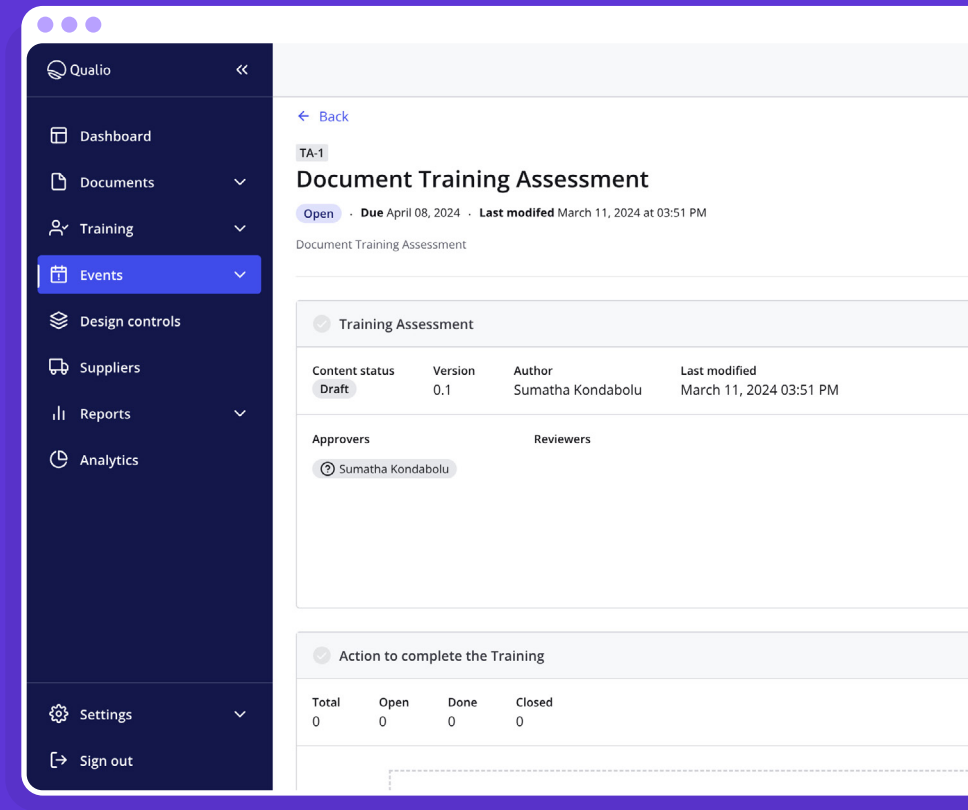
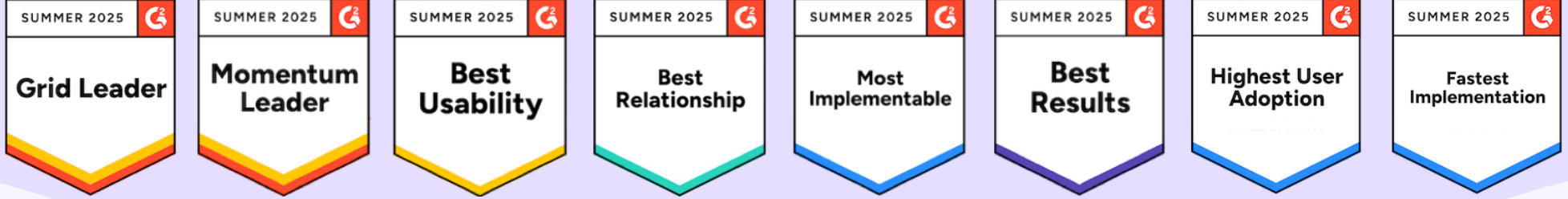
Qualio

QUALIO PRODUCT GUIDE

Qualio Events

For connected, best-in-class quality processes





Qualio's software transforms life science quality and compliance from a burden and a bottleneck into a growth enabler.

Over 700 life science companies across the globe now use Qualio for best-in-class quality and compliance processes.

Our customers enjoy faster market entry, constant audit readiness, multi-standard confidence, automated admin, and much more.

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.

Watch interview snippet

PETER BRUESEHOFF

Director of QA
Watchmaker Genomics

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

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.

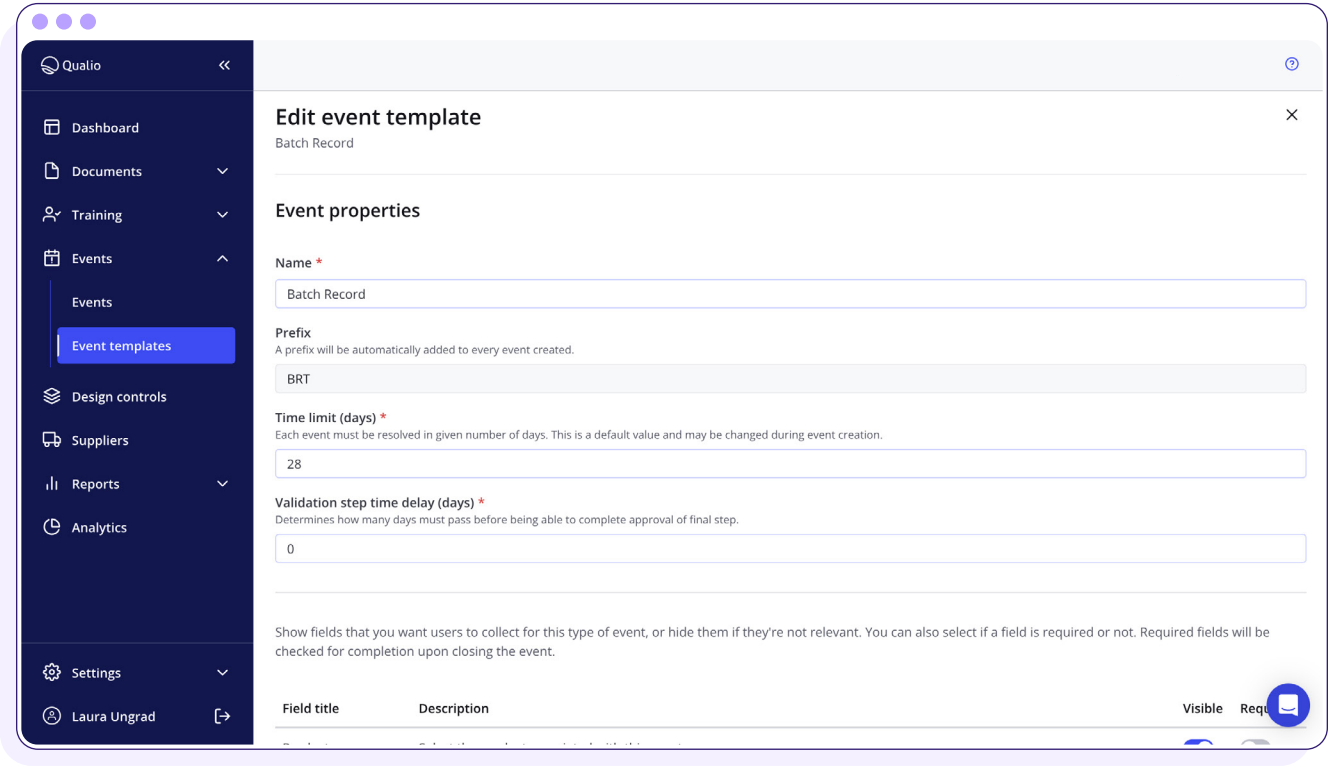
We've picked out the 5 top things we think you should see.

