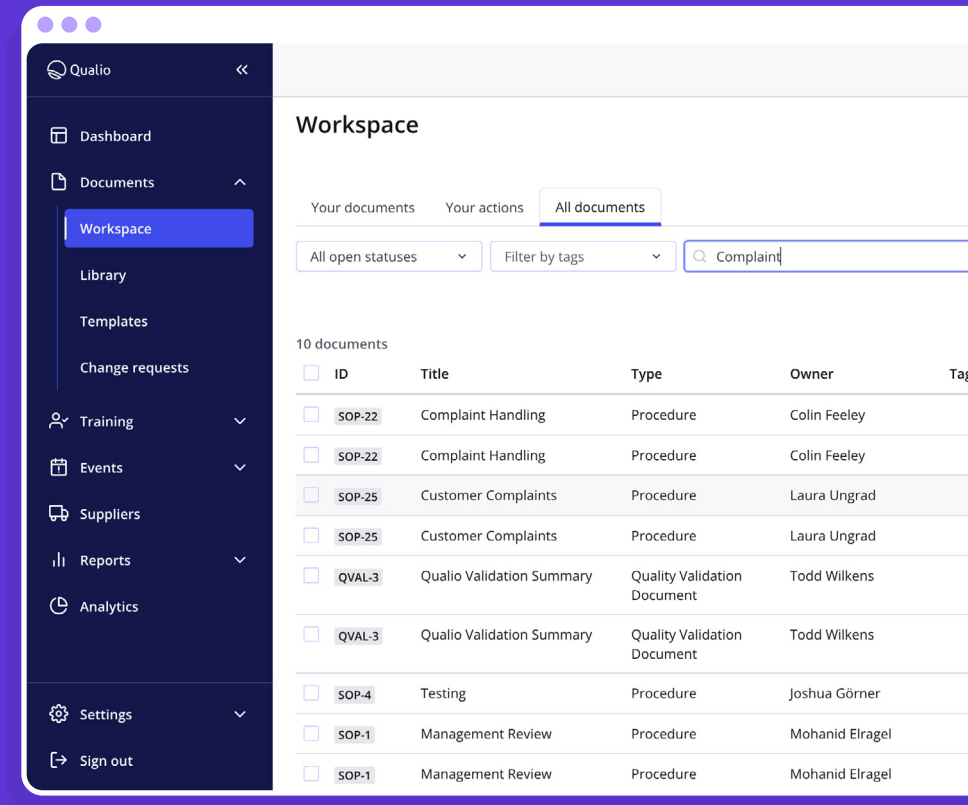
Qualio

QUALIO PRODUCT GUIDE

Qualio Documents

For controlled, compliant and collaborative quality documents



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

Document software for modern life science challenges

What Qualio really did for us was let us work on projects other than document control. That's the big payoff right there. Not having to worry about document control and just being able to work on our projects is a big weight lifted off of our shoulders.

Watch interview snippet

LOWELL HOFFMAN

Director of Quality Assurance
Restech

When your entire focus is, "do we have all the paperwork?", "is it all properly signed?", "is it all properly filed?", you're not moving forward. You can't. Now, because everything is so streamlined, we are making progress. We're finally developing a new product and moving into design controls right now. I don't know if that would be possible if we didn't have Qualio.

Watch interview snippet

AMI ANDERSON

Director of Operations & Quality
NeuFit

Document software for modern life science challenges

Outside of saving a good 90-99% of time, Qualio's given everyone ownership of the quality system. The way they're talking about SOPs has changed. Before, they were 'Angela's SOPs'. Now they're 'our SOPs'.

ANGELA PINKSTON

Quality Assurance Manager
Akadeum Life Sciences

Watch interview snippet

I really hate dealing with documents. It's just not what I'm set up to do. But every time I deal with Qualio, it's a pleasant interaction. I actually told Hallie, "man, I really love Qualio!"

DMITRY FEDOROV

CTO
ViQi

Watch interview snippet

I can co-sign that – he said, "this is really lovely!" Said no person in an eQMS system ever, but Dmitry did!

HALLIE GREENE

Project Manager
ViQi

Our customers report...

>90% reduction in document admin and location time

25% faster document lifecycle processes

Up to 5 document personnel FTE spends mitigated

$10-30K consultancy costs mitigated by pre-built quality document template library

5x faster external audits

More collaborative quality cultures built on controlled information

Simplified compliance with FDA 21 CFR Part 11, GDocP, ISO 27001, ALCOA+ and other document integrity standards

5 software features to optimize your document processes

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

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

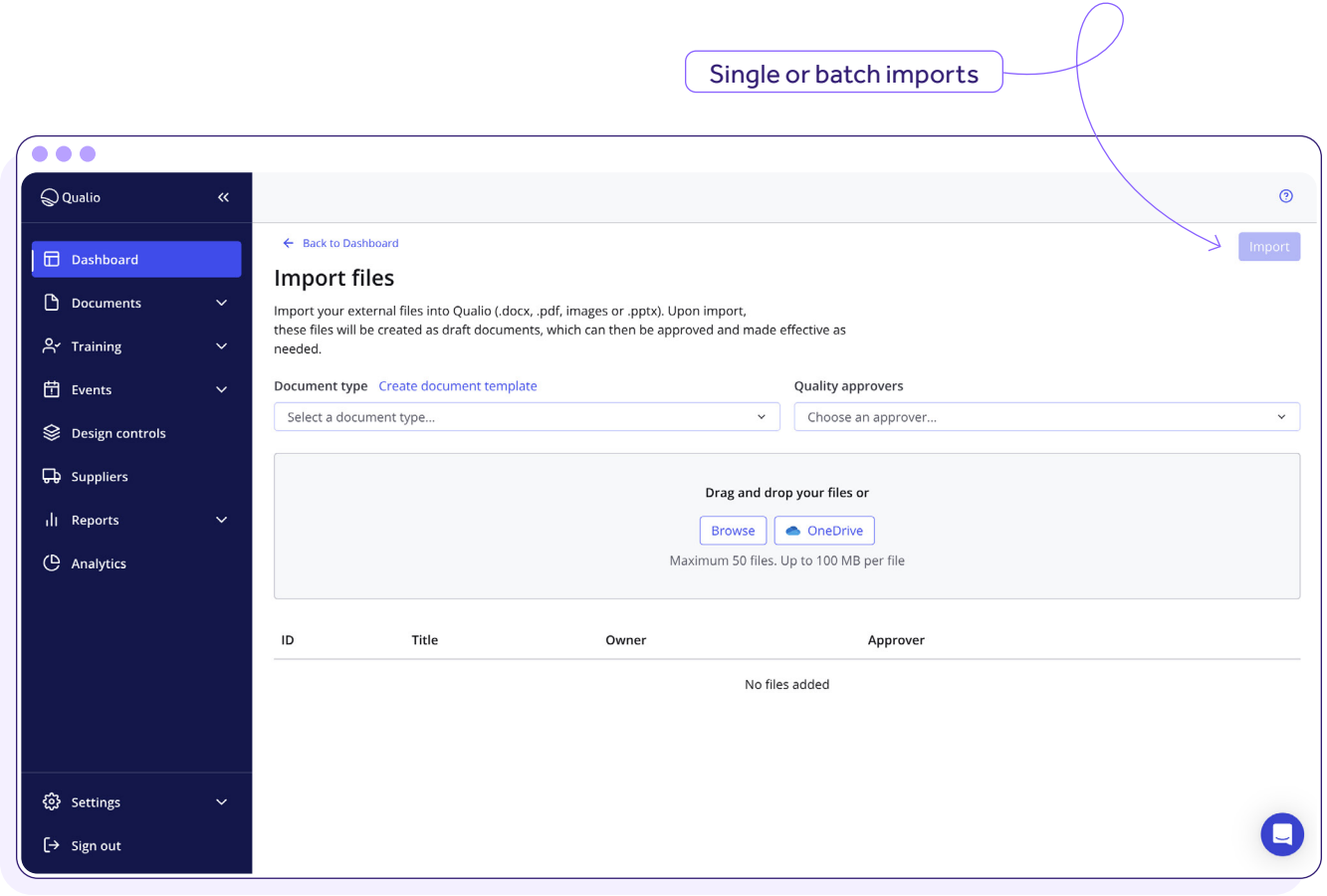
Want to see more, including a walkthrough of Qualio in action? Visit the last page to book a demonstration at a time that suits you.

1 Hybrid document control to have things your way

Qualio gives you a uniquely flexible hybrid approach to manage your critical documentation how you want to.

