns 'Field title' and 'Description', and a 'Visible' checkbox. The user 'Laura Ungrad' is logged in, and a chat icon is visible in the bottom right corner.

Field title	Description	Visible	Required
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1 Templates and workflows for consistent, collaborative action

Event steps can be either:

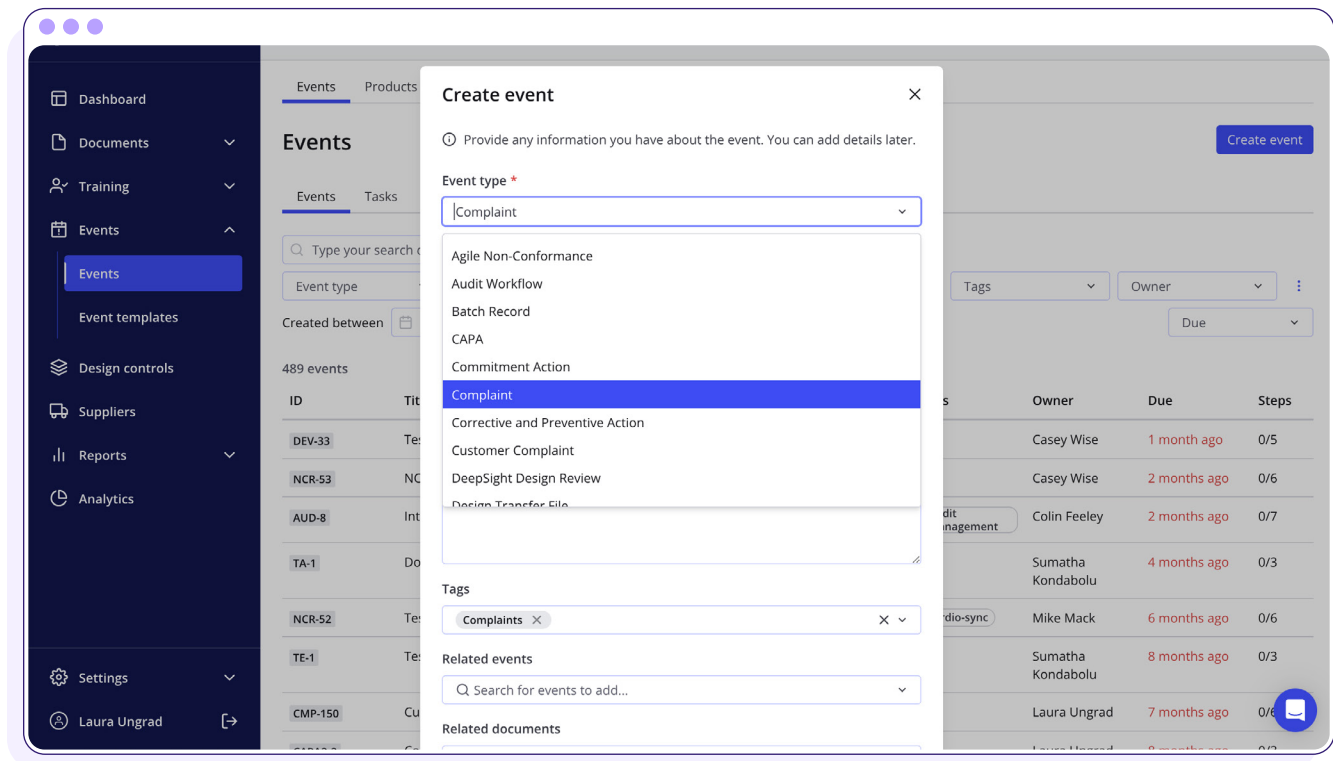
- › Content steps, for capturing and recording information with forms
- › Action steps, such as implementing a process change
- › Validation steps, for final review and sign-off before event closure