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.

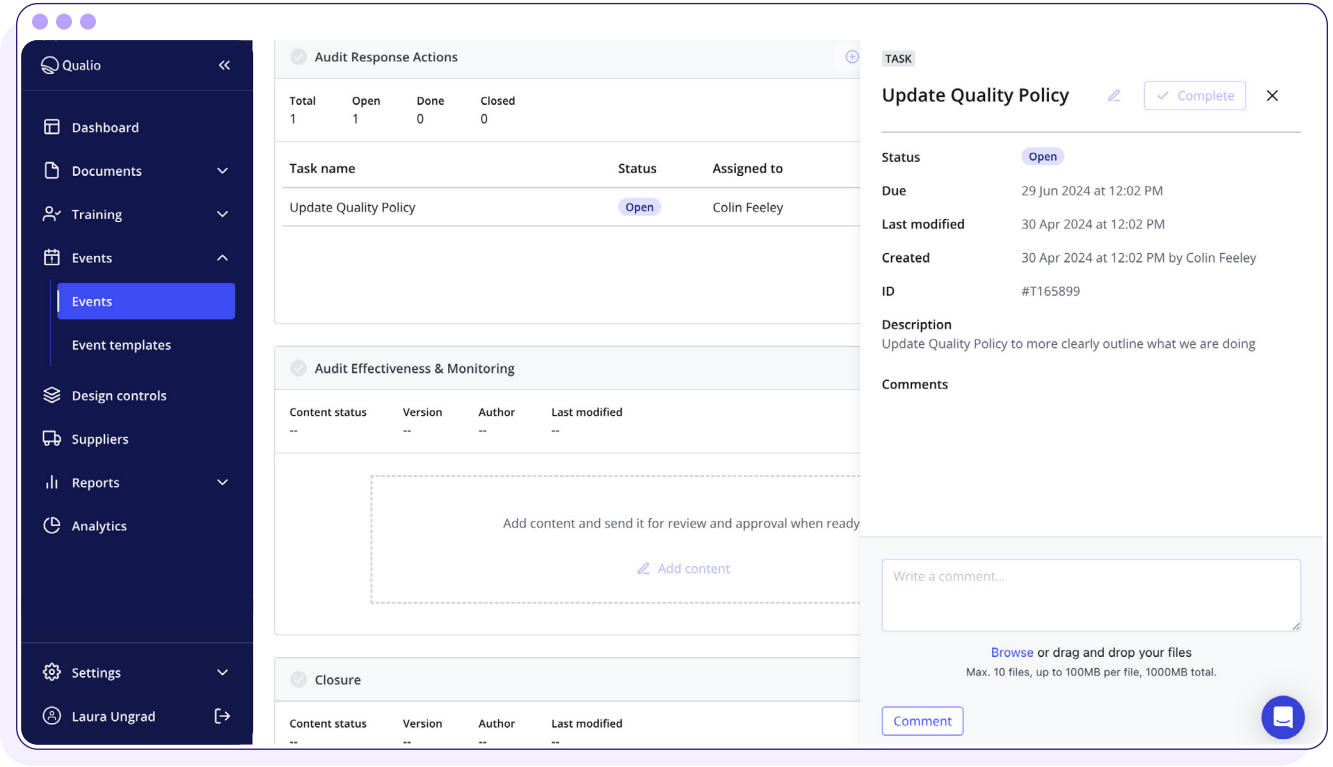
> Set a name and prefix, designate a resolution timeframe target and validation period, then build ordered steps for an automated pathway to completion.



1 Templates and workflows for consistent, collaborative action

Event steps can be either:

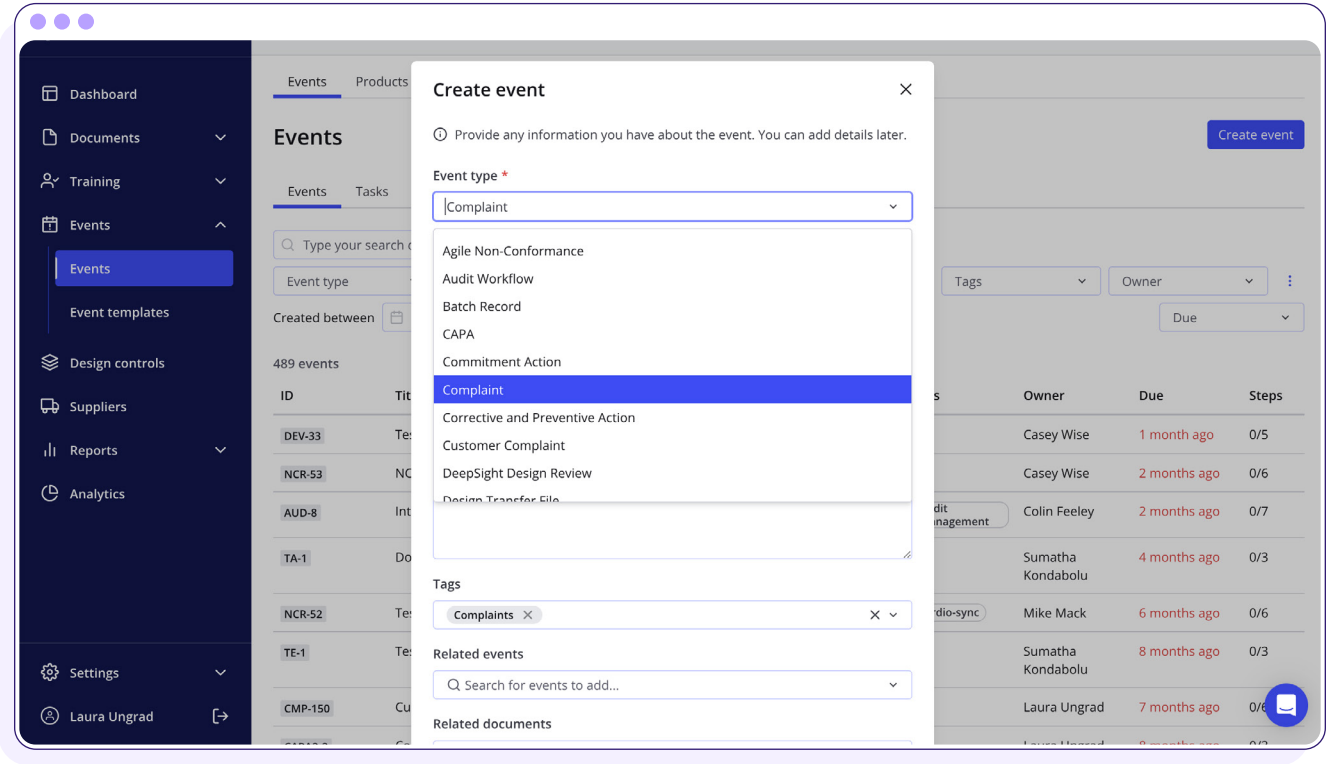
- Content steps, for capturing and recording information with forms
- Action steps, such as implementing a process change
- Validation steps, for final review and sign-off before event closure



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.

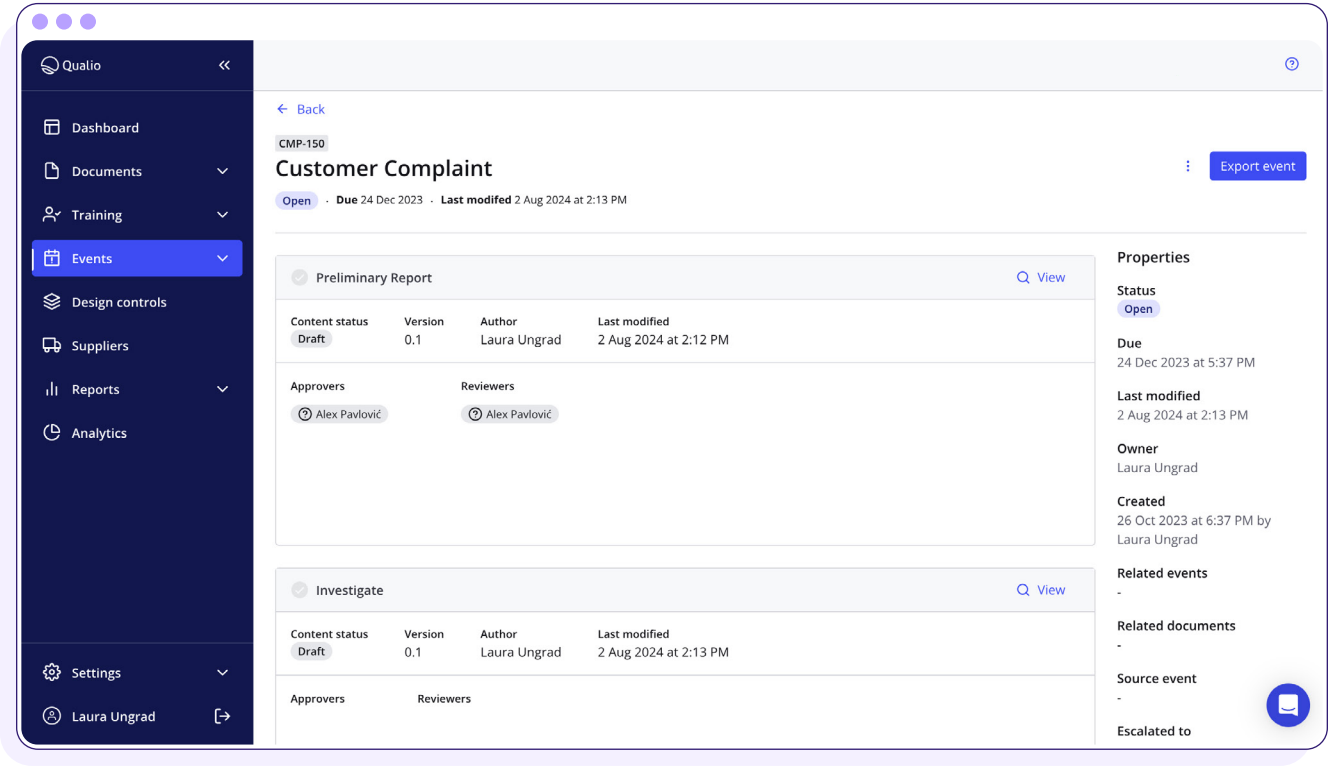
Templates are designed to be fully customizable, giving you a targeted, appropriate and consistent approach for any quality event as it occurs.



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.