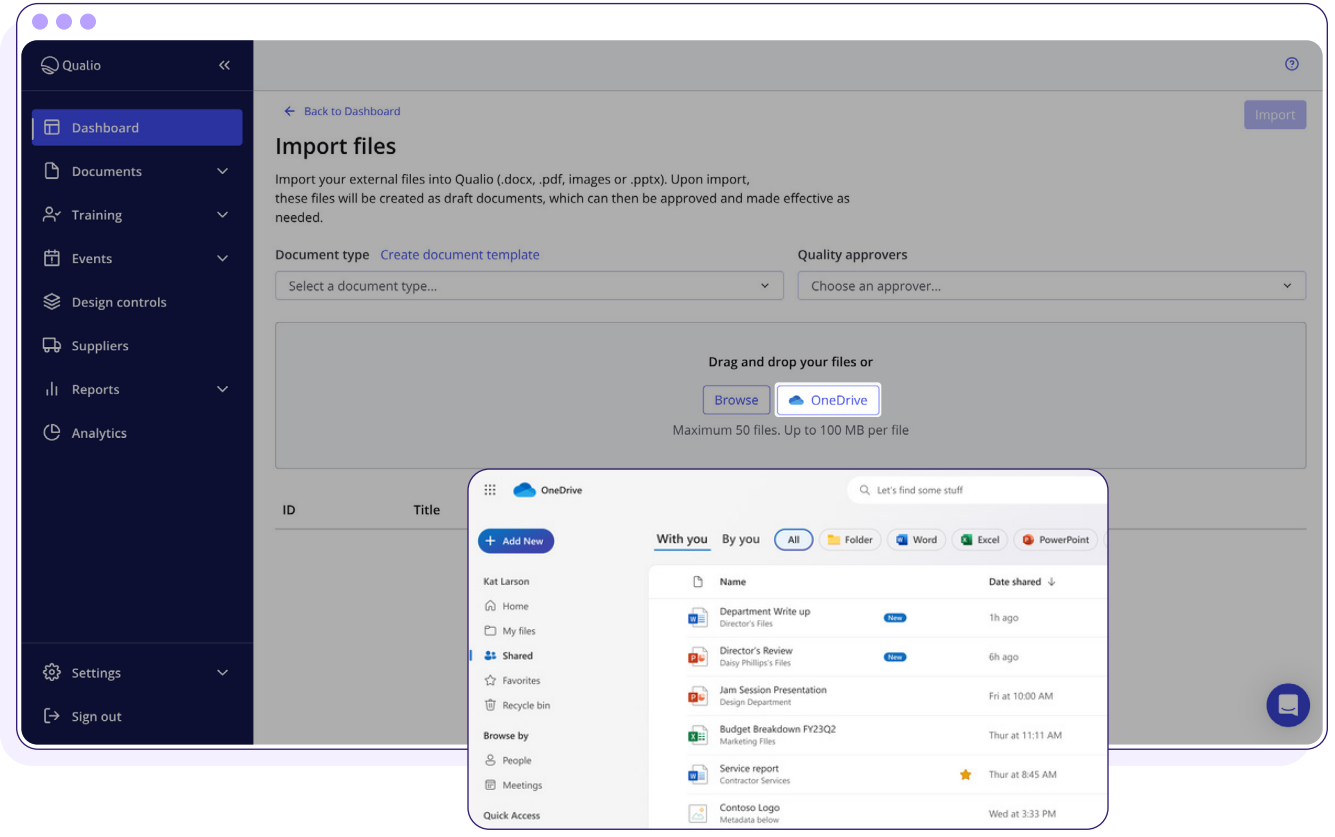
> Upload your existing content into Qualio, in its original format, from SOPs and policies to records, manuals, instructions and technical drawings.

Because Qualio is a dedicated life science eQMS, it's got everything you need baked in to give those uploaded documents instant compliant control, from version and permission controls to e-signatures and customizable action pathways for reviewing, signing off and distributing.



1 Hybrid document control to have things your way

Sync documents, and any ongoing updates, directly from your company OneDrive, letting your colleagues continue using their familiar third-party tools without compromising your data integrity or your compliance.

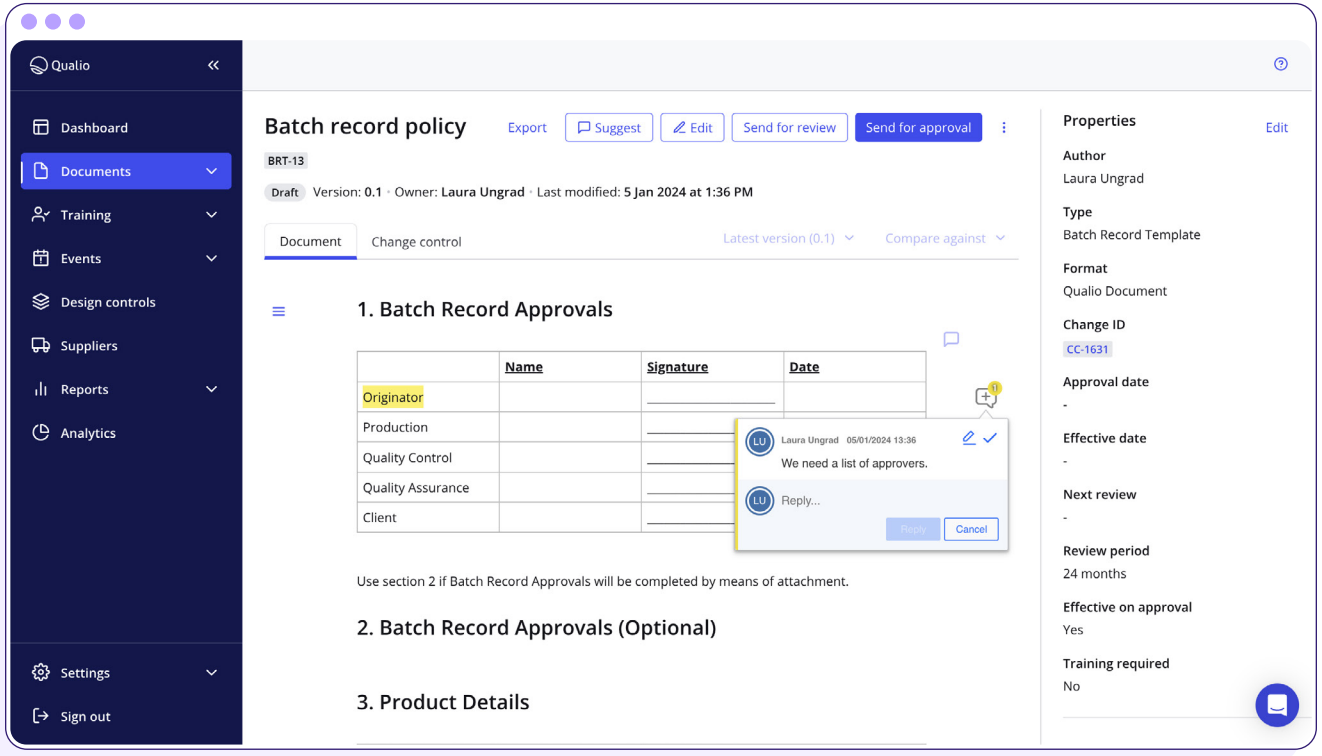


1 Hybrid document control to have things your way

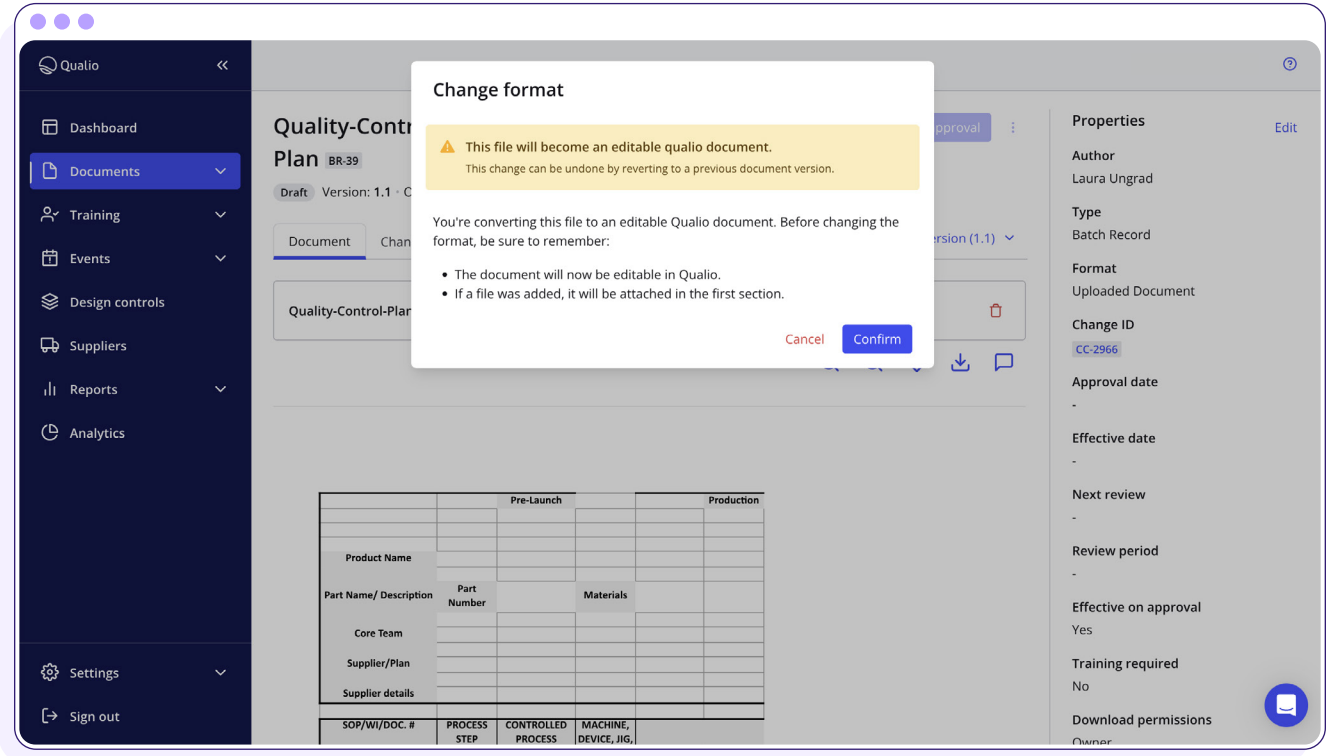
When it's time to make something new, use Qualio's unique, fully in-app document editor to seamlessly collaborate with colleagues. Create, edit, comment and distribute without ever leaving your Qualio system or having to check documents in and out.

