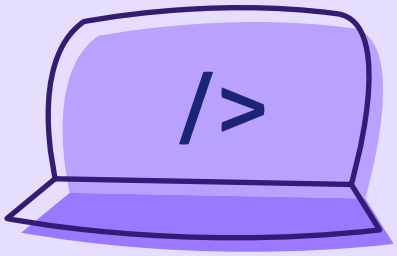
Qualio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Quality event management software

How Qualio empowers you with end-to-end control of any quality event

Table of Contents

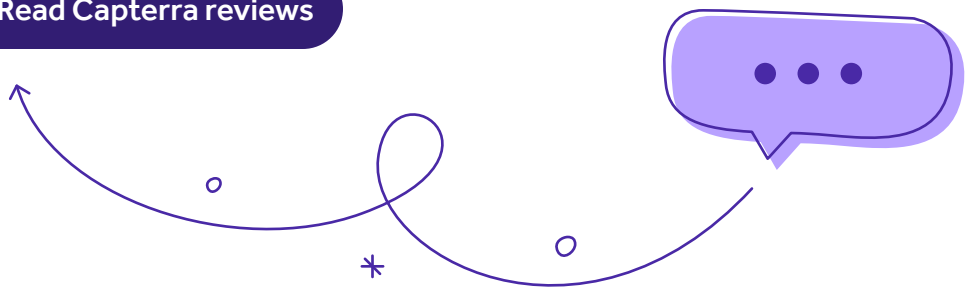
Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

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



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How you respond to quality events and issues is subject to intense regulatory scrutiny. But for ambitious, growth-oriented life science companies, simple quality control and assurance will only get you so far.

Manual quality management systems simply don't arm quality teams with the visibility and control they need to embed real continuous sharpening and refinement.

From managing CAPAs and complaints to stamping out non-conformances and defects, point solutions and paper- and spreadsheet-based systems begin to creak under the weight. Information is missed. Responses are unstandardized and duplicated. And the same problems resurface time and again.

What if you could automate and standardize your quality event processes, and push them into a single source of truth where all actions are tracked, tasks are easily delegated, and you have confidence that resolved events won't return? Now you can.

Meg Sinclair
Quality Operations Manager

Complete quality event control

Qualio's Events area is used by hundreds of regulated life science companies to manage their quality events in a structured, systematic way. The Events area provides a string of powerful operational benefits for your business, including:

1. **Standardized processes for any and every quality event**

   Build bespoke event templates to manage audit findings, batch records, CAPAs, NCRs, complaints, deviations, incidents and so on.

2. **Connect your business**

   Customizable workflows route actions to the right person at the right time. Prompts and reminders keep actions timely and your colleagues on the same page. And our powerful in-app event editor allows you to comment, suggest, and collaborate on events quickly and easily with your colleagues.

3. **Get the info you need**

   Fully flexible event templates let you build your own fields, from checkboxes to attachments, and use your own terminology to ensure information is captured how you want it to be.

4. **Rich reporting**

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

5. **A single source of truth**

   Compile all your quality event information in a single, simple library and demonstrate complete control and compliance to your regulators.

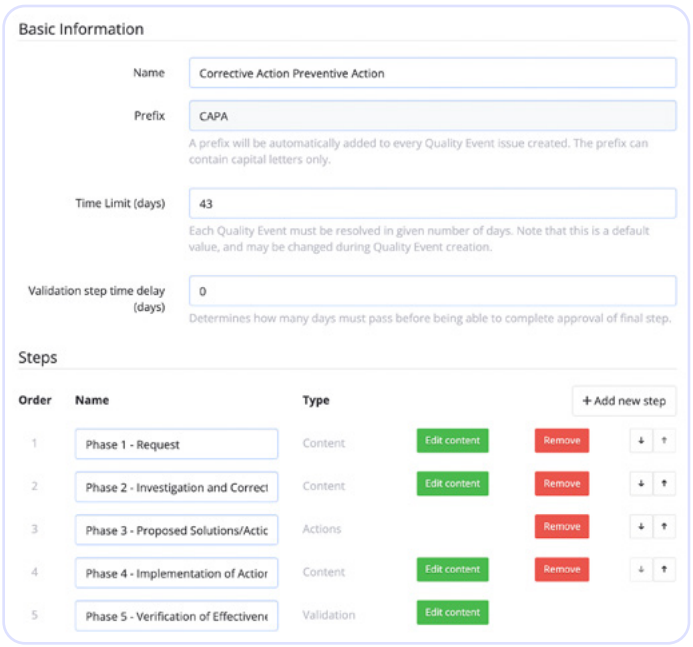
Key system features

Automated templates and workflows

> ***Qualio is easy to work with and makes life much easier in the quality sector. Templates can easily be designed to capture all the records required related to a specific issue or area. Quality events are easy to work with in Qualio.***
>
> **— Sara Viguera**
> Quality Manager, Leaseir Technologies

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.