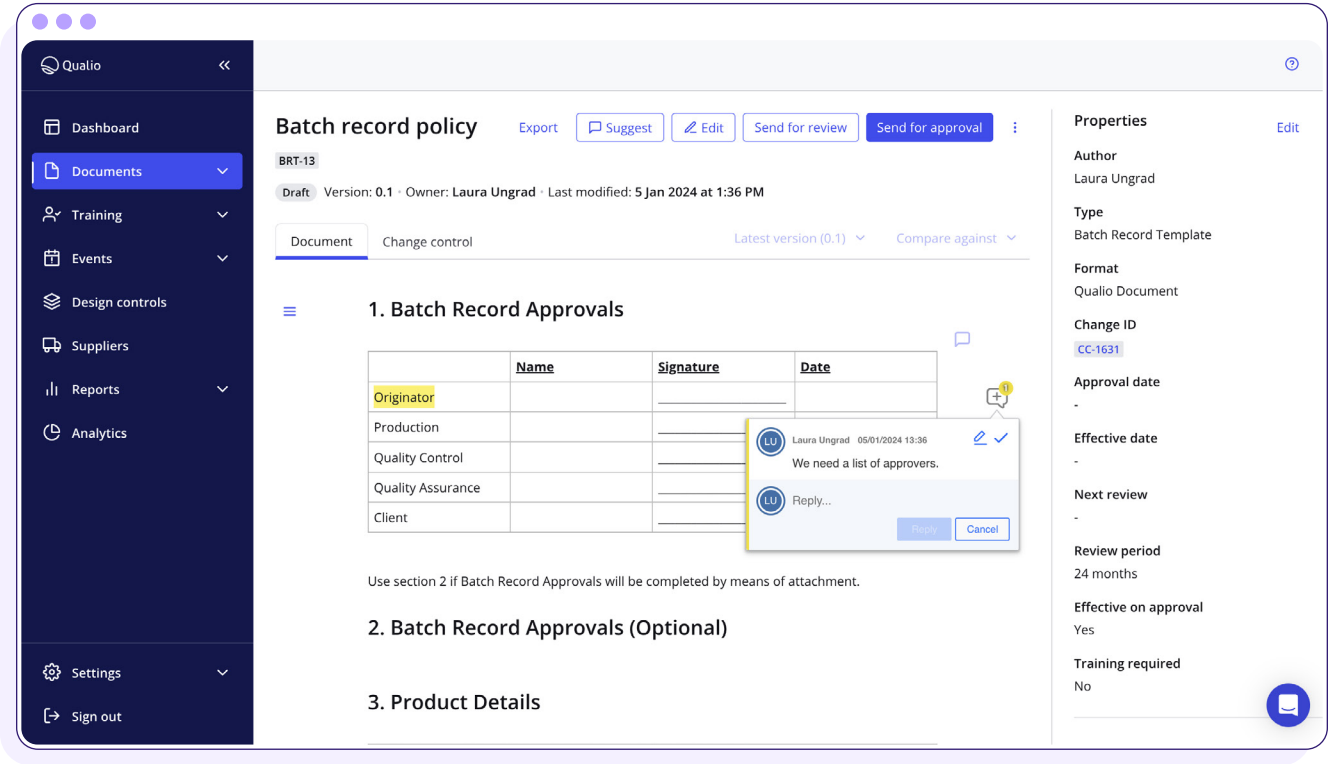
The closed-loop workflow process then drives your action through to completion, recording each individual step and ensuring you comply with your standards, regulations and service level agreements every single time!



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

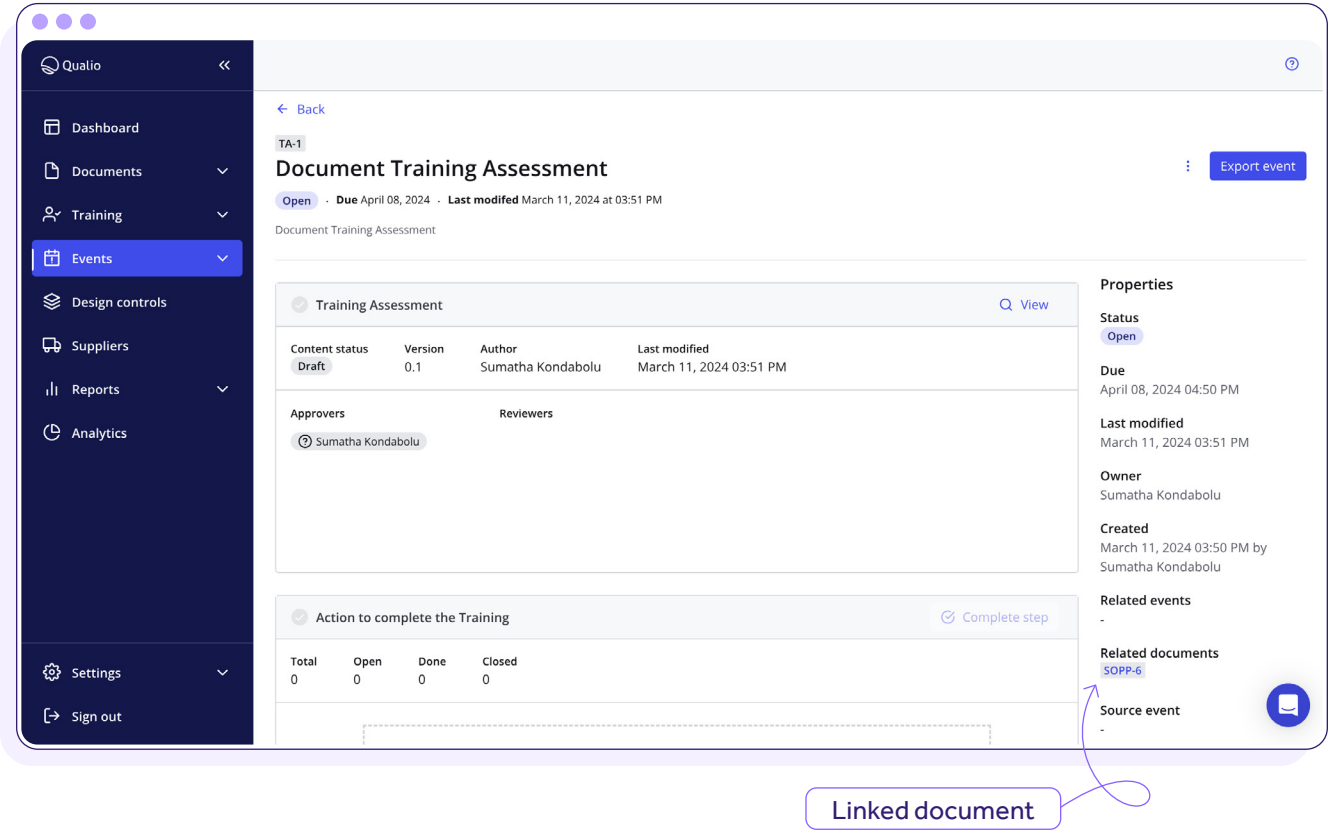
Quality managers need clear, actionable information from all corners of the business in a familiar format.