Already got a document stack?

Don't worry! Qualio offers a complete document migration service during implementation to transfer your existing documents into your new eQMS quickly and easily.



1 Hybrid document control to have things your way

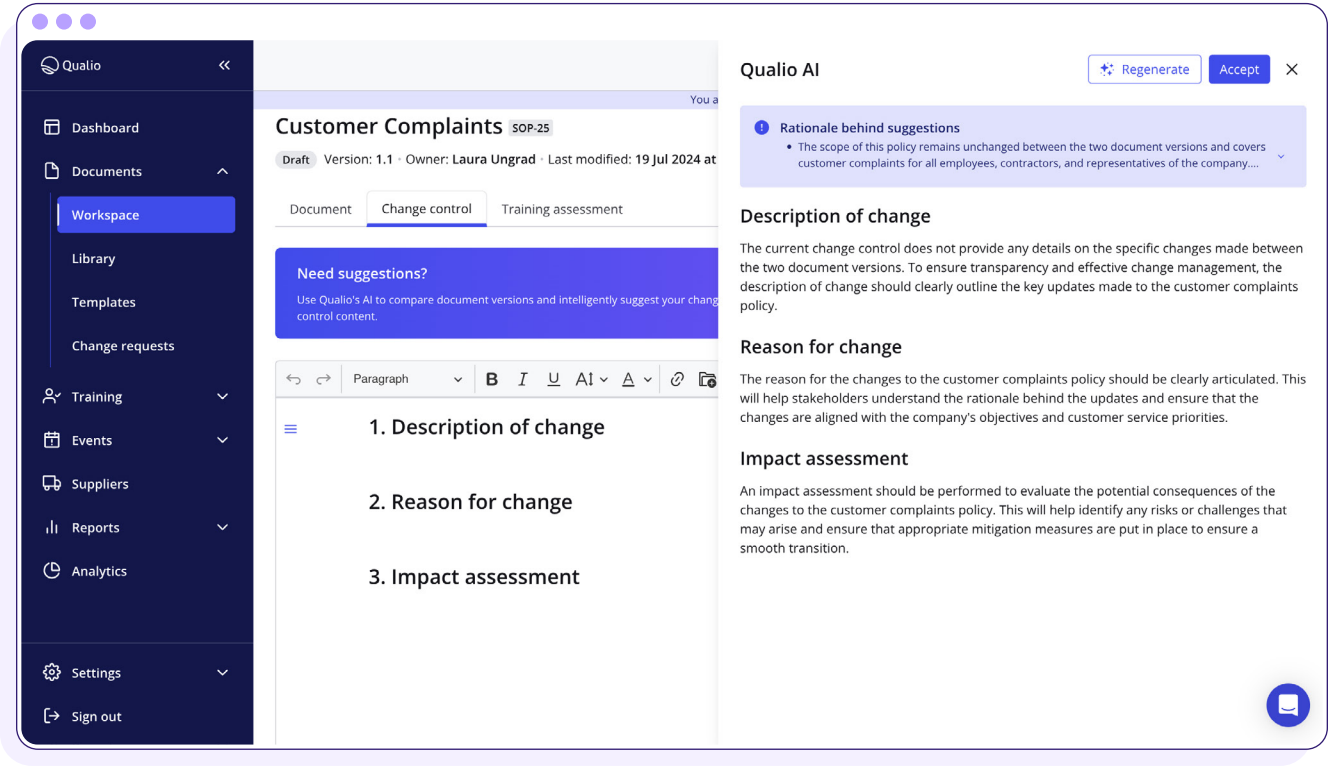


Need to edit one of those documents you uploaded, too? Convert them into an editable format whenever you want to.

2 AI to accelerate your document work

In a regulated life science environment, every document update also requires a change summary to record the description of the change, the reason for it, and its impact.

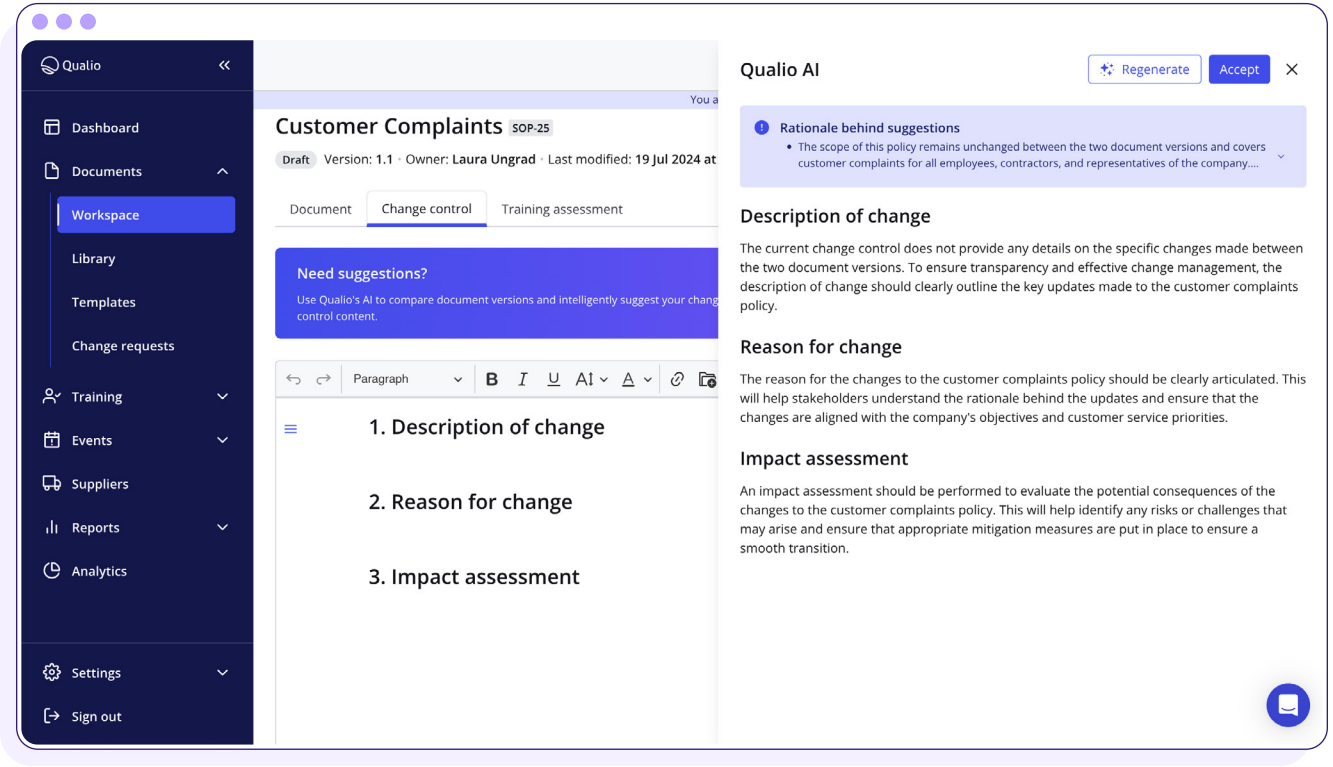
> Our AI Assistant functionality handles this task for you, automatically analyzing document updates as you make them and generating a change summary in seconds.
>
> Your document updates stay recorded and compliant, without the effort of documenting them yourself.
>
> Simply review the summary, tweak it if needed, and hit accept.



2 AI to accelerate your document work

Want to generate a training assessment to ensure a critical document has been understood by your colleagues? Qualio's AI makes that automatic, too!

> When a document's ready, let the AI Assistant fire up a list of questions and answers based on the document content.

