

Welcome to the webinar

Building a culture of compliance

With Sumatha Kondabolu & Henry Tri



Today's hosts



Sumatha Kondabolu

Senior Quality Business Partner
Qualio



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Relationship Manager & Auditor
TÜV SÜD



Today's agenda

01 The 3 components of a compliance culture

02 Demonstrating compliance during an audit

03 Qualio's new compliance AI software

The 3 components of compliance culture

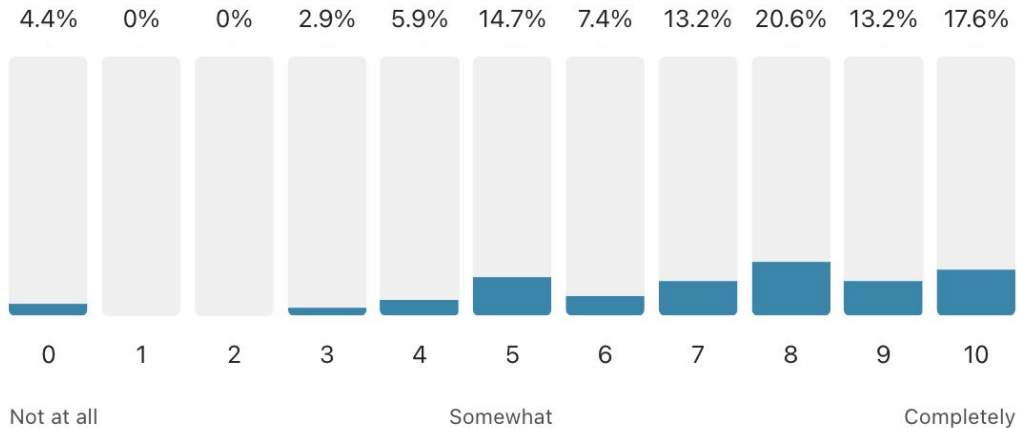


What is a compliance culture?

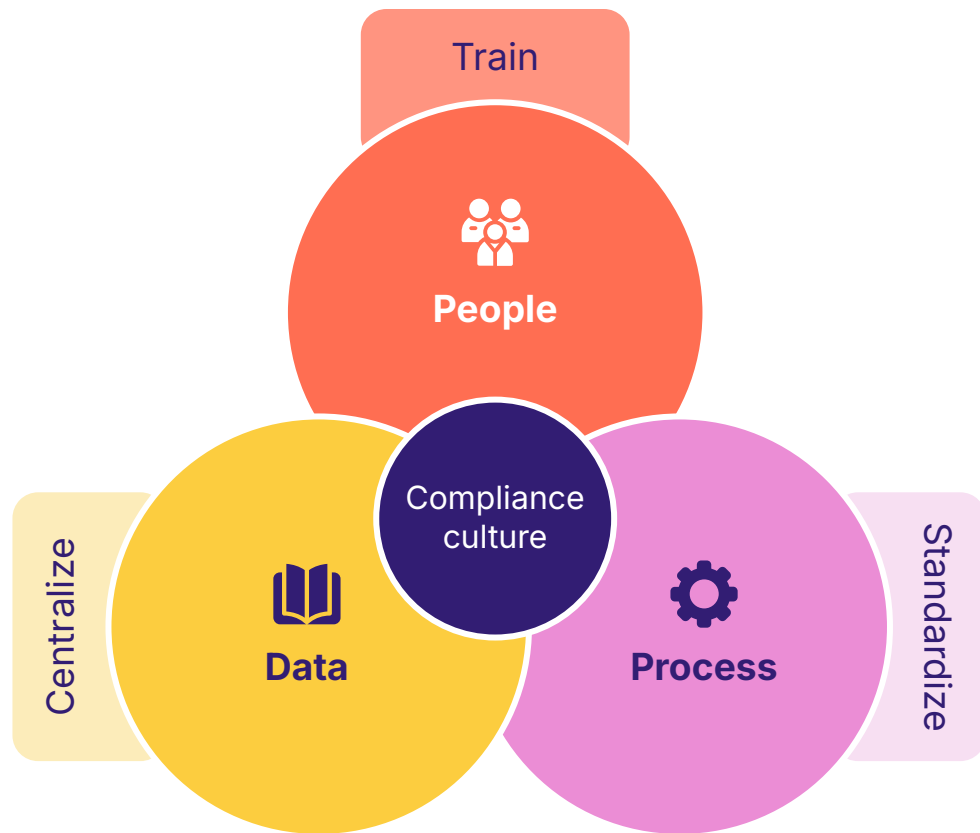
- ✓ Being comfortable with and aware of your compliance demands
- ✓ Being able to quickly and easily demonstrate compliance
- ✓ The entire business (not just the quality manager!) is ready for audits

How do you feel now?

