Welcome to the webinar

Building a culture of compliance

With Sumatha Kondabolu & Henry Tri

Qualio

Today’s hosts

Sumatha Kondabolu
Senior Quality Business Partner
Qualio

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Relationship Manager & Auditor
TÜV SÜD

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Today’s agenda

01 The 3 components of a compliance culture

02 Demonstrating compliance during an audit

03 Qualio’s new compliance AI software

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The 3 components of compliance culture

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What is a compliance culture?

✅ Being comfortable with and aware of your compliance demands

✅ Being able to quickly and easily demonstrate compliance

✅ The entire business (not just the quality manager!) is ready for audits

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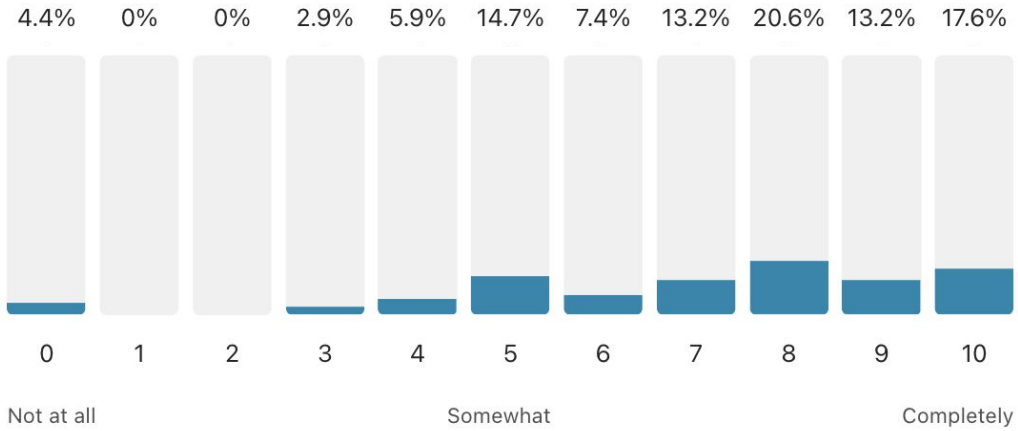
How do you feel now?

"You are confident that everything is there and ready when your auditor arrives." (February 2025 global Qualio survey)



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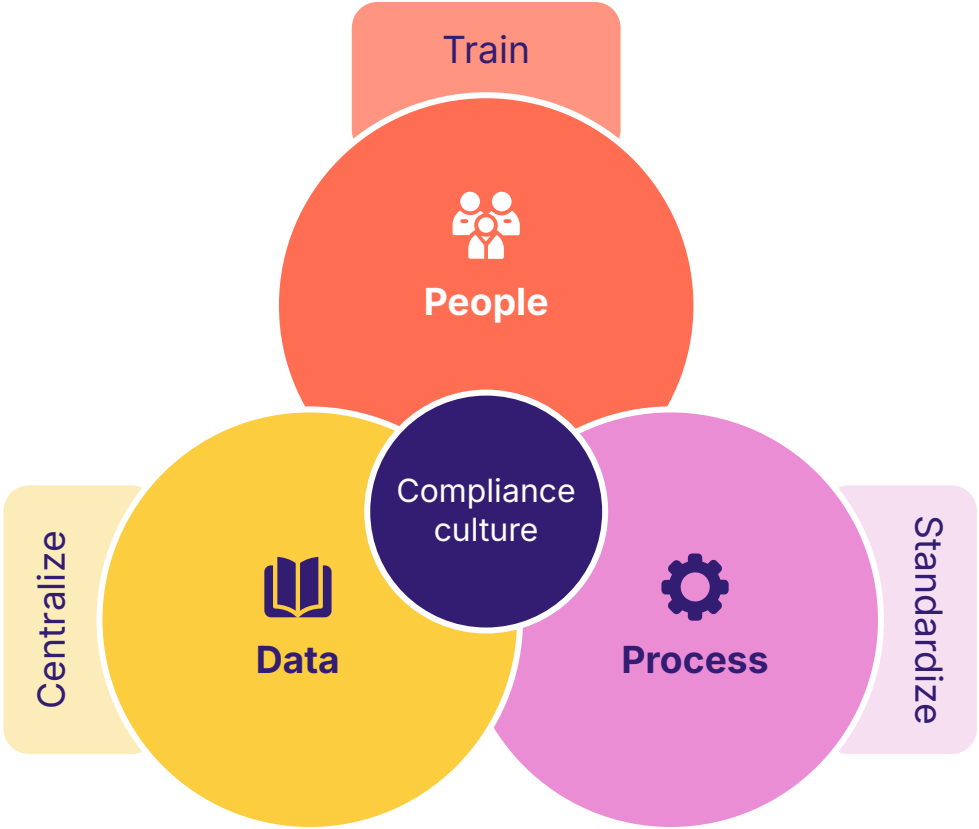
3 components of your compliance culture



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Process

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4 signs your compliance culture needs a boost

Too many systems

Paper, Dropbox, OneDrive, email, Excel, etc.

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4 signs your compliance culture needs a boost

Recurring findings

No improvement: ‘toothless’ audits that don’t drive change

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4 signs your compliance culture needs a boost

Data overload

Ambiguous/ overly complex/ unactionable reports

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4 signs your compliance culture needs a boost