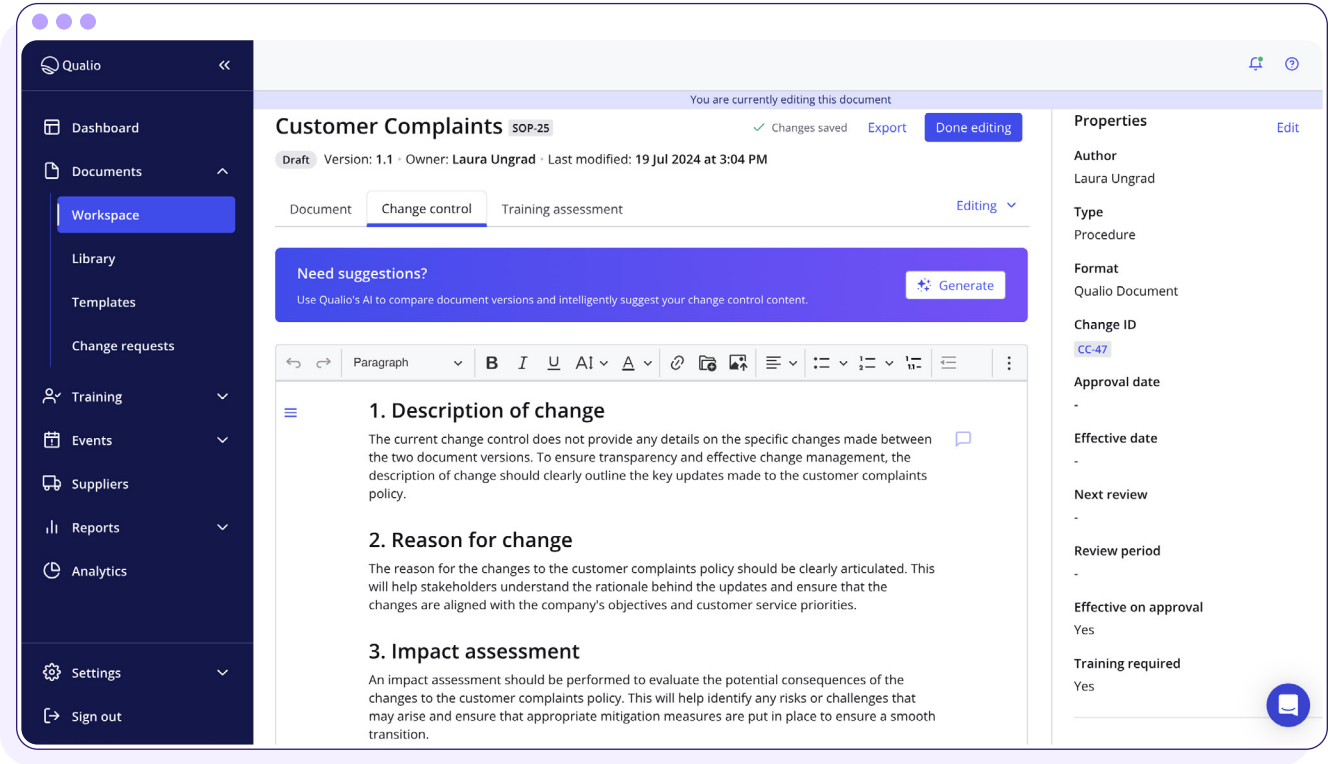


2 AI to accelerate your document work

Need a hand optimizing the content of a document itself?

> Ask the AI Assistant to summarize, improve writing style, simplify, convert paragraphs into step-by-step instructions, or increase the authoritativeness of the document's language.

Clean, crisp, usable documents at the touch of a button.



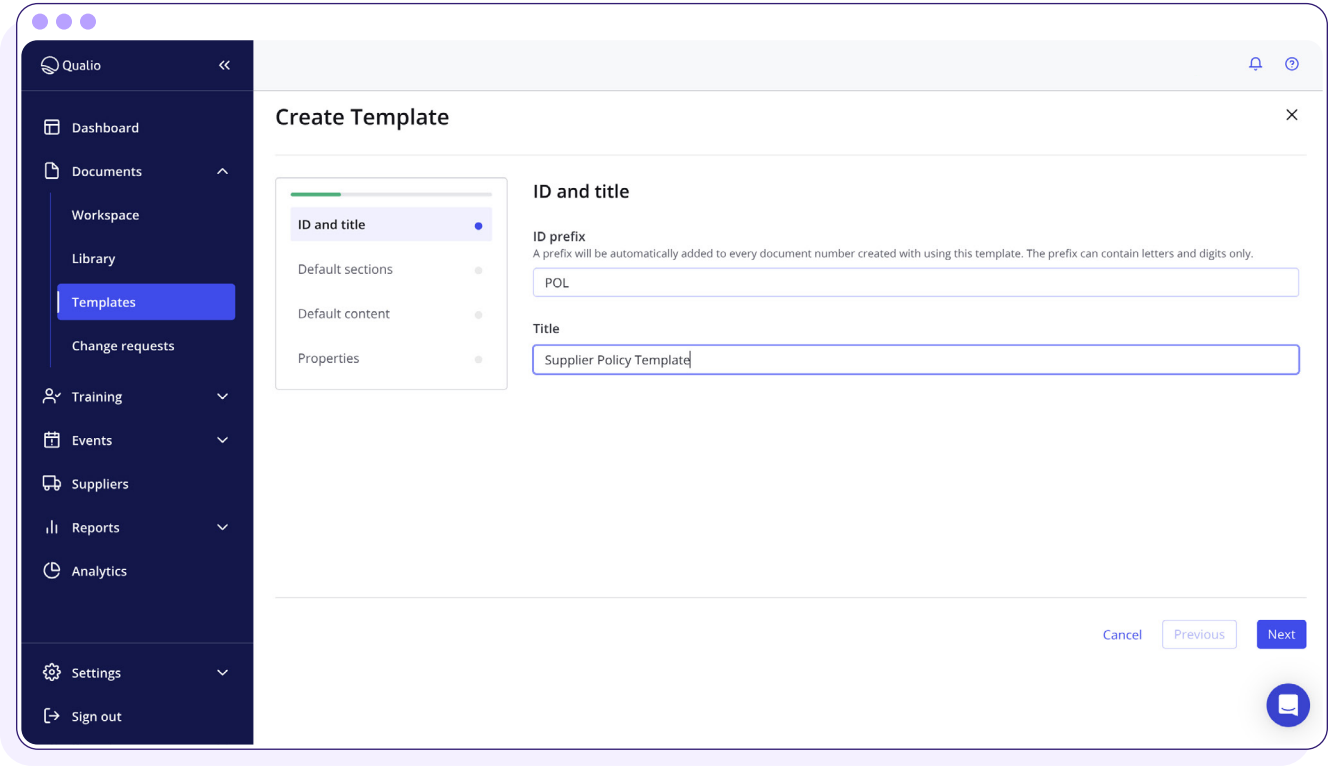
3 Templates for consistent information – and an instant document stack!

An ordered and usable eQMS needs consistently enforced document formats and structures.

That's why the document creation process within Qualio is driven by templates.

Document templates define the structure of a document and mandate a series of default settings. Every document created within Qualio must follow a template.

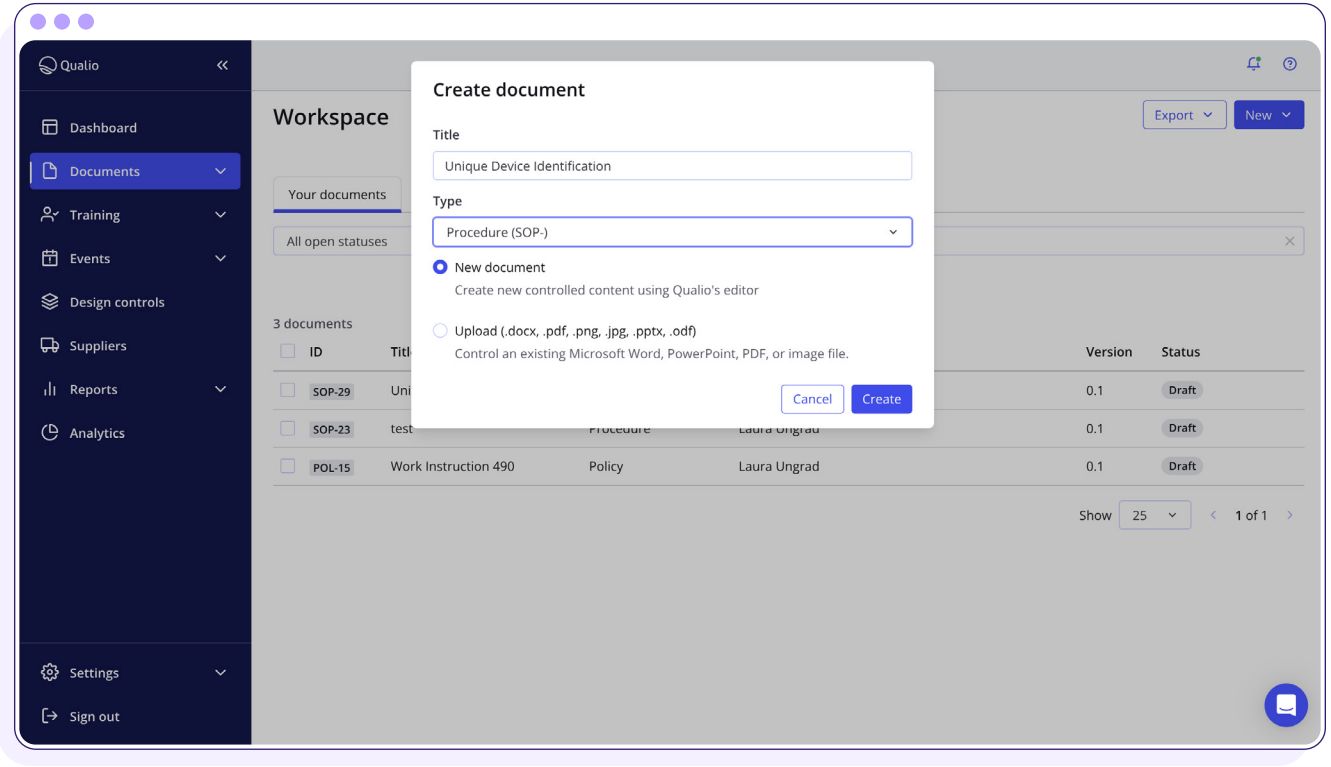
> You can build a document template for every type of document your business uses. Give it a prefix, set training requirements, and mandate review and approval periods.
>
> Then add sections and default content for every future document with that template to follow.