The screenshot displays the Qualio software interface. On the left is a dark sidebar with navigation options: Dashboard, Documents, Training, Events (highlighted), Event templates, Design controls, Suppliers, Reports, and Analytics. At the bottom of the sidebar, it shows 'Settings' and the user 'Laura Ungrad'. The main content area is divided into three sections: 'Audit Response Actions', 'Audit Effectiveness & Monitoring', and 'Closure'. The 'Audit Response Actions' section contains a table with columns 'Total', 'Open', 'Done', and 'Closed', showing values 1, 1, 0, and 0 respectively. Below this is a table with columns 'Task name', 'Status', and 'Assigned to', listing 'Update Quality Policy' with status 'Open' and assigned to 'Colin Feeley'. The 'Audit Effectiveness & Monitoring' section has a table with columns 'Content status', 'Version', 'Author', and 'Last modified', all showing '--'. Below this table is a dashed box with the text 'Add content and send it for review and approval when ready' and a blue 'Add content' button. The 'Closure' section also has a table with the same columns as the previous one, all showing '--'. On the right side of the interface, there is a 'TASK' panel for 'Update Quality Policy'. It includes a 'Status' dropdown set to 'Open', a 'Due' date of '29 Jun 2024 at 12:02 PM', a 'Last modified' date of '30 Apr 2024 at 12:02 PM', a 'Created' date of '30 Apr 2024 at 12:02 PM by Colin Feeley', an 'ID' of '#T165899', a 'Description' of 'Update Quality Policy to more clearly outline what we are doing', and a 'Comments' section with a text input field and a 'Comment' button. At the bottom of the task panel, there is a file upload section with the text 'Browse or drag and drop your files' and 'Max. 10 files, up to 100MB per file, 1000MB total.'.

1 Templates and workflows for consistent, collaborative action

As you trigger an event, the template structure will automatically be followed, ensuring actions are routed and executed in the right order and information is captured systematically.

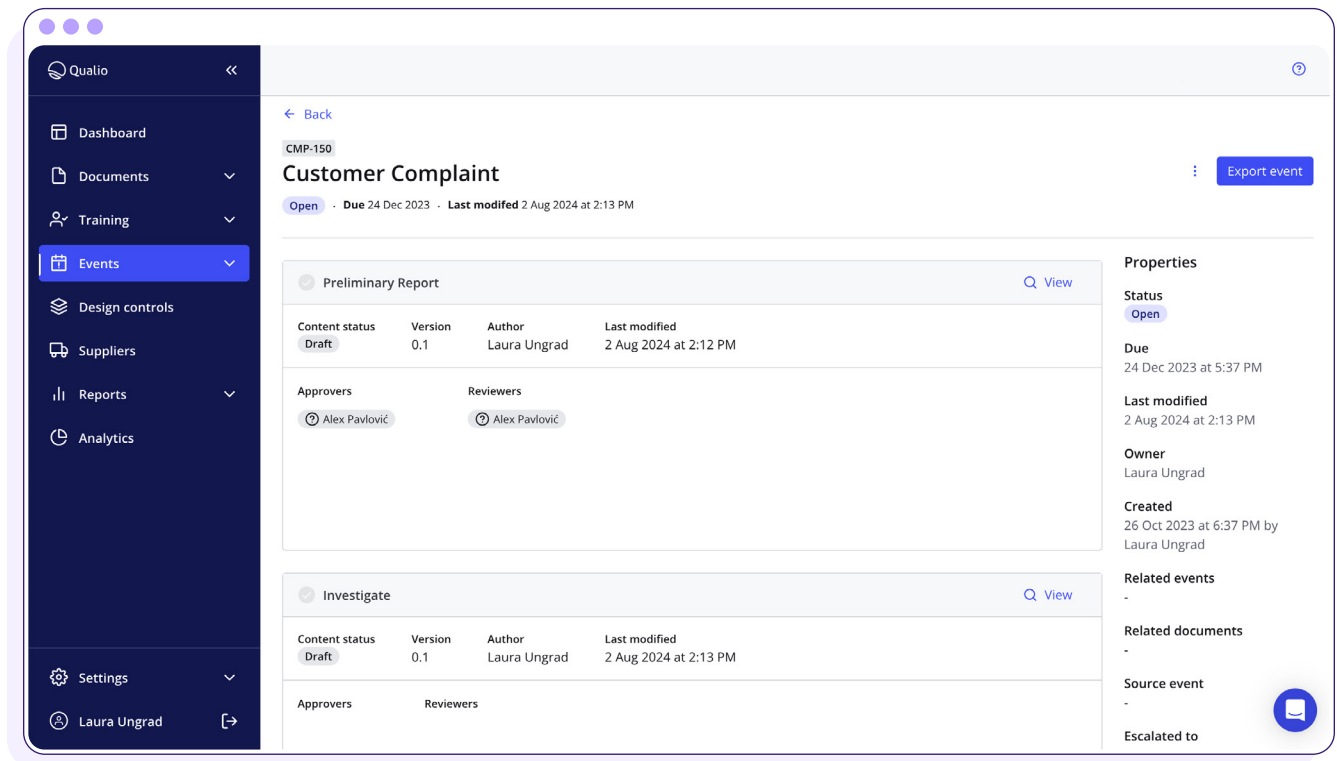
Templates are designed to be fully customizable, giving you a targeted, appropriate and consistent approach for any quality event as it occurs.