Unstandardized processes

Different things done different ways at different times

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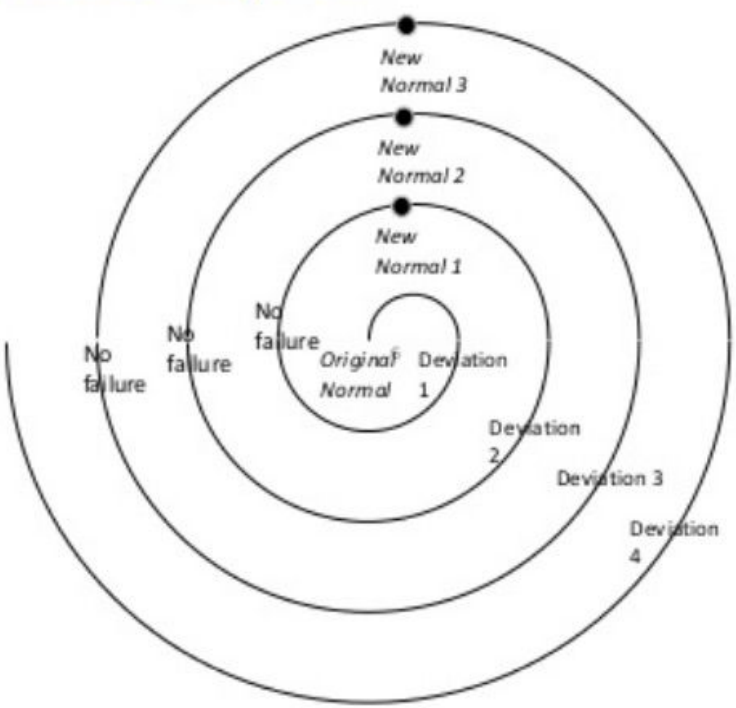
The deviation spiral



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3 top tips

1

Audit your key processes and find SMEs as you go

Involve key process participants in mapping your core processes from end to end, including all interdependencies and interactions, as you audit

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3 top tips

2

Audit processes - *not* functions!

Break away from departmental focus and think on a business-wide level.

If you don't see a discernible documented process — make one!

Core process examples
Product design and development
Risk management
Incident management
Documentation
Feedback
New supplier onboarding
Equipment management
Customer onboarding
Internal auditing
Data retention
Competence management

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3 top tips

3

Audit across departments

Trace processes *across* department lines to see how they vary: are new systems used to continue the same work? Do steps fundamentally change or ‘spiral’? Are lines of communication broken at hand-off points?

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Use ‘As-Is’ to drive internal audits

AS IS

How are current processes executed? Where are the areas of weakness/ non-compliance? What is working well and why?

TO BE

How can processes be made compliant?

How can steps, systems and tasks to be minimized to get there?

TO DO

Which SOPs, policies and instructions need to be created? How will staff be trained? (Use subsequent audits to check progress.)

Track your compliance...

Non-conformances, deviations, complaints, deliveries, etc.

Resolution time

Internal audit findings by month

Standard clauses

QA/RA budget

Closed CAPAs

And your culture itself...

Recurring deviations and nonconformances

SMEs per department

Internal document and training engagement by month

Ratio of corrective to preventive actions

Compliance gaps flagged by quality vs. by wider business

% of actions where assigned resources exceeded plans

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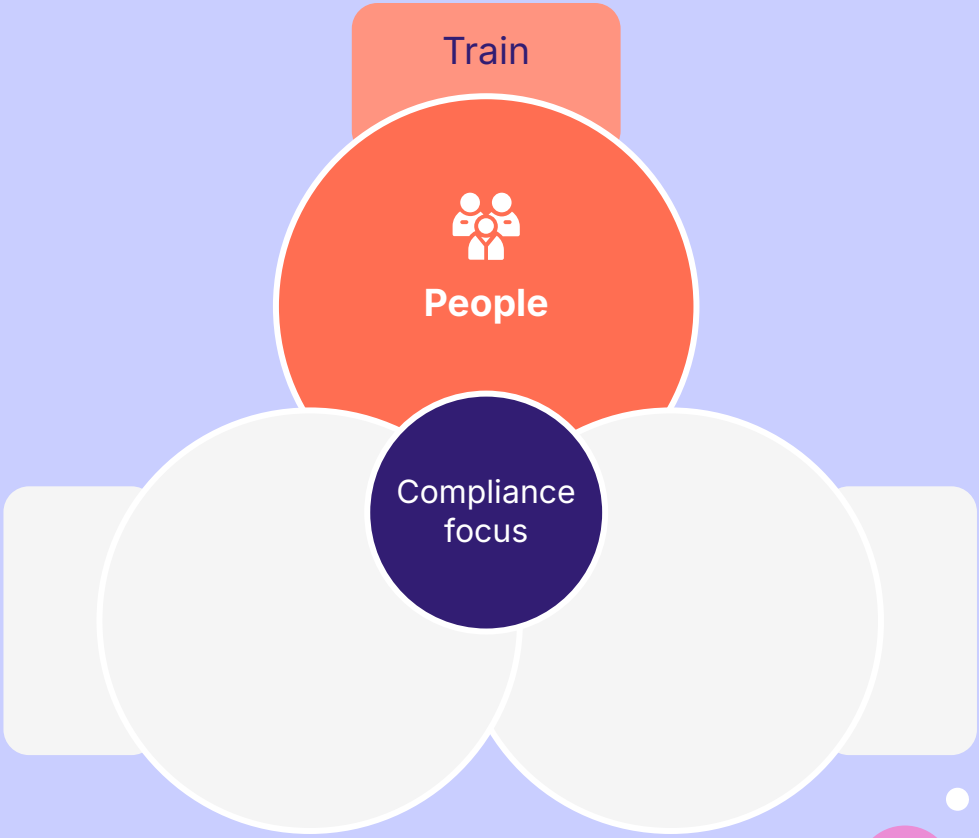
People