Build an event template and customize its component steps.

Event steps can be either:

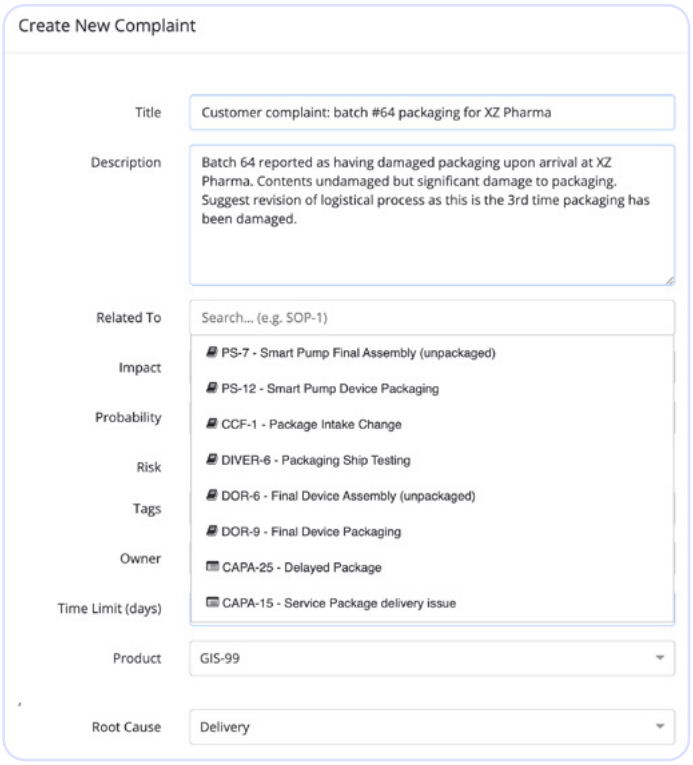
- Content steps, for capturing and recording information with forms
- Action steps, such as implementing a process change
- Validation steps, for final review and sign-off before event closure

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.

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.



Select a template and populate the details fields to kick-start an event. Associate events with documented information like relevant SOPs, set risk levels, tag for reference, and assign a product and root cause.

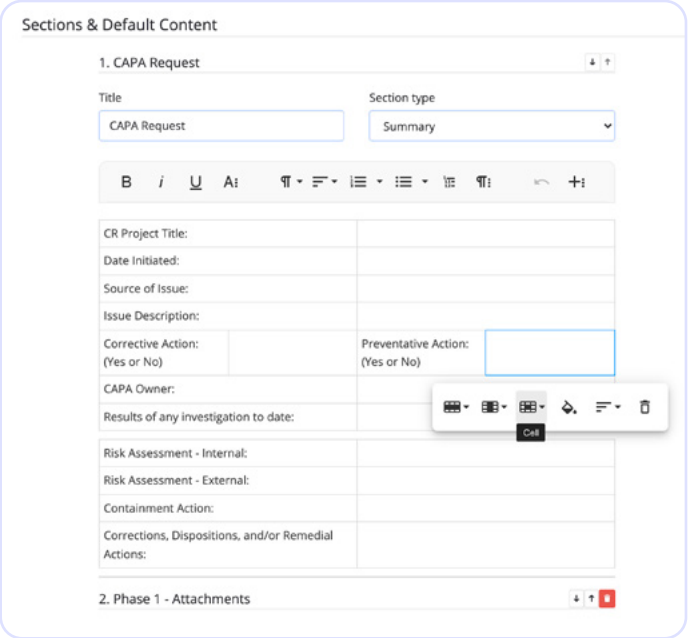
Complete information capture

> *The customization that Qualio offered was a huge differentiator from other solutions we looked into. We were able to build forms to look like our old ones so there was not a huge change for internal folks. The steps were the same.*
>
> **— Gene Vought**
> Custom Design Engineer, Cirris

Quality managers need cogent, 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.

Plus, associate events to documents in your Qualio system for cross-referencing.



Build event forms to look and feel how you want with Qualio's powerful web editor.