1 Templates and workflows for consistent, collaborative action

You define the best practice workflow process you need, assign responsibility and permissions to individuals or groups, hide or mandate fields as required, and set a timescale.

The closed-loop workflow process then drives your action through to completion, recording each individual step and ensuring you comply with your standards, regulations and service level agreements every single time!



2 Flexible info capture to track the data you need to see

Quality managers need clear, actionable information from all corners of the business in a familiar format.

Qualio's web editor functionality allows information capture forms within content steps to be 100% bespoke. Add as few or as many fields as you require, arrange paragraph, checkbox, table and list sections to taste, and build summary, text and attachment fields to capture the information you need to see.

2 Flexible info capture to track the data you need to see

Plus, use smartlinks to associate events with documents, and build a system-wide resource library of reusable data objects to reference common data points, like departments, products, tickets, customers and equipment numbers, across your entire eQMS.

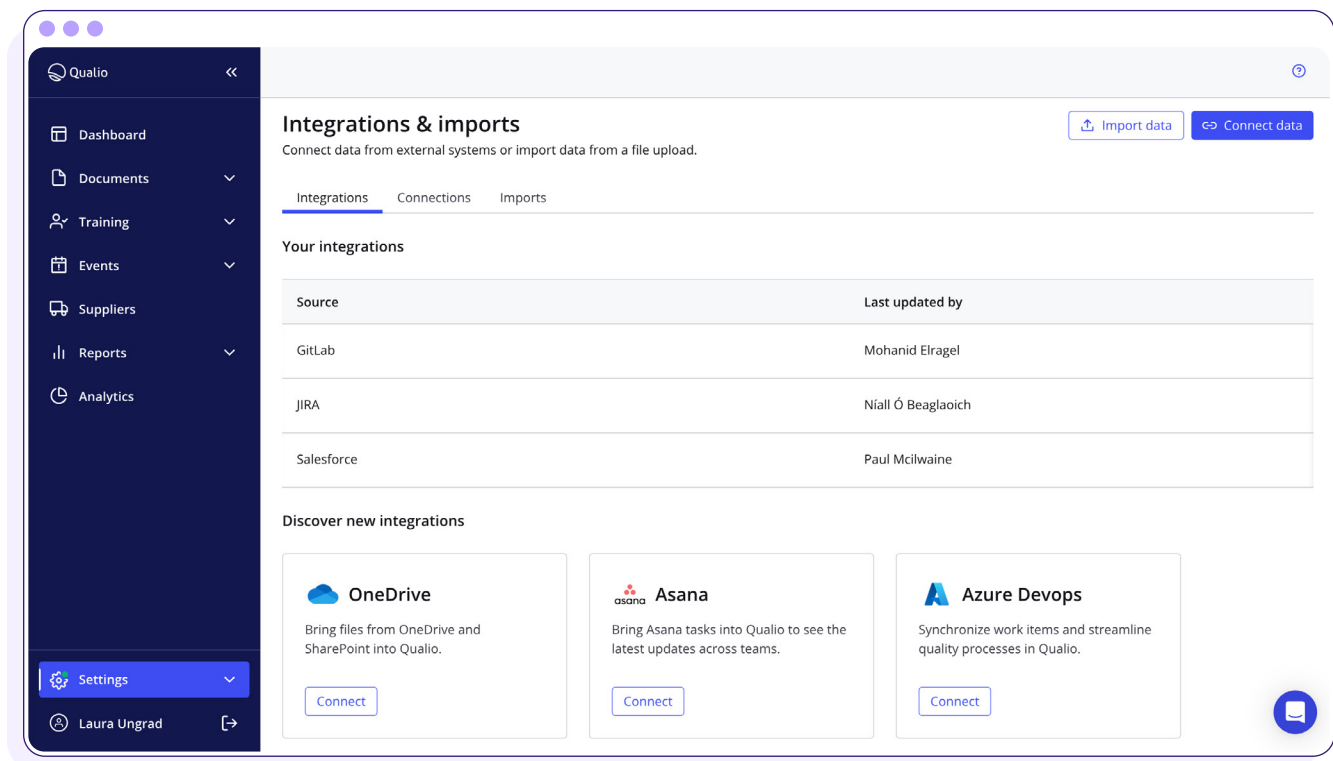
The screenshot displays the Qualio web application interface. On the left is a dark sidebar with navigation links: Dashboard, Documents, Training, Events (highlighted), Design controls, Suppliers, Reports, and Analytics. The main content area shows a 'Document Training Assessment' page