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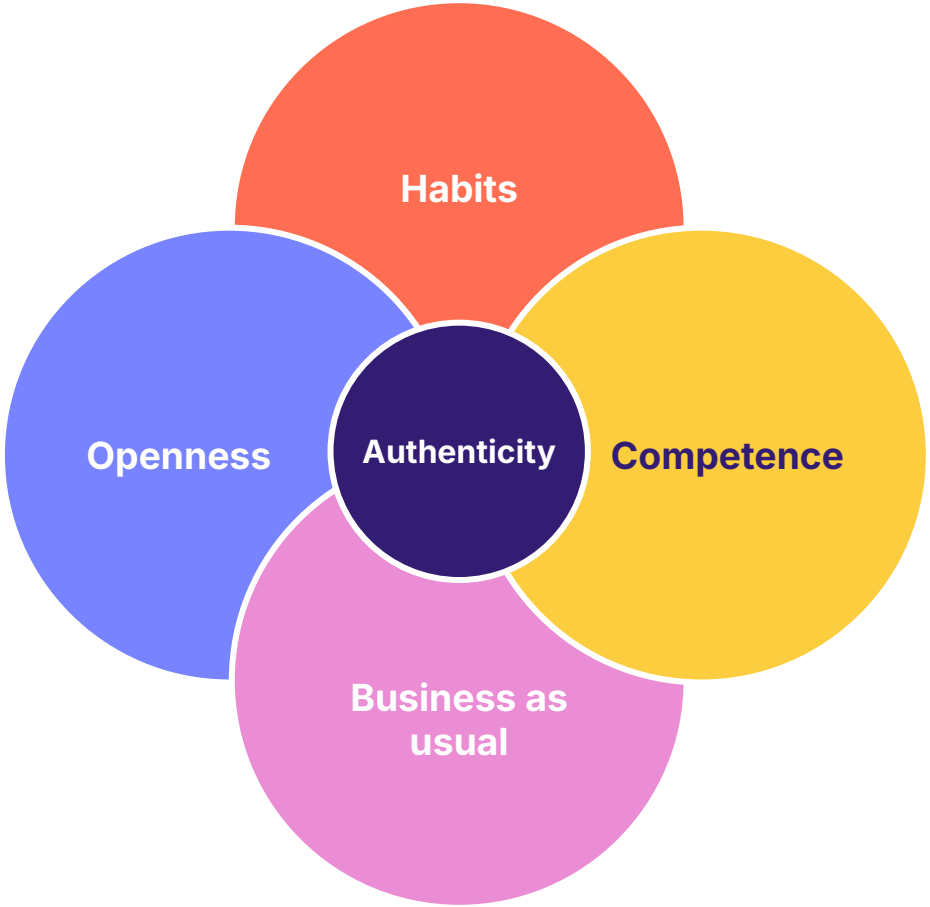
Your culture needs to be *authentic*



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Assign your SMEs!

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Your subject matter experts should...

Demonstrate expertise and understanding

Own their areas and make the right first impression

Explain without a script

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Choosing the right people to represent your compliance

- Confident and competent
- Authentic
- Don’t let personality type (shy, abrasive, talkative) inform your decision! The most knowledgeable person is always the right person

Assemble your ‘A’ (audit) team

Authorized escort: point of contact who escorts the auditor

Scribe: takes notes, records pertinent details

Runner: brings relevant documents to the auditor

Subject matter experts (SMEs): answer questions about their specific processes

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Bring leadership into your compliance

Do your leadership team...

Inform everyone of the importance of compliance?

Actively collect and respond to feedback about processes from SMEs?

Make themselves available for audits?

Integrate compliance KPIs into management reviews?

Invest in systems and tools to simplify compliance?

Encourage a culture where processes can be challenged and improved?

Set constant compliance as a key operational goal?

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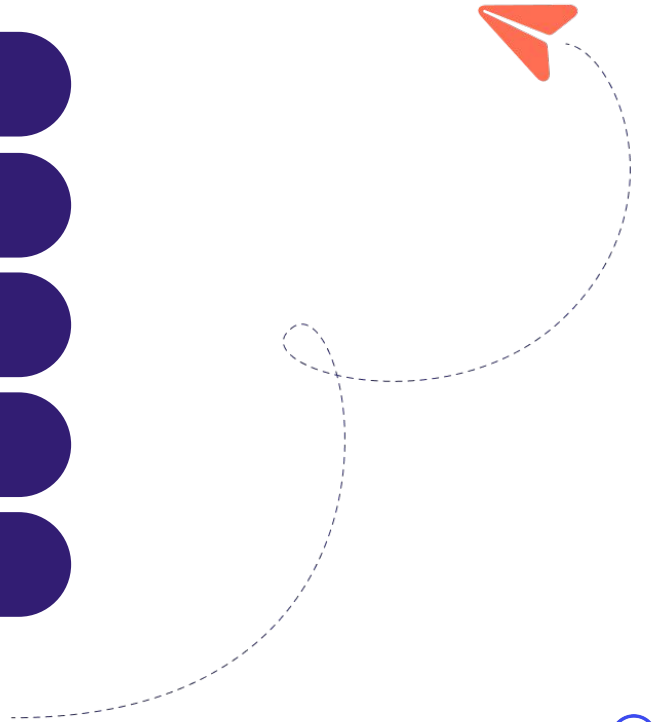
Common cultural blockers

Blocker	Solution
No direct line to leadership	Secure access to the executive team by pushing for QA/RA presence at board meetings, through an appointed director or at least a dedicated representative. In larger organizations, the executive team's focus is typically on commercial effectiveness without necessarily addressing the link between compliance and operational performance. Be clear what you want (and need!) leadership to do
Leadership sees compliance as a cost	Demonstrate how compliance ties in with market access, new product launches and building customer trust
Not speaking the language of the business	Train all QA/RA staff on the broader commercial and patient impacts of their compliance work. Ensure quality-specific language is only used within and between members of the quality department
Not knowing who is engaging with compliance	Move away from manual paper-based quality management and consider a digital eQMS that unlocks data about compliance status, such as document throughput, completed training and clause-by-clause adherence

5 things to demand from your leaders

1. Clear definition of organizational hierarchy, roles and performance – with compliance involved!
2. SMART goals and mission
3. Performance monitoring
4. Time to review, every week
5. Clear, collective corporate culture



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From this...

Saying compliance is important

Lots of industry language

Lots of QA/RA conclusions and action points

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...to this

Showing *how* compliance is important

Normal language - add some excitement!

Business-wide conclusions and action points

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Celebrate compliance!

Consider ways to reward teams for contributing to your compliance culture

Set friendly competitions around your KPIs: reward the site with the fewest nonconformances, or the department with the most flagged issues

If employees suggest an improvement and it’s implemented, reward them and encourage further suggestions

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Data

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Build your core of objective evidence

Give yourself a mechanism for controlling, reviewing and distributing SOPs, quality manuals, objectives, etc.