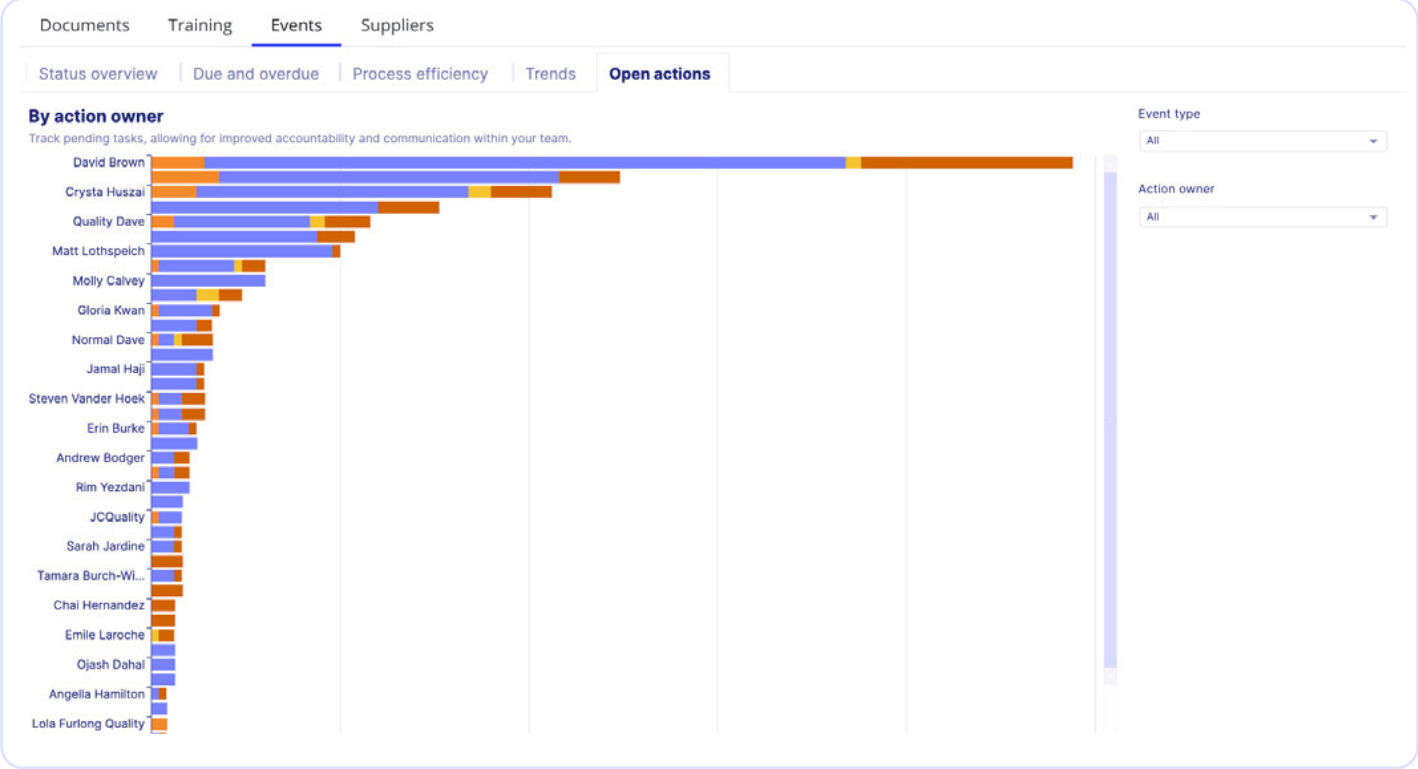
Event logs

> *We changed our quality system to fit to whatever Qualio does. Truth be told, it's a lot easier. The way we had it was a really old way of doing things; there were a lot of unnecessary steps. Qualio simplified things a lot for us.*
>
> **— Adolfo Ramirez**
> Director of Information Systems & Data Compliance, Irisys

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.



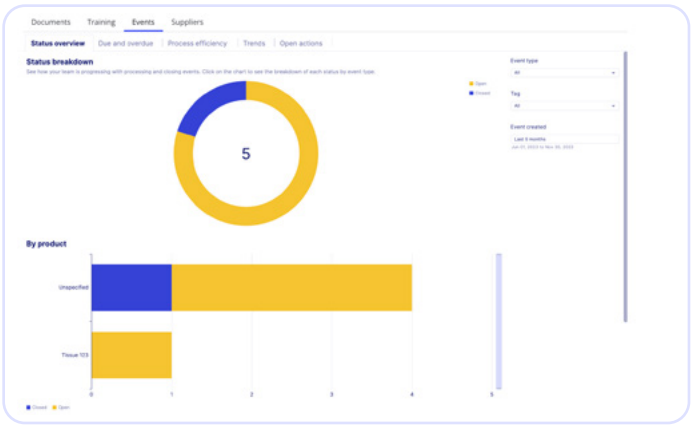
Access event analytics from a dedicated area for at-a-glance insights

Powerful reports

> *Qualio gives us fundamental knowledge about several aspects [of our QMS], including better understanding of our workflows and better continuous improvement.*
>
> **— Vasanth Ramar**
> Medical Technologist, Centogene