3 Templates for consistent information – and an instant document stack!

> Once a document template is complete, simply select it as you build a new document, then work through the template structure with Qualio's intuitive native editor to build your document on the fly.

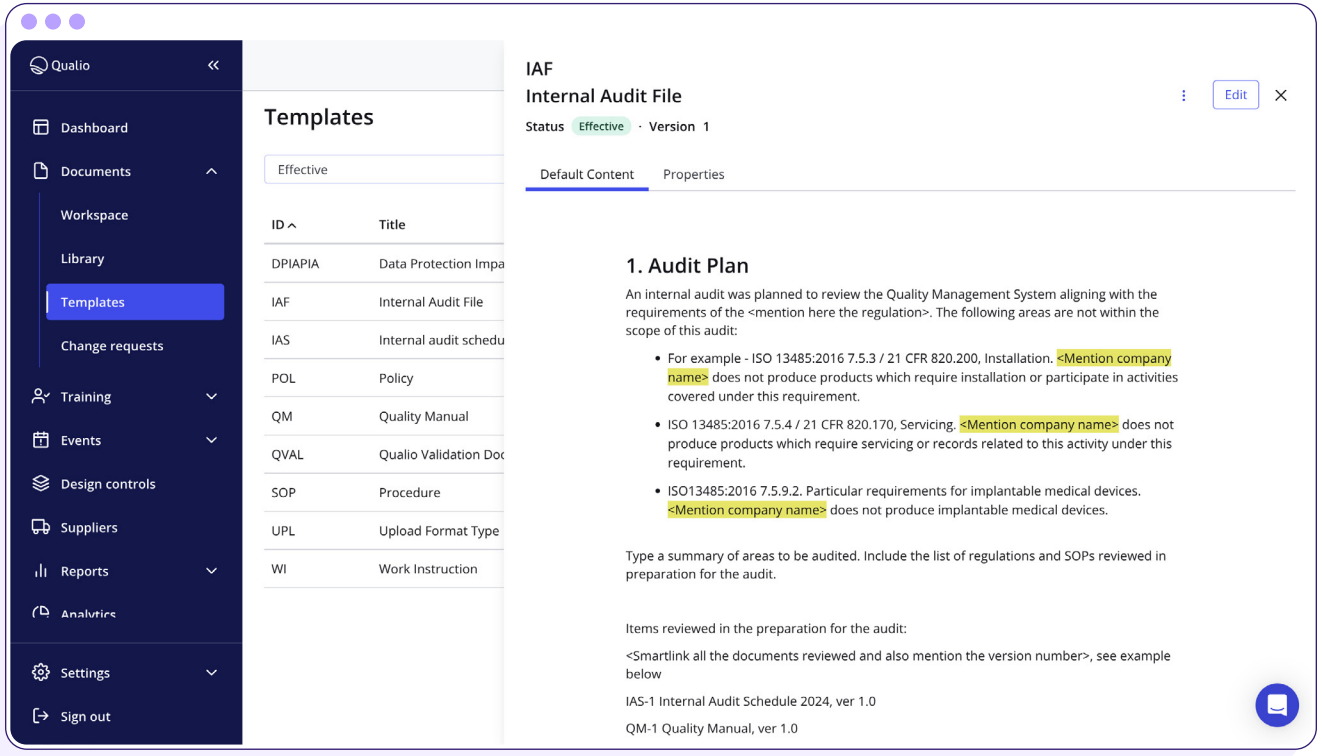
Give your document a title. Add categorization tags. Assign as many or as few reviewers and approvers as you require, then populate the template sections — all without ever leaving the system.



3 Templates for consistent information – and an instant document stack!

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.

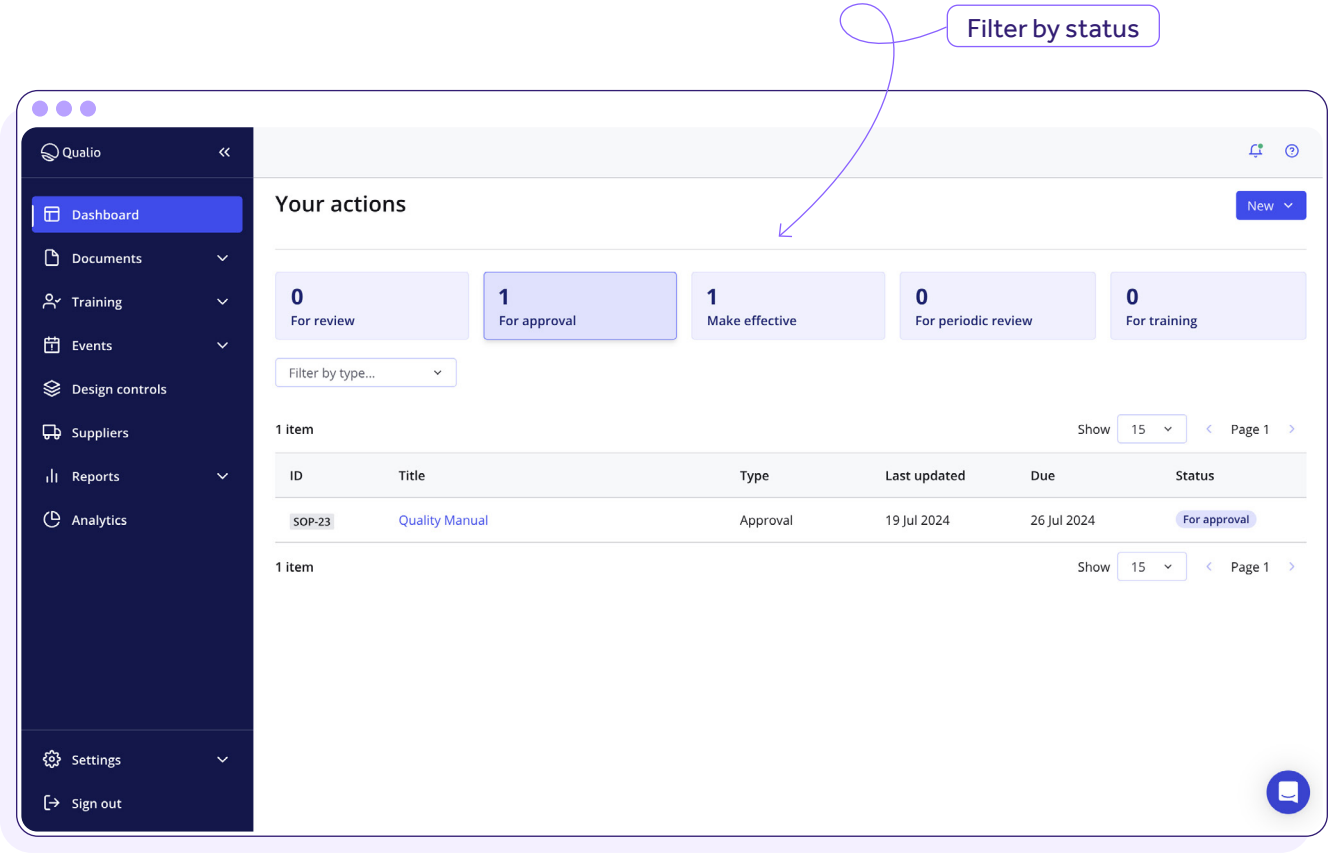


4 Collaboration and connection for a quality culture

Your document system should be the bedrock of centralized information that knits your company together.

Qualio offers an integrated workflow-driven environment for the collaborative management of documents — so the right people can guide a document process at the right time with complete traceability.

> Once a document draft is launched, its assigned reviewers and approvers are notified (and reminded) by email and via their Qualio Workspace 'to do' list to ensure nothing is missed.