Don’t forget the basics: embed ALCOA+ and GDocP as automatically as possible with digital tools

Ensure information can be quickly exported and shared as required

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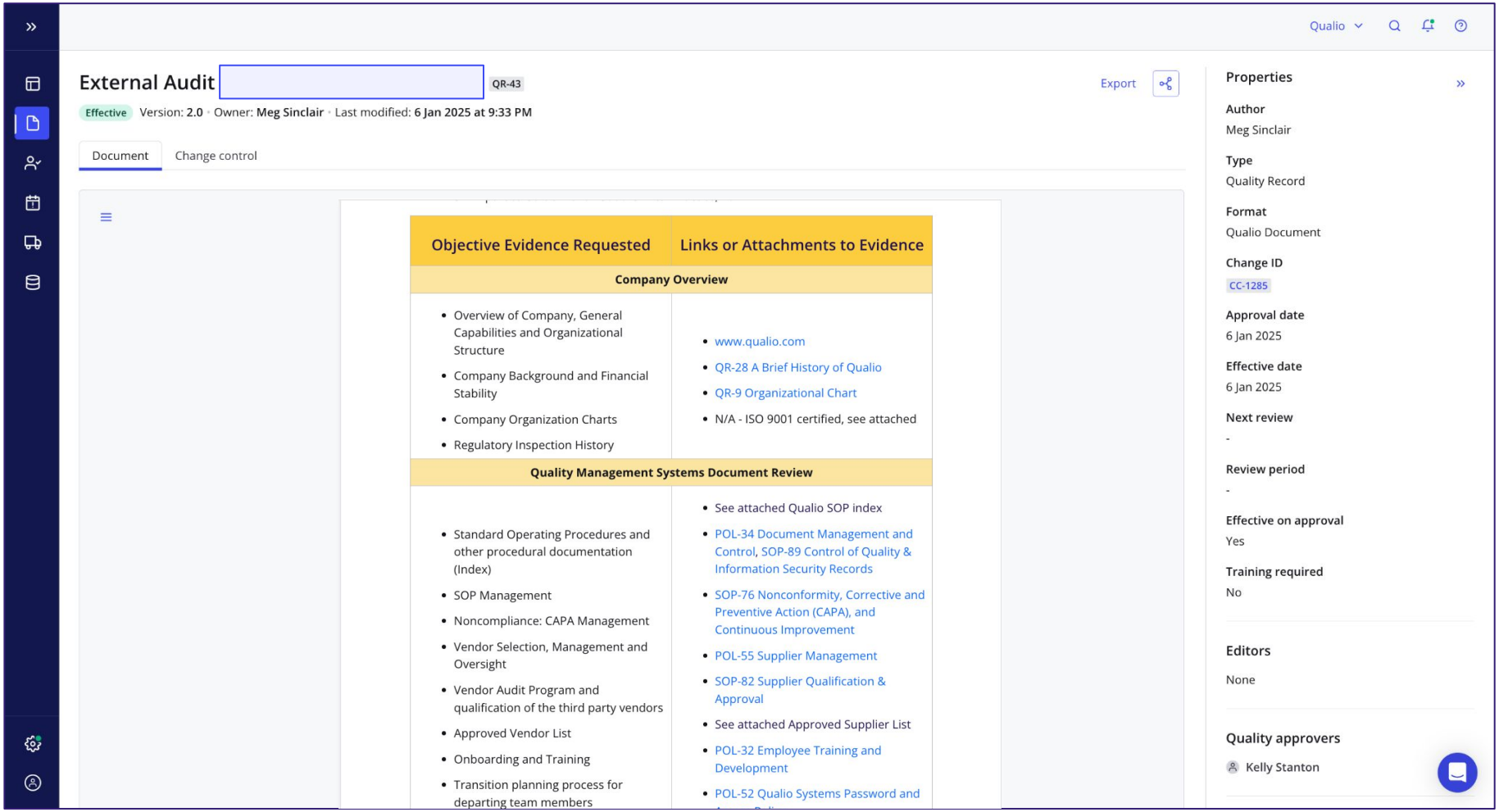
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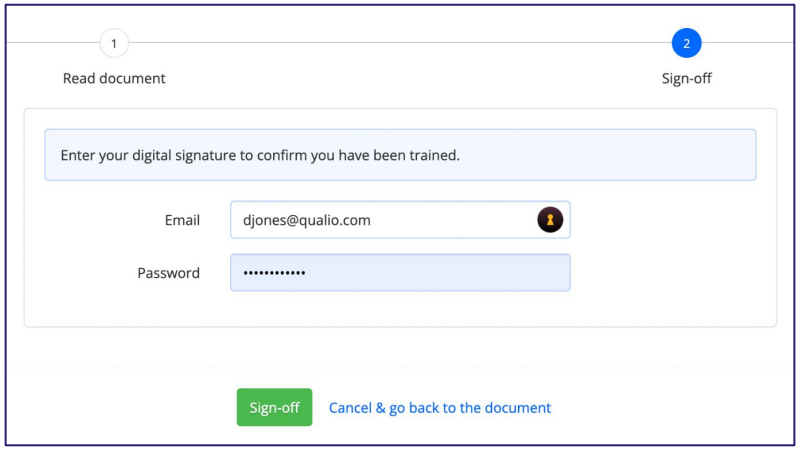
External Audit
QR-43
Export
Effective Version: 2.0 · Owner: Meg Sinclair · Last modified: 6 Jan 2025 at 9:33 PM
Document
Change control
Objective Evidence Requested
Links or Attachments to Evidence
Company Overview
Overview of Company, General Capabilities and Organizational Structure
Company Background and Financial Stability
Company Organization Charts
Regulatory Inspection History
www.qualio.com
QR-28 A Brief History of Qualio
QR-9 Organizational Chart
N/A - ISO 9001 certified, see attached
Quality Management Systems Document Review
Standard Operating Procedures and other procedural documentation (Index)
SOP Management
Noncompliance: CAPA Management
Vendor Selection, Management and Oversight
Vendor Audit Program and qualification of the third party vendors
Approved Vendor List
Onboarding and Training
Transition planning process for departing team members
See attached Qualio SOP index
POL-34 Document Management and Control, SOP-89 Control of Quality & Information Security Records
SOP-76 Nonconformity, Corrective and Preventive Action (CAPA), and Continuous Improvement
POL-55 Supplier Management
SOP-82 Supplier Qualification & Approval
See attached Approved Supplier List
POL-32 Employee Training and Development
POL-52 Qualio Systems Password and
Properties
Author
Meg Sinclair
Type
Quality Record
Format
Qualio Document
Change ID
CC-1285
Approval date
6 Jan 2025
Effective date
6 Jan 2025
Next review
-
Review period
-
Effective on approval
Yes
Training required
No
Editors
None
Quality approvers
Kelly Stanton