for event 'TA-1'. It includes a 'Back' link, an 'Open' status, a due date of April 08, 2024, and a last modified date of March 11, 2024. Below this is a 'Training Assessment' section with a 'View' link and a table showing content status (Draft), version (0.1), author (Sumatha Kondabolu), and last modified date (March 11, 2024 03:51 PM). There are also sections for 'Approvers' (Sumatha Kondabolu) and 'Reviewers'. At the bottom, an 'Action to complete the Training' section shows a table with columns for Total, Open, Done, and Closed, all with a value of 0. On the right, a 'Properties' sidebar lists details: Status (Open), Due (April 08, 2024 04:50 PM), Last modified (March 11, 2024 03:51 PM), Owner (Sumatha Kondabolu), Created (March 11, 2024 03:50 PM by Sumatha Kondabolu), Related events, and Related documents (SOPP-6). A 'Source event' link is also present. A callout box labeled 'Linked document' points to the 'SOPP-6' document in the 'Related documents' list.

2 Flexible info capture to track the data you need to see

Qualio integrates with your third-party systems, too, to let you pull these data objects and event triggers from your CRM, ticketing and help center platforms straight into your eQMS.

Received a complaint about a particular product from a customer in Salesforce or Intercom, for instance? Had an adverse event reported as part of your pharmacovigilance or post-market surveillance activity?

Automatically trigger a resolution workflow in Qualio, with pre-designated personnel and tasks, to set things right at lightning speed.