> 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.

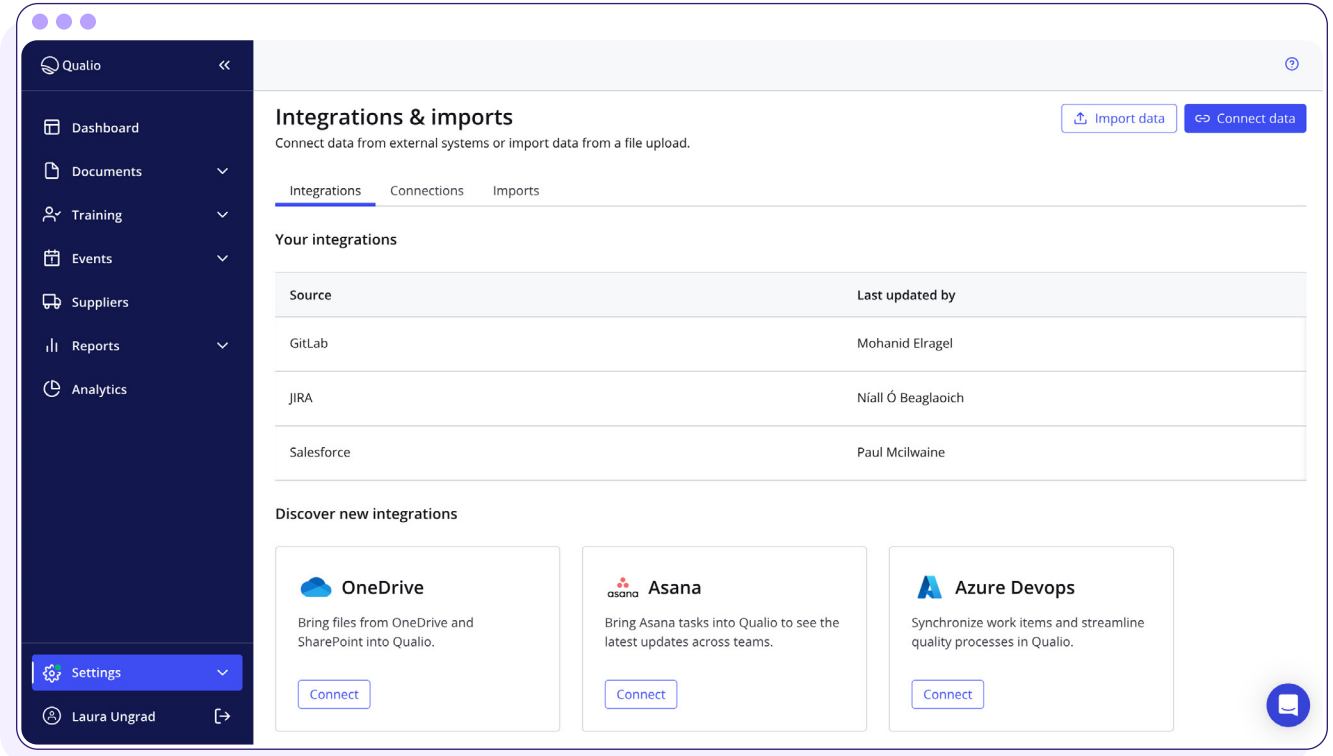


2 Flexible info capture to track the data you need to see

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.