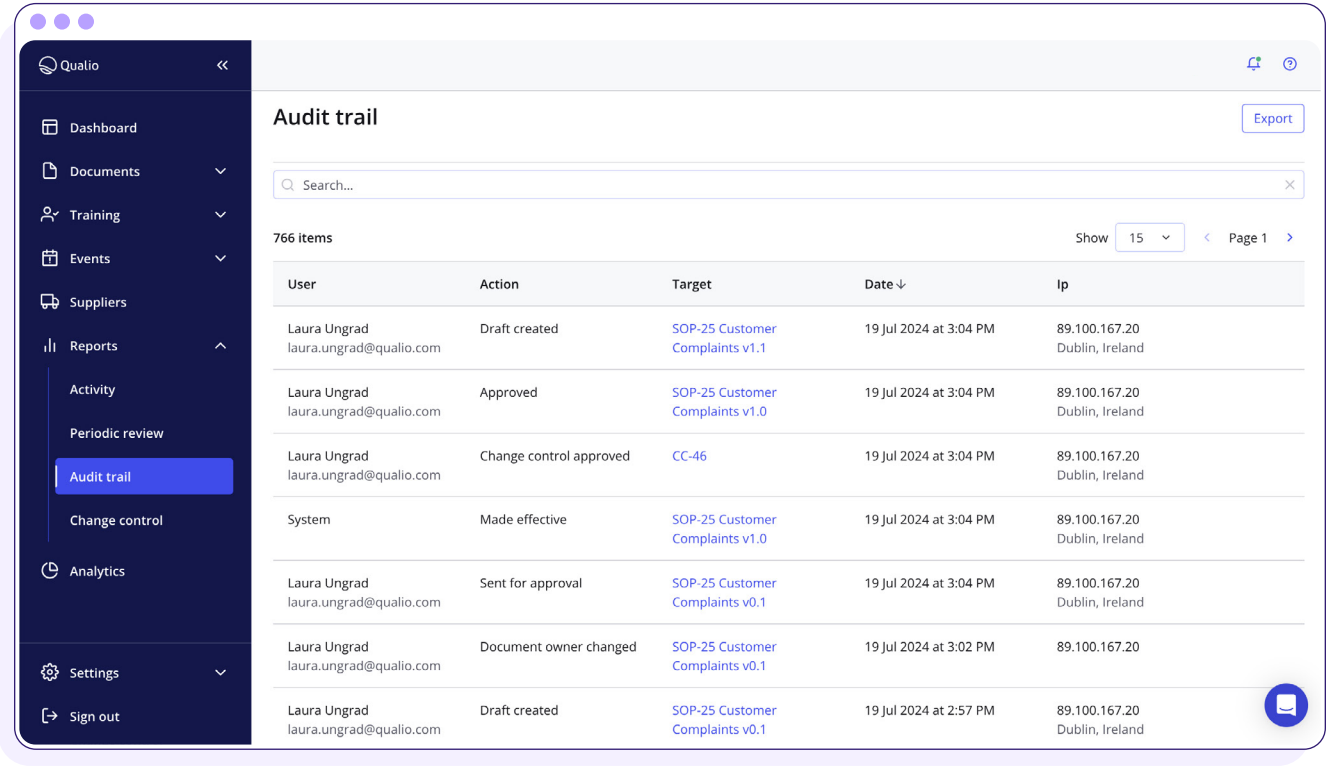


4 Collaboration and connection for a quality culture

> Revert to draft and make edits. Add comments and loop in other users in real time. Compare changes between versions. And enjoy complete visibility as your document evolves — with every update completely audit-trailed and activity reports available at the touch of a button.

And once a document is approved and published, its assigned review settings will activate a review workflow at your set future date to ensure it remains accurate, compliant and fit for purpose.

No more chasing colleagues for signatures and approvals!

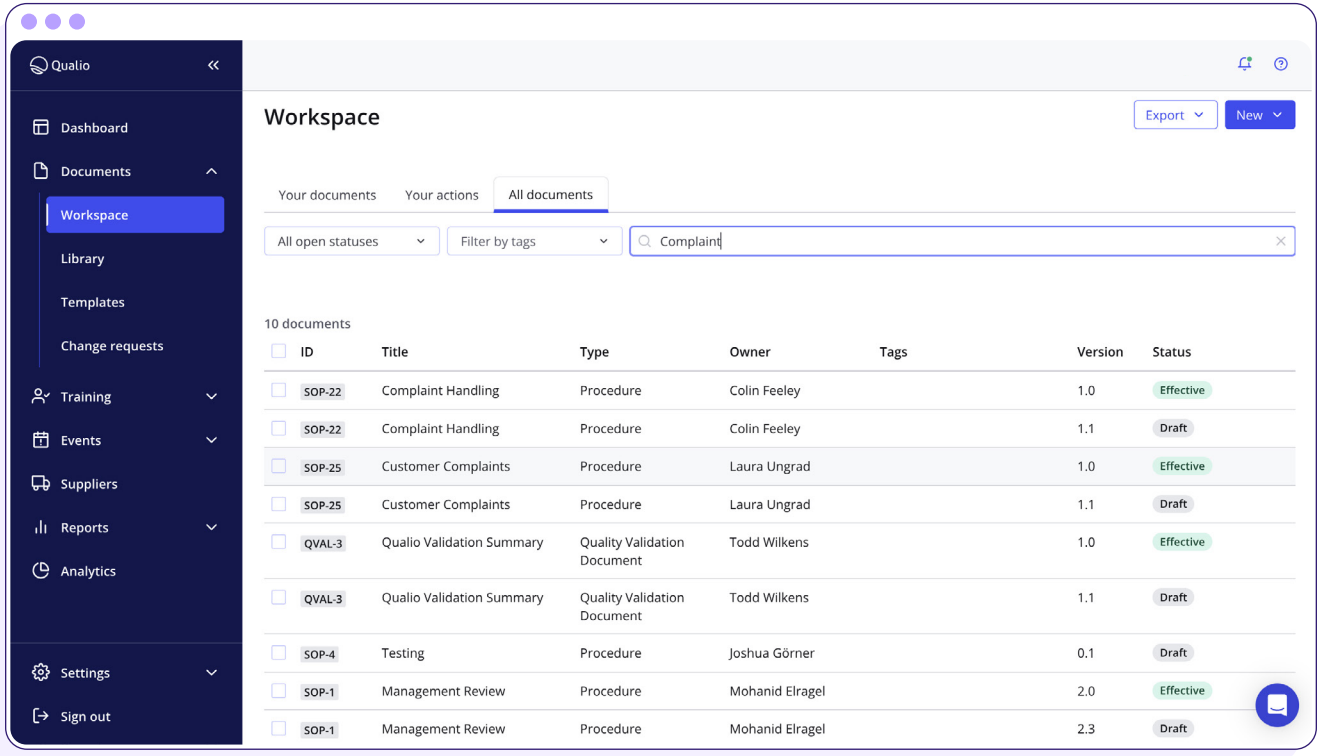


4 Collaboration and connection for a quality culture

McKinsey estimates that knowledge workers with legacy document systems spend 20% of their day just searching for the information they need to do their jobs. That's the equivalent of 1 in 5 of your teammates doing no productive work at all!

Qualio gives your business a single, central, fully paperless cloud-based library for your entire document stack. No more filing cabinets, nests of SharePoint folders, or confused colleagues.

> Powerful search functionality and document tagging let your team find the information they need in seconds rather than minutes.