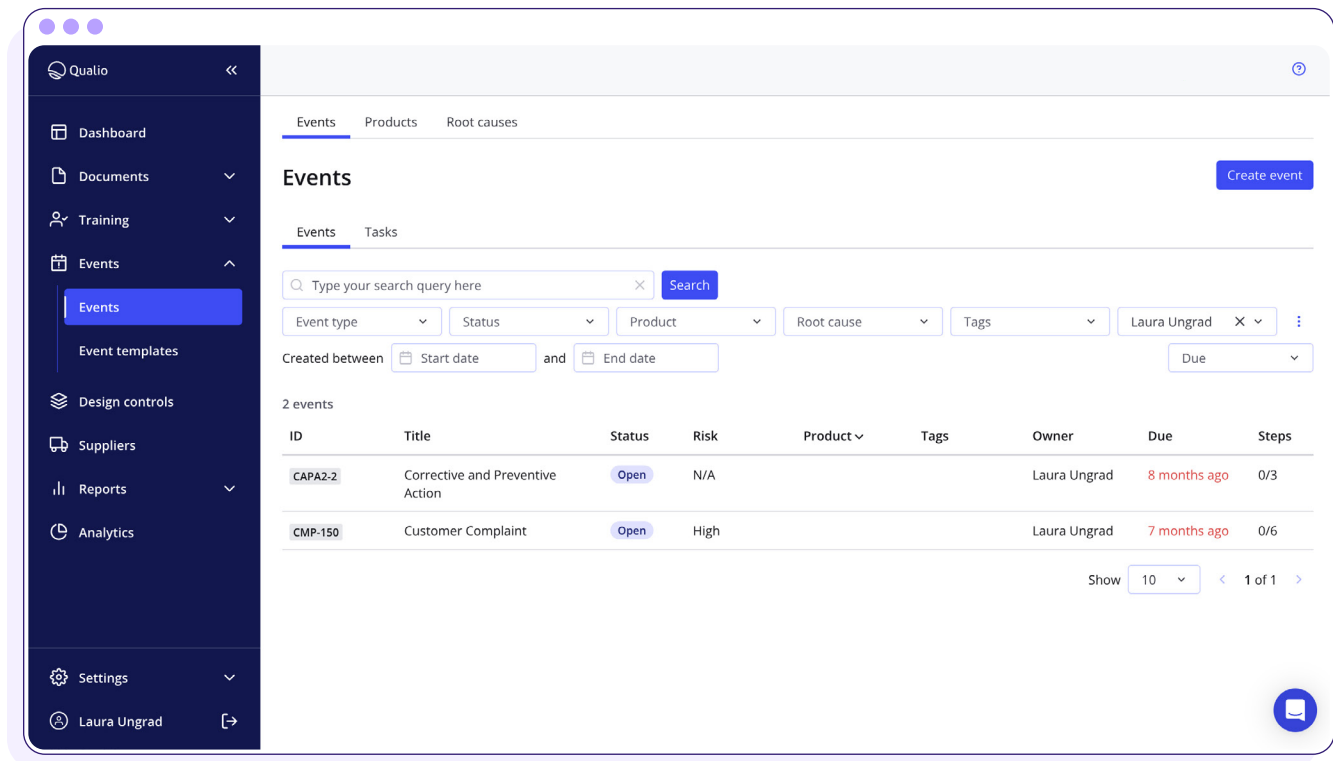


3 Complete traceability for control and compliance

Your auditors and regulators will expect to see fully recorded in-depth histories of your responses to past quality events.

Qualio's Events area acts as an incorruptible repository of your organization's entire quality event landscape, from last year's complaint resolution rate to this quarter's CAPA plan history.