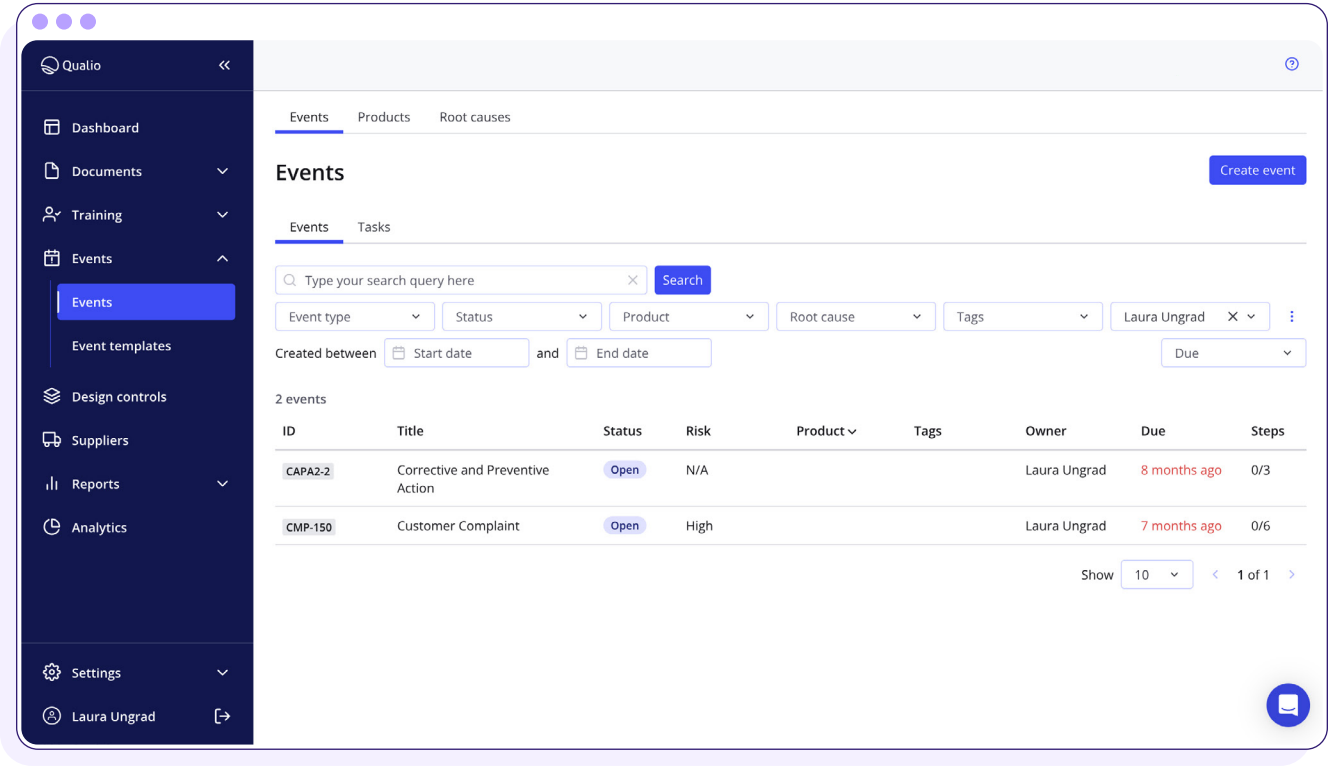


3 Complete traceability for control and compliance

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.

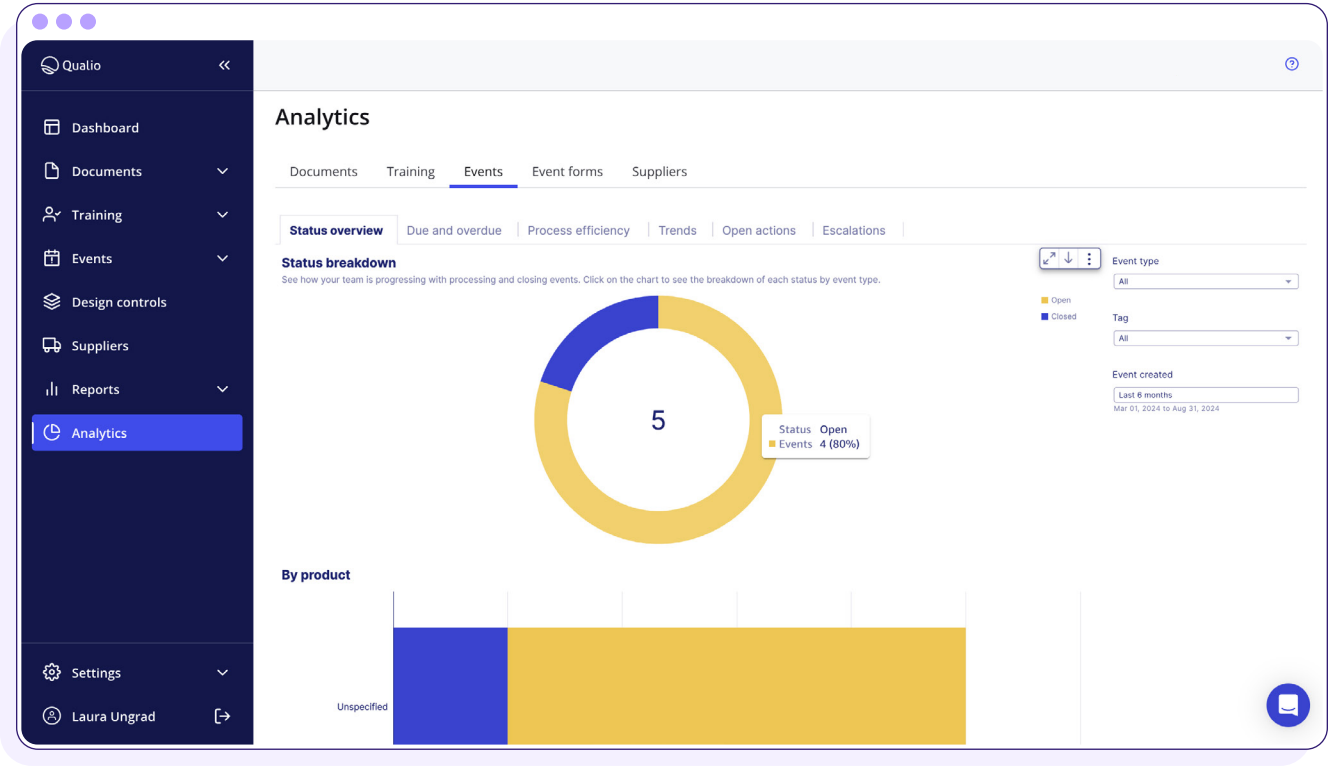
> View open and closed events, filter by event types with tags, and access visual graphs for at-a-glance understanding and progress checks.