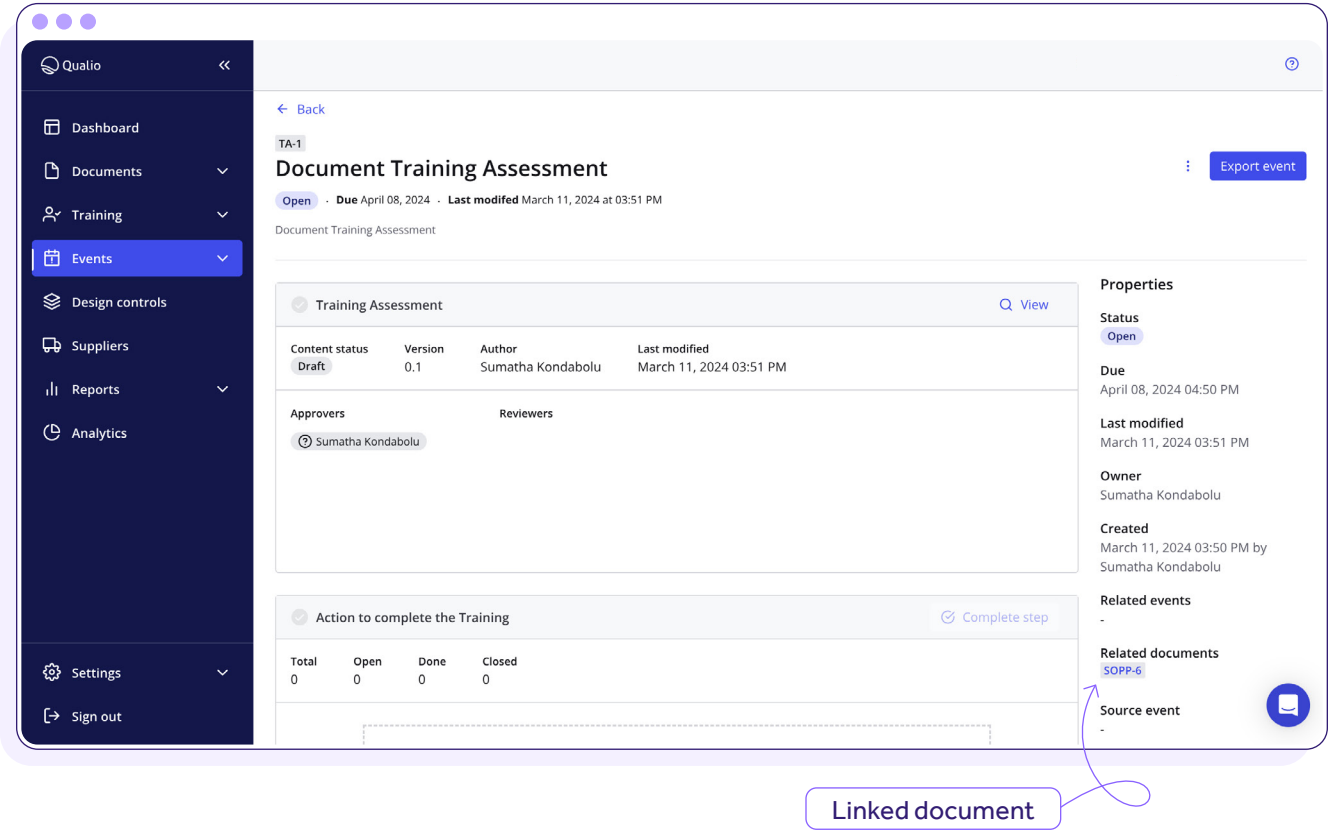


4 Collaboration and connection for a quality culture

Smart links connect documents to each other and to other elements of your eQMS like events and supplier records.

Bespoke view, edit and download user permissions ensure information is shared in a controlled manner across your business.

And superseded document versions are automatically archived to enforce version control and slice duplication.

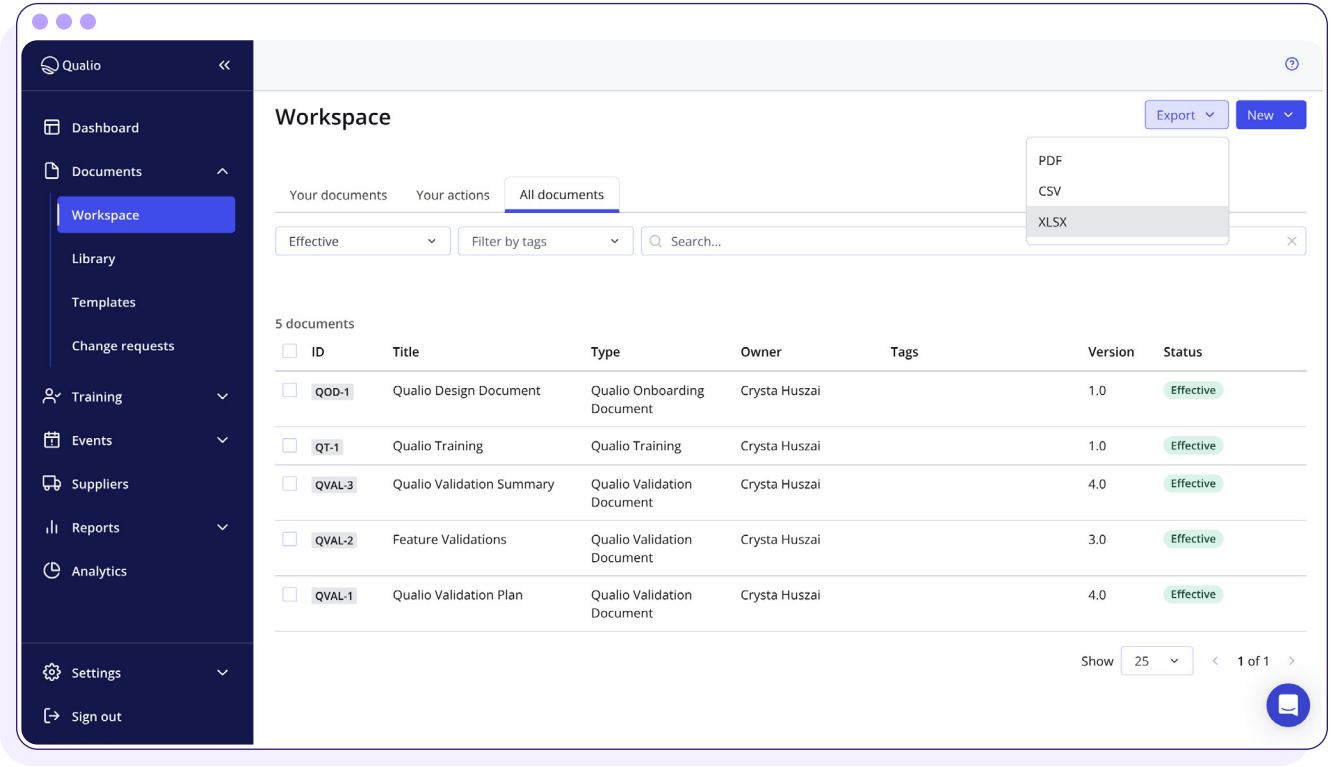


4 Collaboration and connection for a quality culture

Qualio is designed to place your quality management system at the front and center of your business — so policies, processes and procedures are easily found and followed by everyone.

Since Qualio is cloud-hosted, you can dive into your document management system from anywhere in the world with an Internet connection.

> Plus, all documents are exportable at the touch of a button into PDF, CSV or XLSX formats for easy sharing with your interested parties, like customers or auditors.

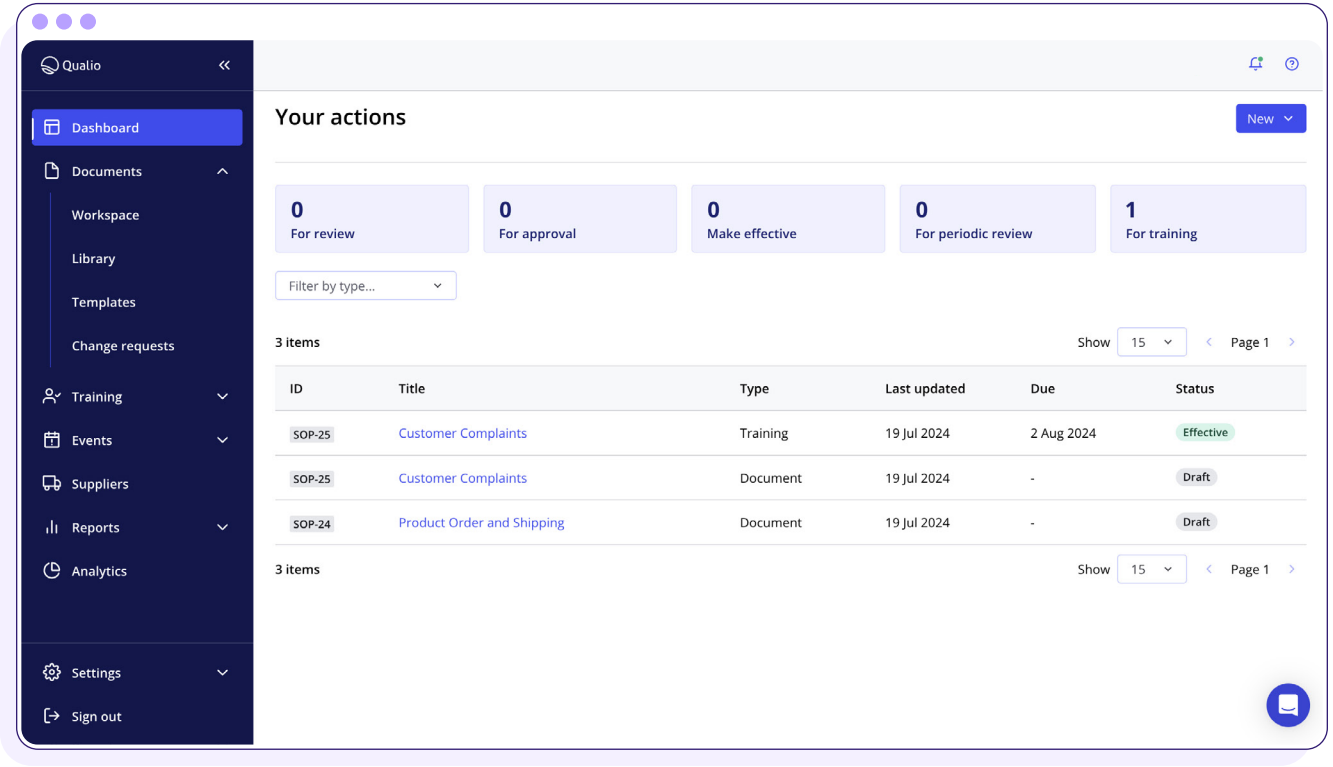


5 Automatic compliance for peace of mind

None of this would matter if your document system was non-compliant. Qualio is designed to embed unshakable out-of-the-box compliance into your document activities.

Qualio cannot be accessed without a secure username and password, keeping your vital documents under lock and key. Qualio documents may be archived and versioned, but never deleted – preventing information gaps from emerging.