Make compliance painless

- Nobody likes long, paper-based compliance tasks! Make unavoidable quality work like training quick and painless with modern tools
- Connect employees to a shared source of truth to make *their* jobs easier
- Make ease of use, accessibility and roll-out your key criteria for any system you plan to adopt



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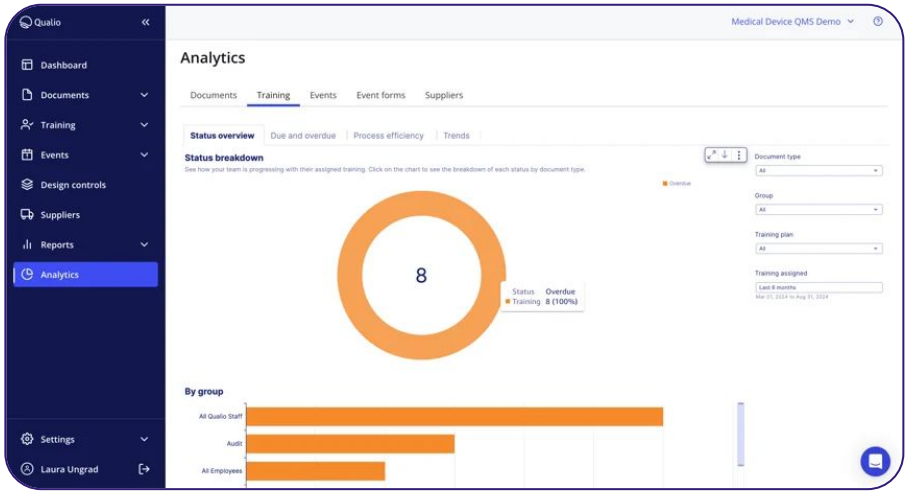
Train train train!

- Get a mechanism in place for training staff on processes and confirming understanding
- Check training completion rate for each and every key process
- Actively capture feedback on new processes as you train: if people don't like them, they won't follow them!



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Make your compliance view simple and digestible

Get a tagging system in place to designate objective evidence that auditors, customers and prospects will be able to view

Consider how to present an ‘auditor view’: a clean, representative but minimized picture of your compliance that doesn’t overwhelm

Complexity doesn’t impress — it only confuses! Simple visual links between compliance requirements and supporting evidence are best

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Demonstrating compliance during an audit

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Mid-audit: create the environment

- Wi-Fi
- Private workspace
- Food and drink

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Learn how to react

Communicate real-time developments mid-audit to relevant personnel

If you know someone will be called in, arm them with context and info gleaned from the auditor so there's no surprise

Learn how to react

Plan how to minimize ‘catch-out’ moments

- Have answers and explanations ready for past mistakes
- Auditor spotted something you haven’t? Be honest and don’t try to hide it

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Learn how to react

Respond to the auditor's preferences in real time

- Are they fixating on a particular product, process, department, regulatory requirement?
- Can you anticipate where they'll go next with that in mind?

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Compliance culture can’t be faked

Stage-managed

- QA/RA manager stealing the show
- Same soundbites repeated
- Feels overly rigid and planned

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Compliance culture can’t be faked

Authentic

- Shared participation
- Natural conversation
- Comfortable, spontaneous engagement from everyone involved

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The Goldilocks approach

Too hot 🥵

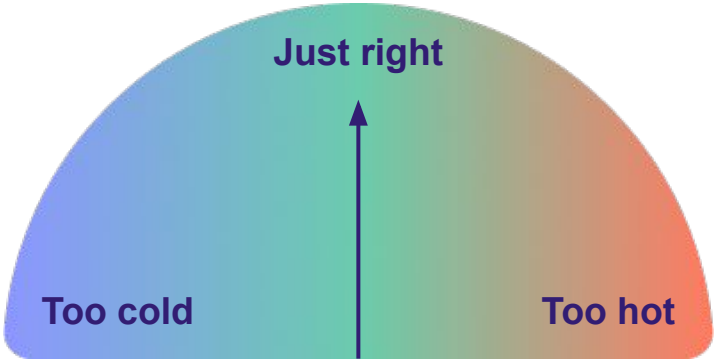
- Small talk (after first 5 minutes of auditor arriving)
- Detailed explanation of documents/repeating contents
- Answering questions you weren't asked

Too cold 🥶

- Unhelpful answers
- Evasiveness/shiftiness
- Not elaborating when asked

Just right 🤝

- Objective evidence does the talking
- Helpful extra information provided as needed



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It’s all about balance...

Information underload

Can’t locate requested documents

Information gaps

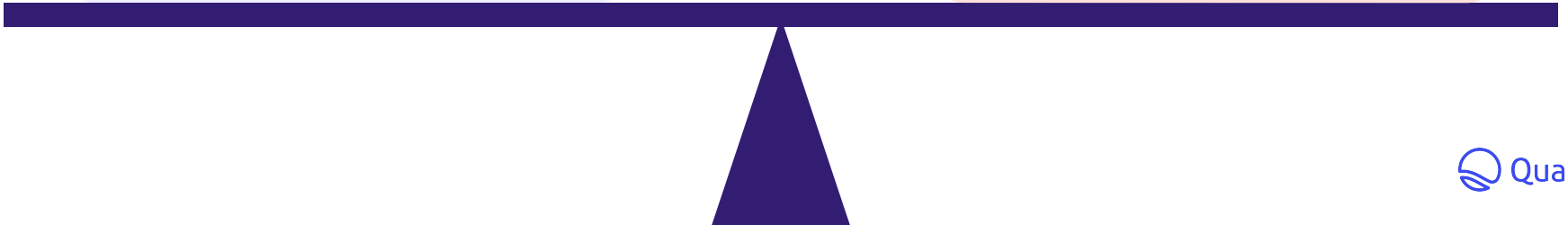
Awkward time-consuming trips to dig out info

Information overload

Irrelevant/inappropriate information

No clear narrative

Wasted time and effort



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A good response is your springboard to an optimal compliance culture

What went well? Why?