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

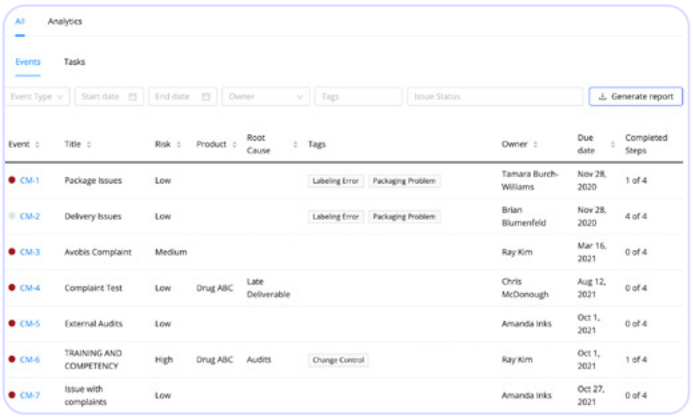
That's why the Events area comes with powerful reporting functionality to let you slice and dice your quality event data how you wish. Understand trends, compare timeframes, build visual pie and bar charts, and access your real-time event landscape without ever leaving the system.



View reports at the touch of a button. Filter by product or root cause and access powerful system analytic charts to make your quality management system even stronger and more data-driven.

More of a list person?

View system lists of quality events and their associated tasks. Filter by type, status, owner, timeframe and tag.



Dive into lists of events and system tasks, and export reports easily.

10 reasons to manage your quality events with Qualio

01. Construct bespoke response templates for any type of quality event

02. Route tasks to the right person at the right time with flexible workflows

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

04. Dive into complete real-time lists and records of all quality activity at your business

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

06. Guarantee compliance with fully trackable closed-loop event management

07. Unlock continuous quality improvement with rich data analysis at your fingertips

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

09. Make quality front and center with to do lists, prompts and reminders

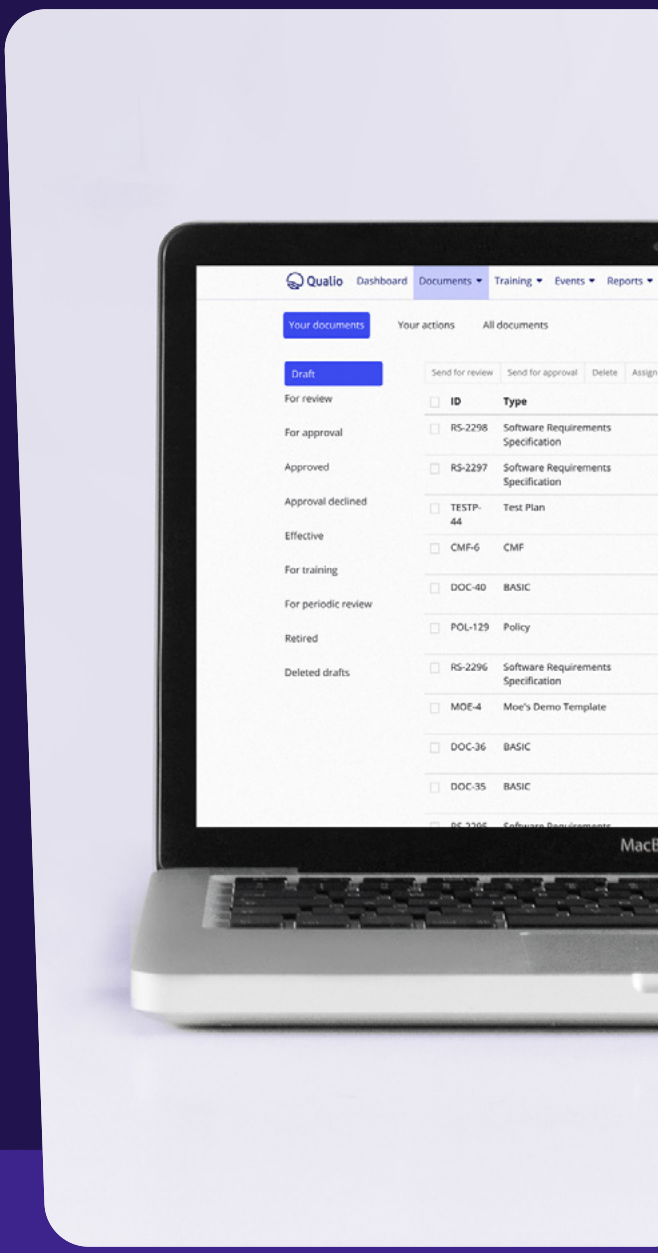
10. Meet your standards, regulations and SLAs every single time

Qualio

Ready to manage your quality landscape with complete control and visibility?

We'll answer your questions, give you a live private tour of the product and help you determine if we're a good fit for your quality event management needs.

Schedule a demo with us



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