4 Deep visibility and reporting for data-driven action

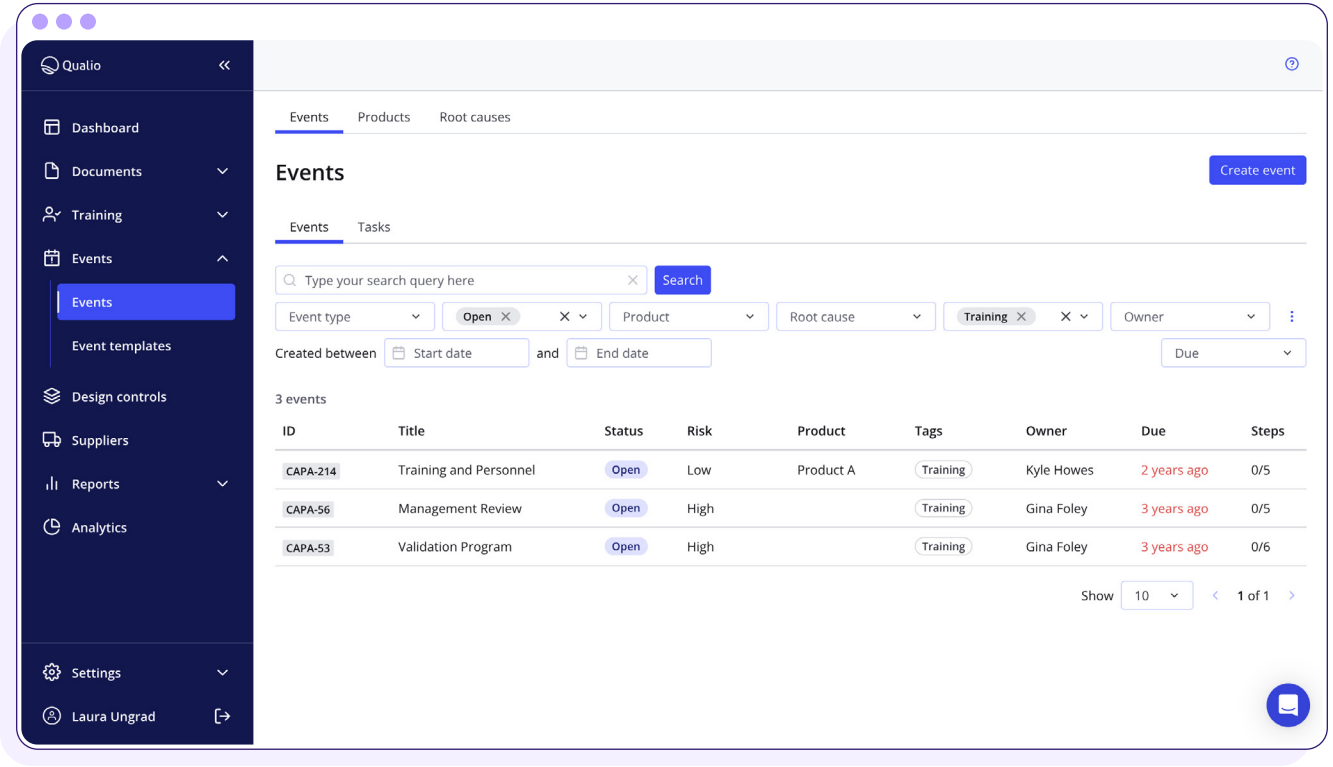
Continuous quality improvement is impossible without unpicking root causes and placing your finger on key operational trends within your business.

> 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

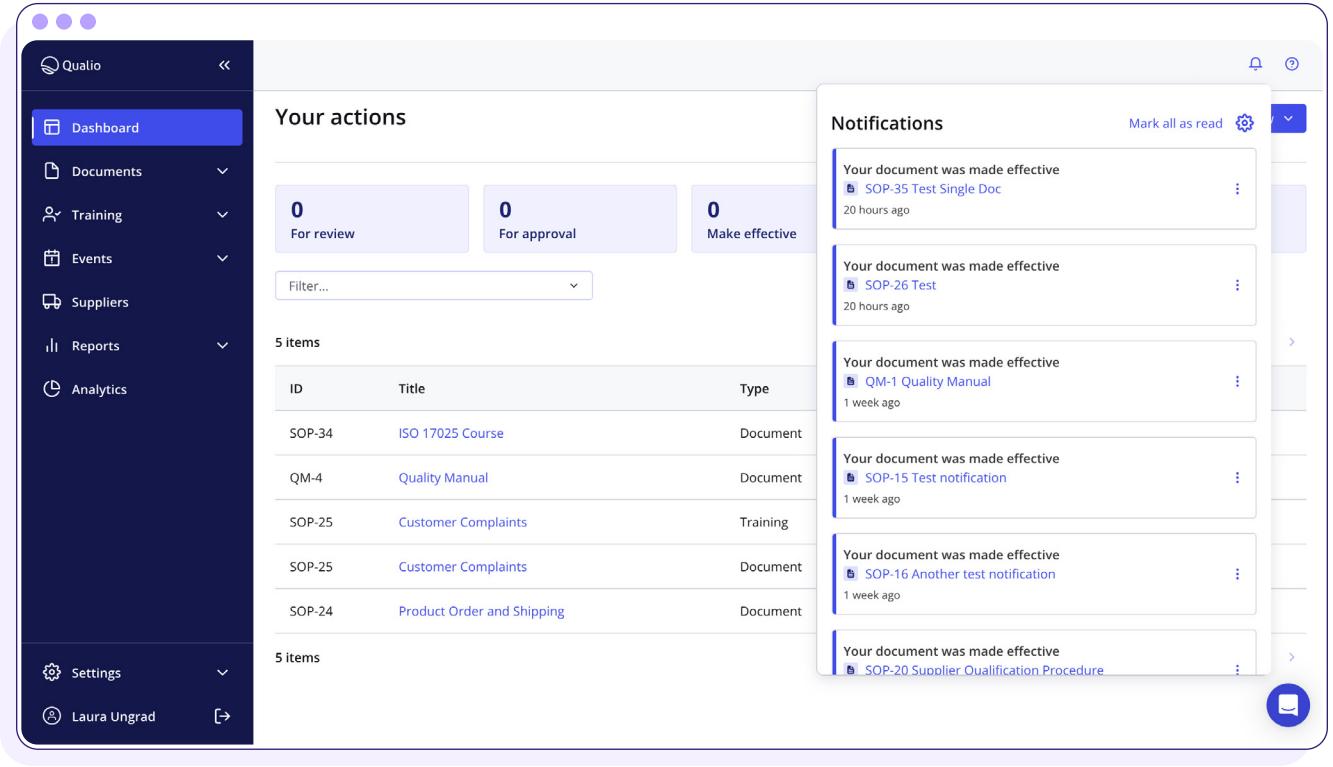
More of a list person? View system lists of quality events and their associated tasks. Filter by type, status, owner, timeframe and tag.