What can be improved on?

How will you drive those improvements?

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Post-audit tips

Treat findings as positive improvement opportunities for your next audit – not a slap on the wrist!

Don’t waste time: get your scribe to record, categorize and assign action points on the day. It doesn’t hurt to let your auditor know you’re doing this!

Don’t overcommit with your CAPAs: ensure findings are acted on, and quietly work on anything else you think you need to without overburdening yourself with raised expectations in your next audit

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Qualio's new compliance AI software

What is a compliance culture?

✅ Being comfortable with and aware of your compliance demands

✅ The entire business (not just the quality manager!) is ready for audits

✅ Being able to quickly and easily demonstrate compliance

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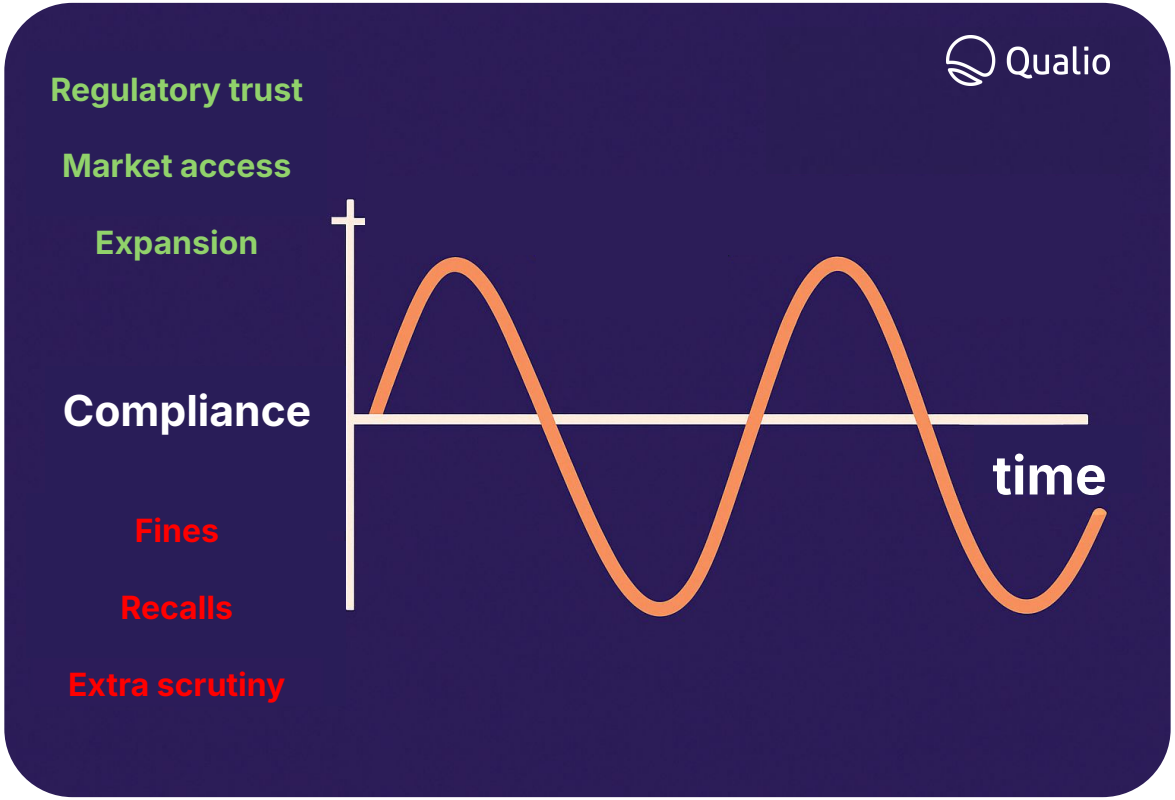
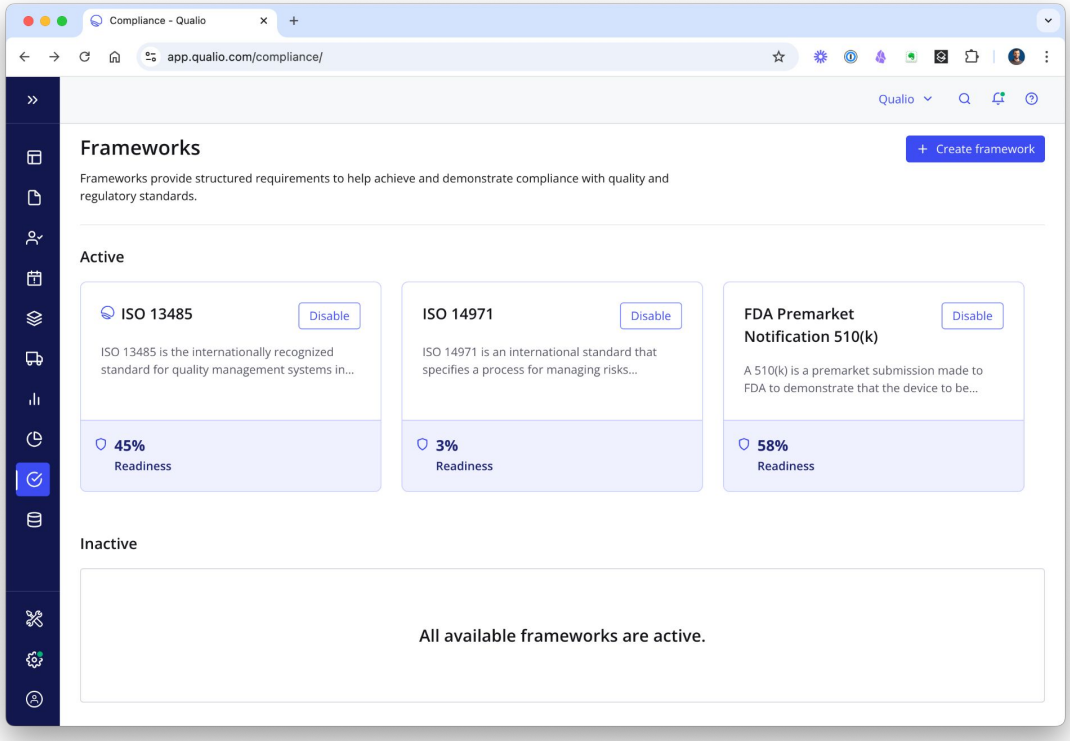
The world has changed.