> And Qualio's Documents area seamlessly integrates with Qualio Training to provide fully audit-trailed, traceable acknowledgment and understanding of system documents to meet your regulatory requirements.

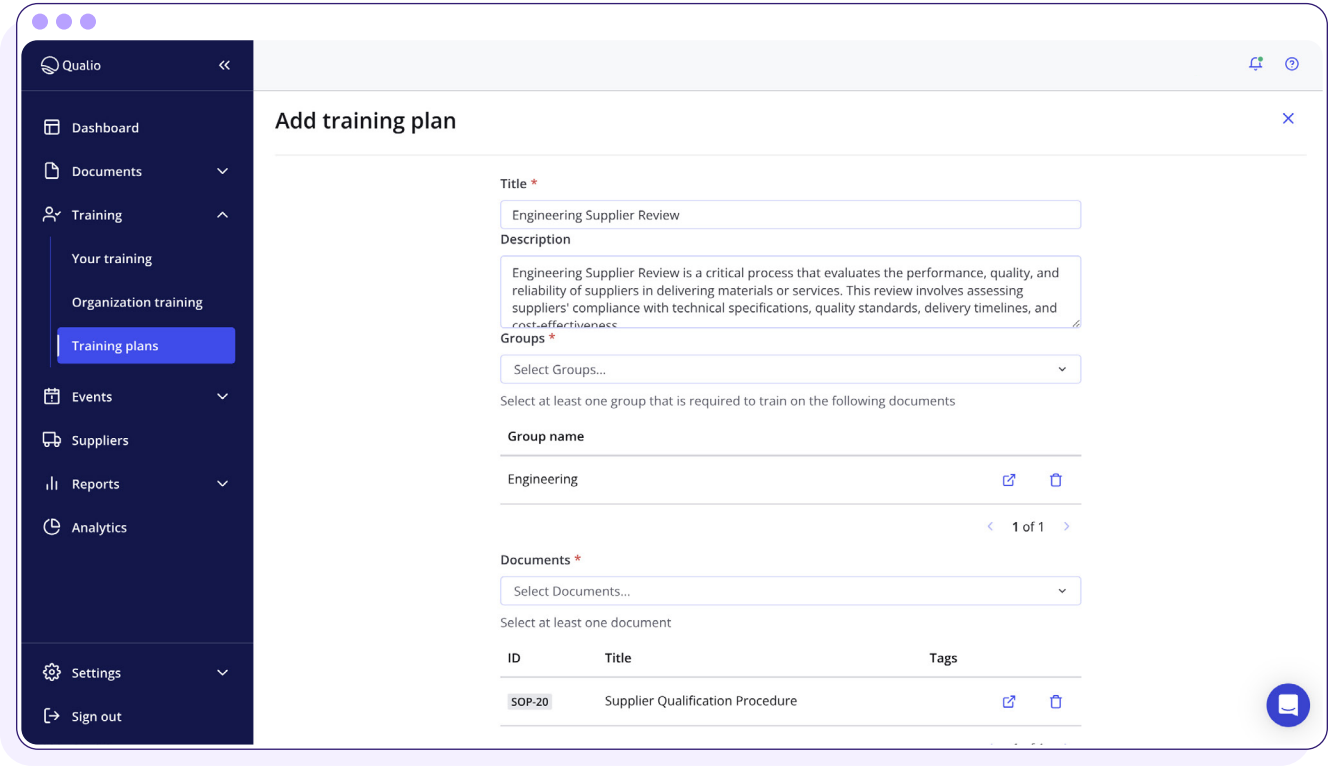


5 Automatic compliance for peace of mind

> Launching a new SOP? Set a Training Plans workflow to kick-start for specific departments and team members as soon as the document goes live, and add quizzes to test understanding.

Assignees are notified of their training requirements and deadlines instantly. Confirmation of training completion, like all system activity such as approving a document, is underpinned by binding e-signatures compliant with regulations like FDA 21 CFR Part 11 and EU Annex 11.

And every document management action performed within the system is fully time-stamped and audit-trailed too: drill into training summary reports, comment and collaboration activity histories, change control logs, and even archived document versions to demonstrate complete control and visibility to your auditors.



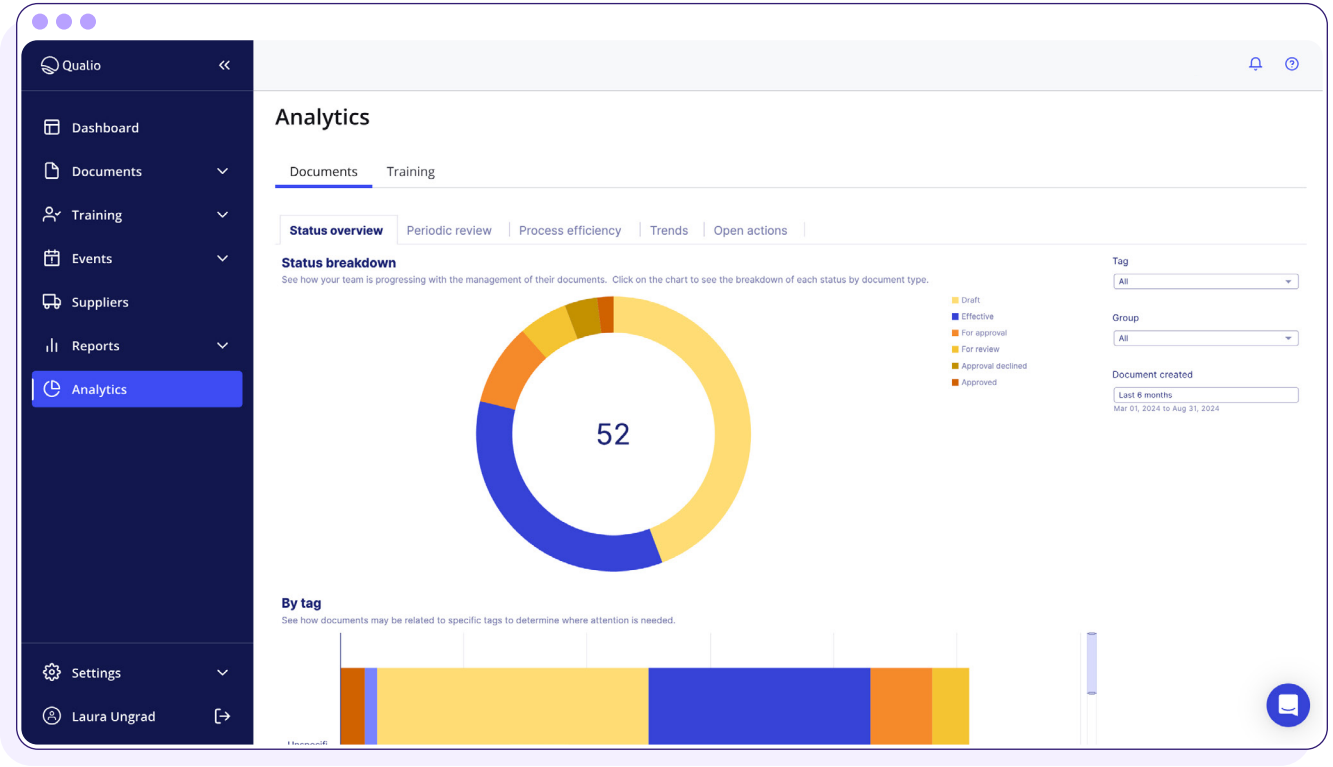
5 Automatic compliance for peace of mind

Plus, dive into the Analytics area of Qualio for instant top-down visibility of your entire document landscape at any time, from status breakdowns by document types to overdue approvals, document actions by individual users, and process trends.

Qualio offers complete assurance that your document management system is compliant with the requirements of:

- FDA 21 CFR Part 11
- EU Annex 11
- ALCOA+
- GDocP
- ISO 9001:2015
- ISO 27001:2022

And more!



The ROI of Qualio

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

Get your ROI figure ›

The average company spends:

$20 on labor to file a document

$120 in labor to find a misfiled document

$220 in labor to reproduce a lost document

7.5% of paper documents get lost and 3% misfiled

Watch interview snippet

5 FTEs to provide the same level of document control as Qualio

$25,000 spent every year by small, paper-based businesses on production, usage and storage costs of hard documents

$2,000 per year to maintain a single filing cabinet of documents

12 reasons to manage your documents within Qualio

Read our whitepaper!
Why your life science business needs electronic document management ›

1. Dedicated life science eQMS vendor with over 650 regulated customers
2. Lean, cost-effective document management without extra headcount
3. Built-in training functionality for understanding and acknowledgment of your key documents
4. Only in-app editor in a life science eQMS
5. Secure cloud-based access from anywhere
6. Hybrid document management, from OneDrive sync to original file format uploads and native document building
7. Audit trailing, e-signatures and action histories for total compliance
8. Pre-built document templates for instant market readiness
9. Customizable workflows for the entire document lifecycle
10. Clean and intuitive UX with ease of use at the forefront
11. Deep analytics to keep on top of your document activity
12. AI functionality to automate and accelerate work

Qualio

Ready to take your documents to the next level?

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