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.

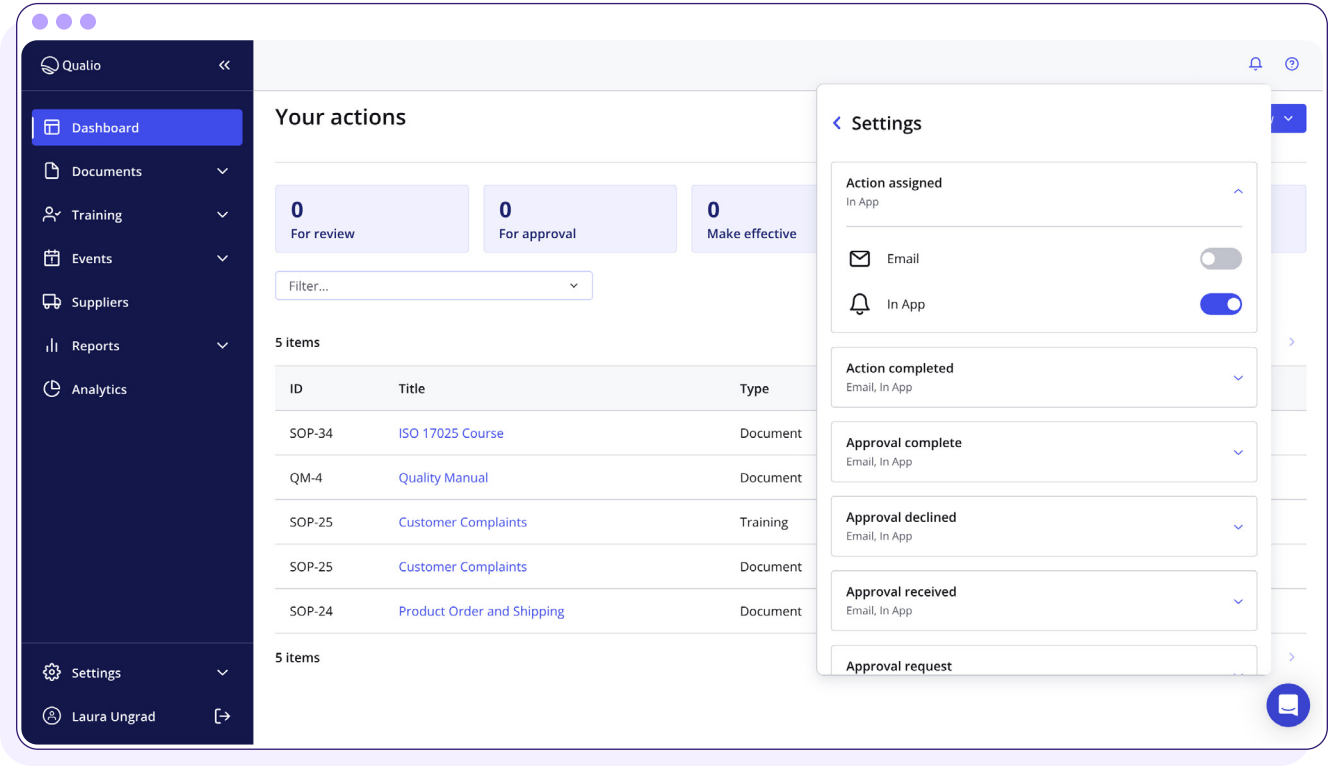
> Qualio's unified notification system drives collaboration and engagement both within and outside your quality team.



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

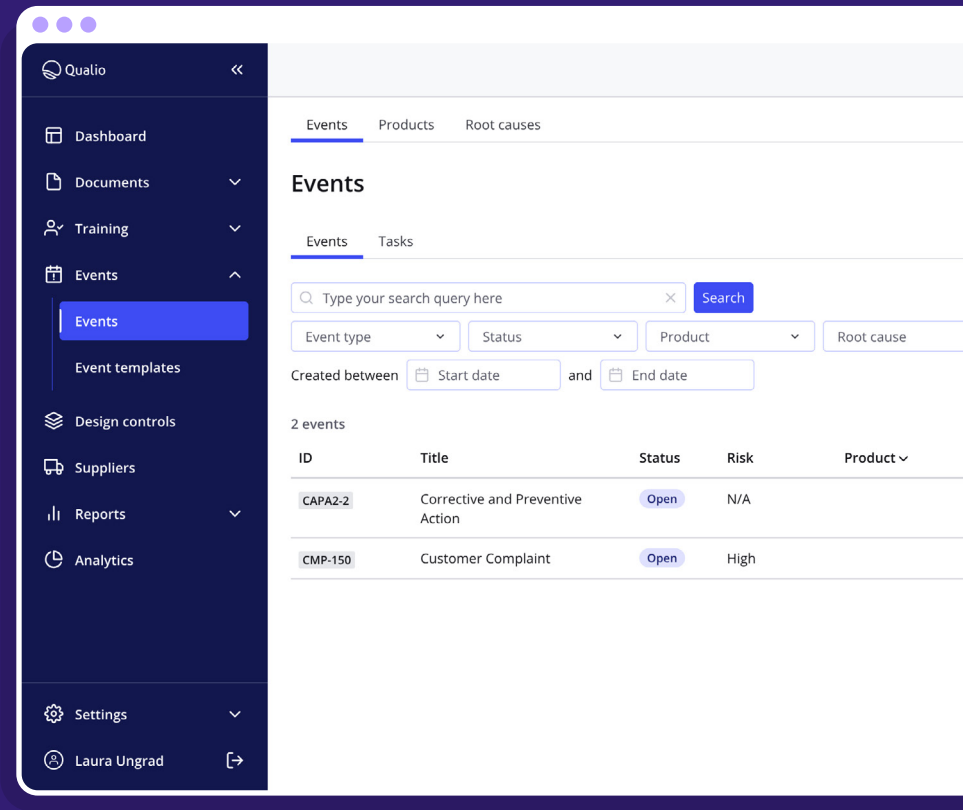
12 reasons to manage your events within Qualio

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

Qualio

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