Compliance is holding innovation back.


Qualio
Regulatory trust
Market access
Expansion
Compliance
Fines
Recalls
Extra scrutiny
time

Introducing: our new compliance solution



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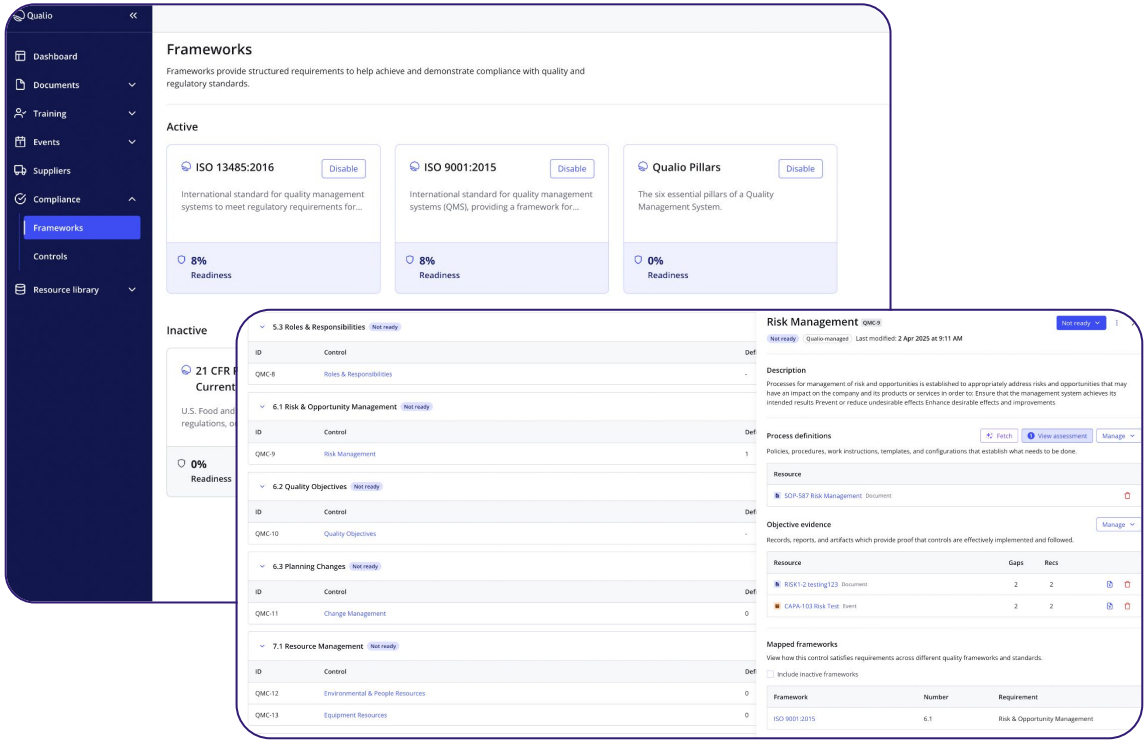
Know your requirements

- Built-in compliance frameworks aligned to standards like ISO 9001, ISO 13485, the MDSAP, ICH Q10, ISO 27001, and more
- Mapped controls that connect your actual processes, documents and data to your requirements
- Qualio manages updates to standards and requirements - so you stay compliant without the overhead!



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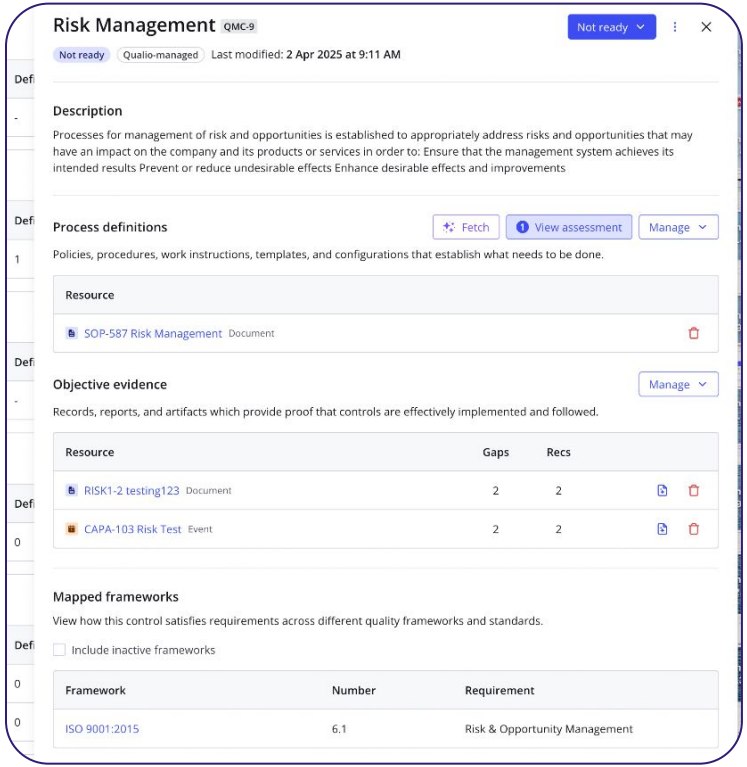
AI automation to organize your compliance headache