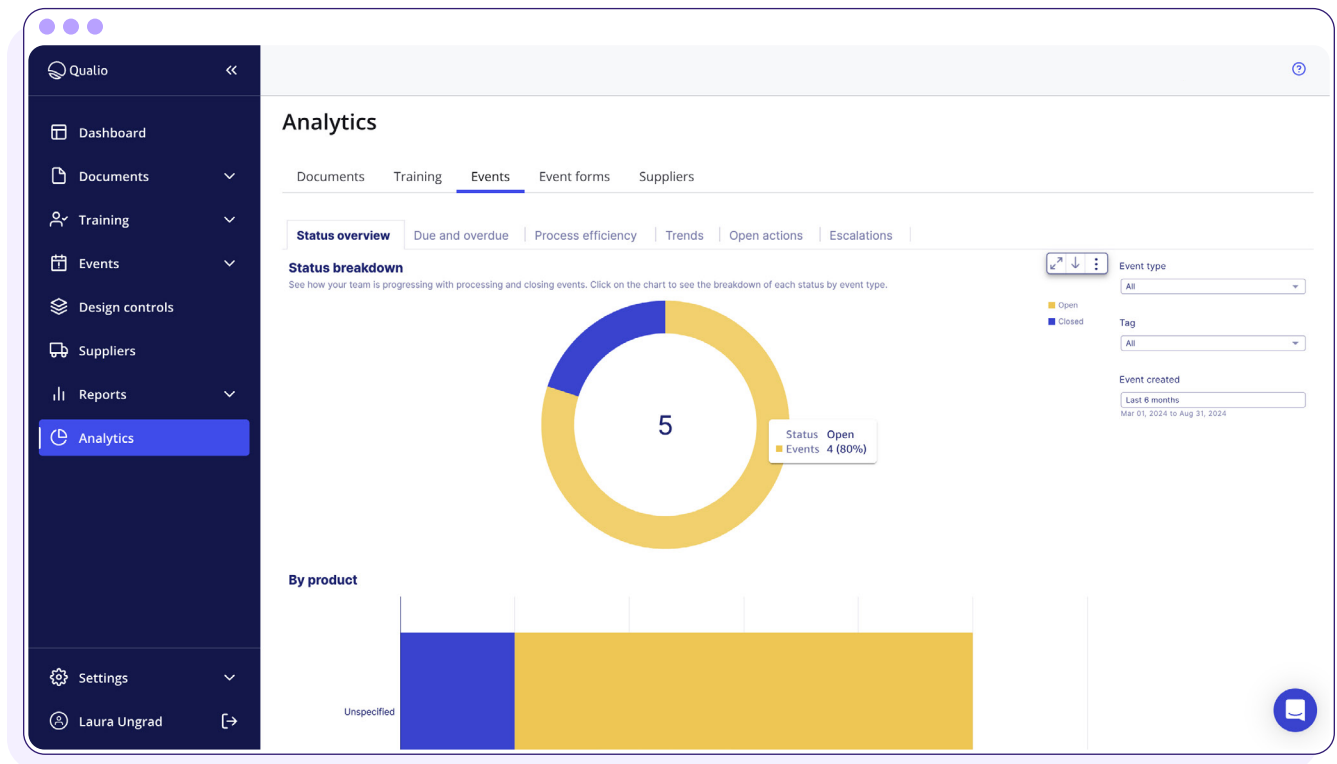
View open and closed events, filter by event types with tags, and access visual graphs for at-a-glance understanding and progress checks.



4 Deep visibility and reporting for data-driven action

Continuous quality improvement is impossible without unpicking root causes and placing your finger on key operational trends within your business.

That's why the Events area comes with powerful reporting functionality to let you slice and dice your quality event data how you wish. Understand trends, spot process bottlenecks, compare timeframes, build visual pie and bar charts, and access your real-time event landscape without ever leaving the system.



4 Deep visibility and reporting for data-driven action

More of a list person? View system lists of quality events and their associated tasks. Filter by type, status, owner, timeframe and tag.

The screenshot displays the Qualio 'Events' page. On the left is a dark sidebar with navigation links: Dashboard, Documents, Training, Events (selected), Event templates, Design controls, Suppliers, Reports, Analytics, Settings, and a user profile for Laura Ungrad. The main content area has tabs for 'Events', 'Products', and 'Root causes'. The 'Events' tab is active, showing a 'Create event' button and a search bar. Below the search bar are filters for Event type (Open), Product, Root cause, Training, and Owner. A date range filter 'Created between' with 'Start date' and 'End date' inputs is also present. The table below lists 3 events:

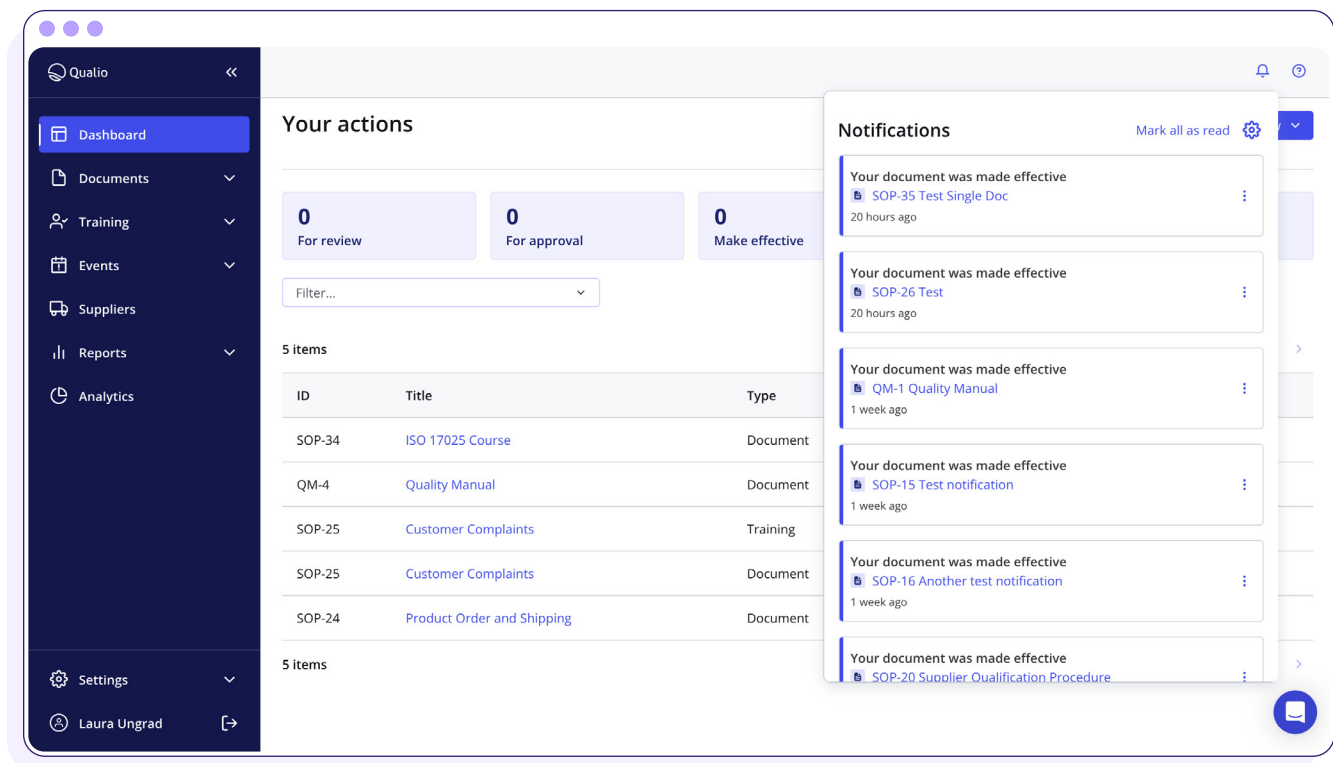
ID	Title	Status	Risk	Product	Tags	Owner	Due	Steps
CAPA-214	Training and Personnel	Open	Low	Product A	Training	Kyle Howes	2 years ago	0/5
CAPA-56	Management Review	Open	High		Training	Gina Foley	3 years ago	0/5
CAPA-53	Validation Program	Open	High		Training	Gina Foley	3 years ago	0/6

At the bottom right of the table, there is a 'Show' dropdown set to 10 and a pagination indicator '1 of 1'.

5 Unified notifications to keep things moving

Optimized quality management needs your entire organization to be on the same page, connected to unified and collaborative processes.