- AI-powered search scans your eQMS and connects policies, procedures and work instructions to the relevant controls
- New additions are automatically organized and collated
- Integrate with other systems to capture and organize quality information from across your tech stack



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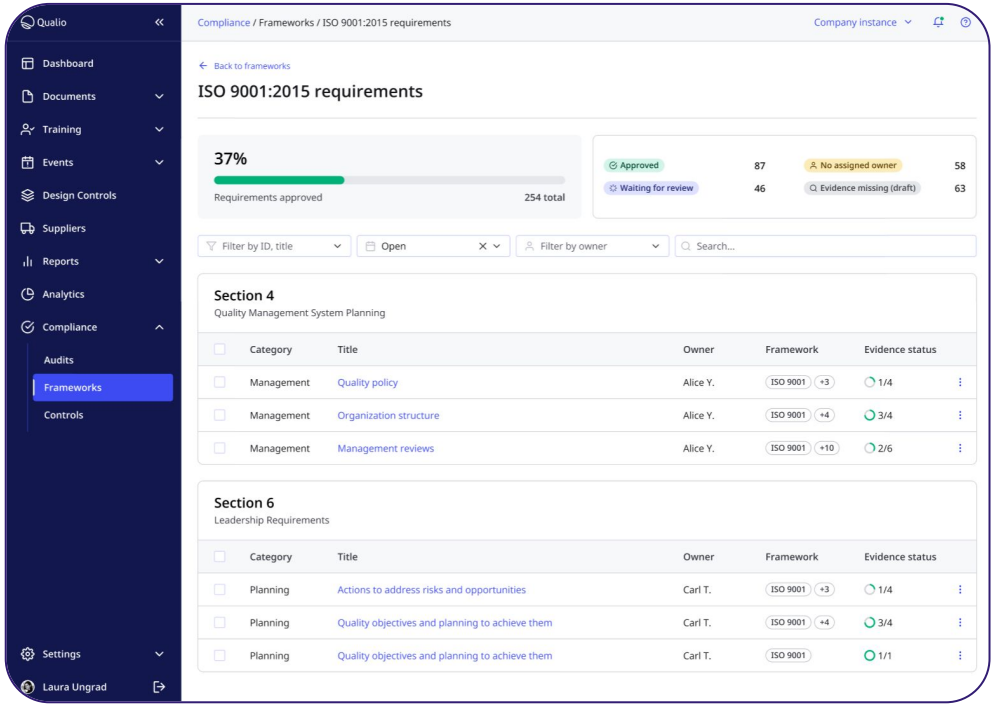
Cross-company collaboration

- Controls have clear owners — so there's no ambiguity about who's responsible for maintaining compliance
- Tasks can be assigned across your organization — whether it's providing evidence, updating documentation or reviewing a process
- Notifications, reminders and status updates ensure everyone knows what's expected of them and when



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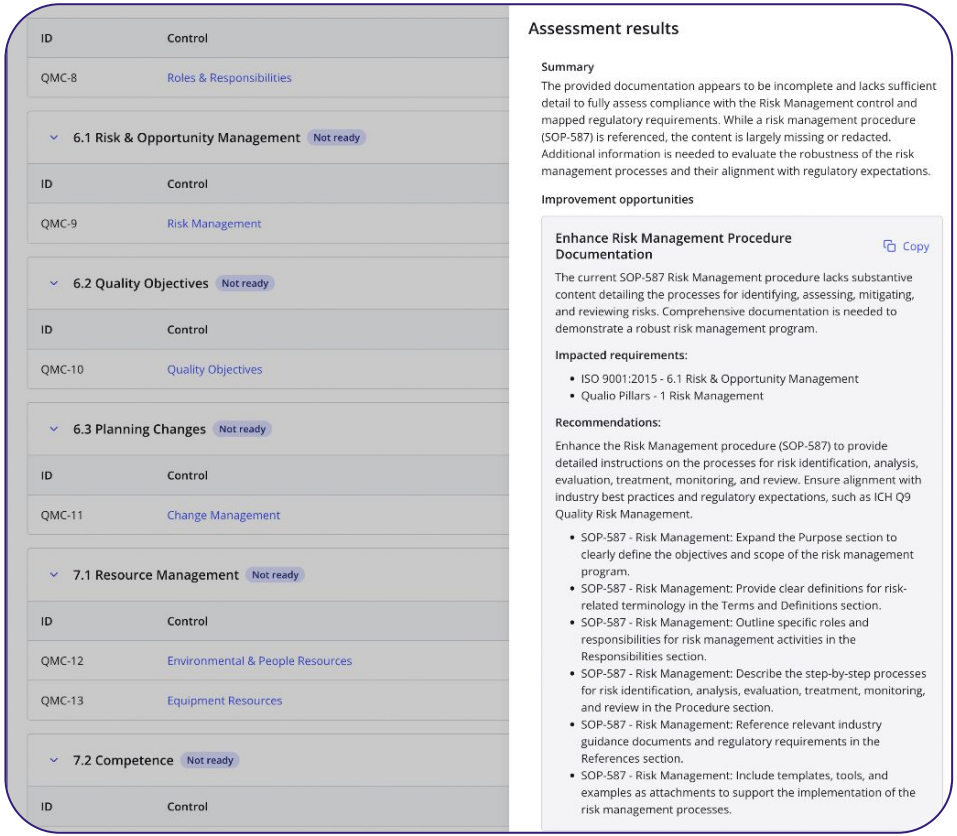
AI-powered continuous compliance

- AI-powered assessments and monitoring to flag gaps and recommendations
- Smart warnings help highlight and fix issues
- Real-time visibility into what's covered and what needs attention



Where we're going

Connected Quality

Compliance Intelligence

Product Lifecycle

Trusted Ecosystem

Qualio Platform

Continuous control/ monitoring

100+ integrations

Analytics

Qualio AI

Collaboration

Qualio API

Audit trail

Qualio

Register your interest

qualio.typeform.com/compliance-ai

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Thank you!