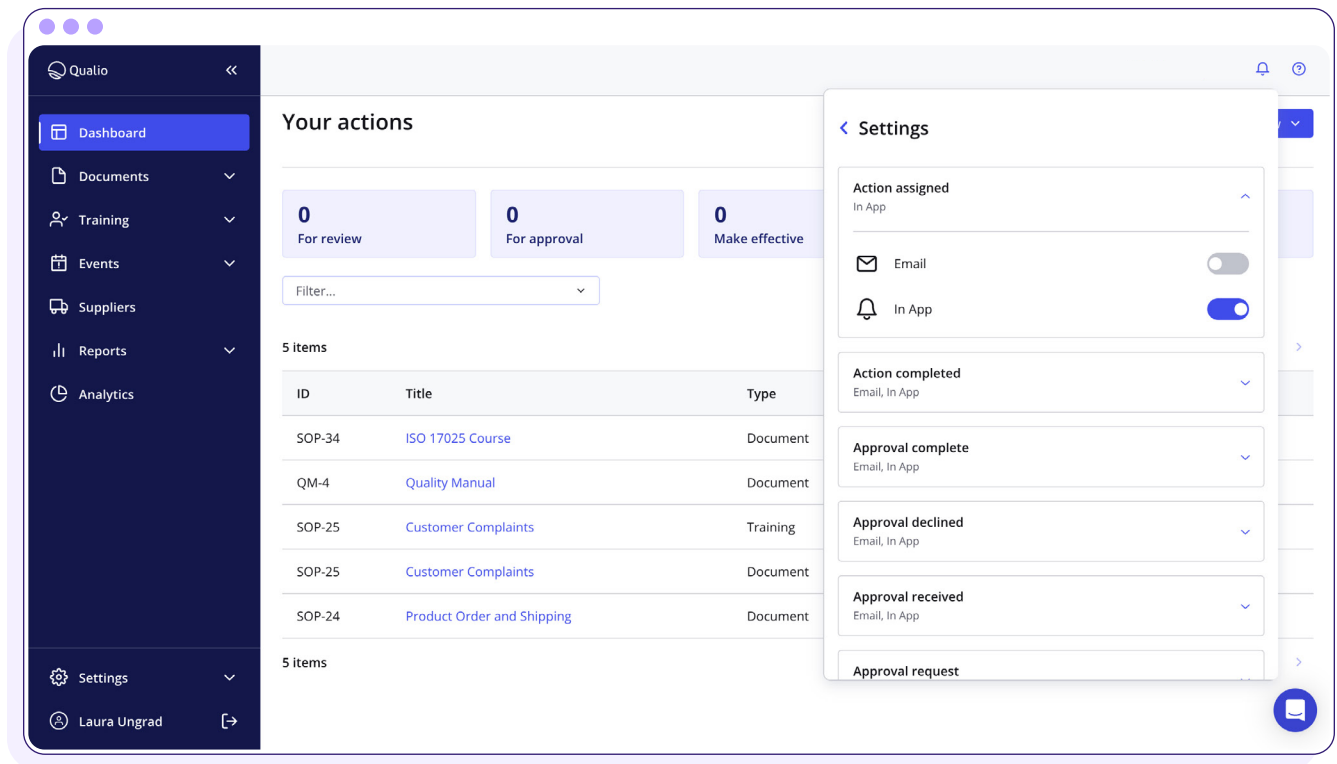
Qualio's unified notification system drives collaboration and engagement both within and outside your quality team.



5 Unified notifications to keep things moving

Clean and user-friendly prompts and reminders within Qualio, as well as automated email comms, help your teams quickly and easily collaborate on time-sensitive quality issues, saving time and effort by reducing missed tasks and actions.

Qualio empowers users to customize their individual notification setup, increasing engagement and responsiveness — while driving faster resolution of your quality issues.



The ROI of Qualio

Manual, paper-based quality systems bring a slew of hidden costs to your business, which a Qualio investment completely eliminates.



[Get your ROI figure >](#)

\$8m Average cost of a product recall

\$400k Average cost of an FDA warning letter

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

\$1 not properly spent on proactive nonconformance prevention =

\$10 of extra appraisal costs

\$100 of extra remediation costs

12 reasons to manage your events within Qualio



Hear from our customers!

[Explore our successful customer stories ›](#)

1

Dedicated life science eQMS vendor with over 650 regulated customers

2

Route tasks to the right person at the right time with flexible workflows and steps

3

Unlock continuous, data-driven quality improvement with rich data analysis at your fingertips

4

Secure cloud-based access from anywhere

5

Meet your standards, regulations and SLAs every single time

6

Audit trailing, e-signatures and action histories for total compliance

7

Capture the info you need with customizable forms, attachments and links

8

Guarantee compliance with fully traceable closed-loop event management

9

Build bespoke templates for any type of quality event

10

Drive and trace your quality events from reporting and planning to close-out

11

Report on anything in your quality system, from audit findings to CAPA history

12

Put quality front and center with to do lists, prompts and reminders



Take your quality processes to their optimum

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](#)