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



3 components of your compliance culture



Process



4 signs your compliance culture needs a boost



Too many systems

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

4 signs your compliance culture needs a boost



Recurring findings

No improvement:
'toothless'
audits that
don't drive
change

4 signs your compliance culture needs a boost



Data overload

Ambiguous/
overly
complex/
unactionable
reports

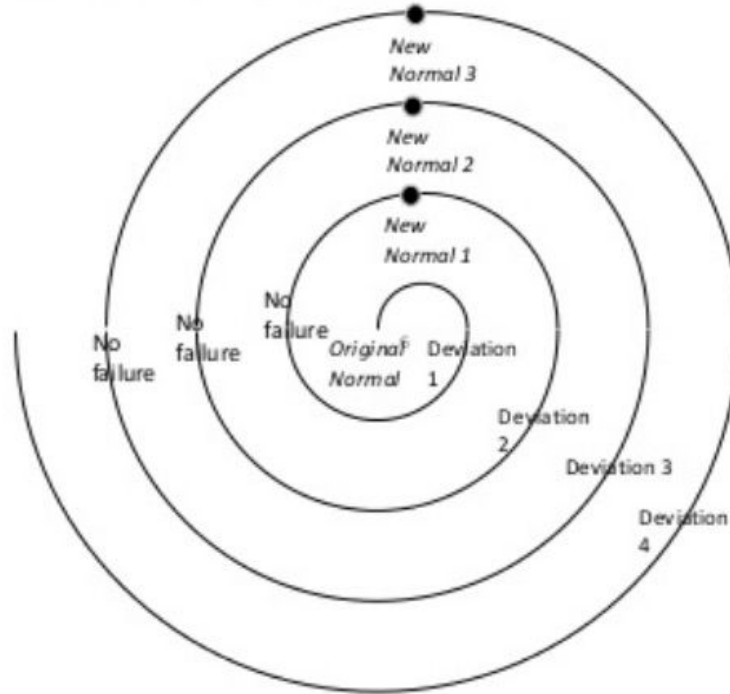
4 signs your compliance culture needs a boost



Unstandardized processes

Different things
done different
ways at different
times

The deviation spiral



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

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

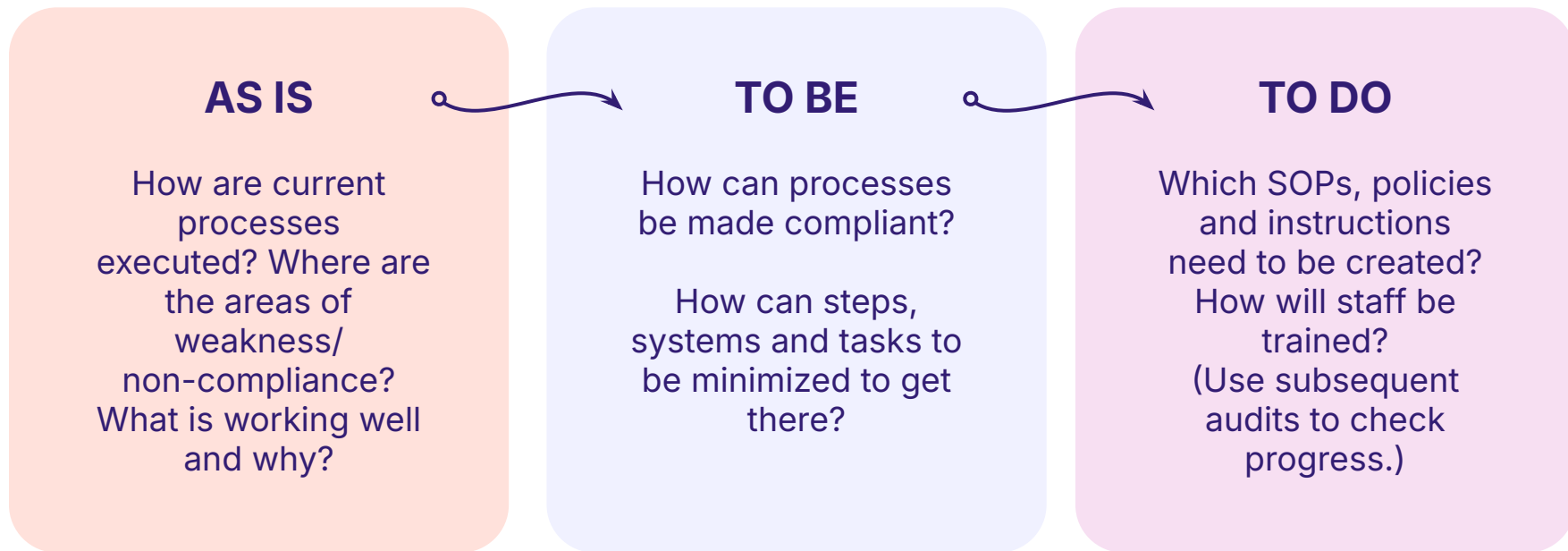
3 top tips

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?

Use 'As-Is' to drive internal audits



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

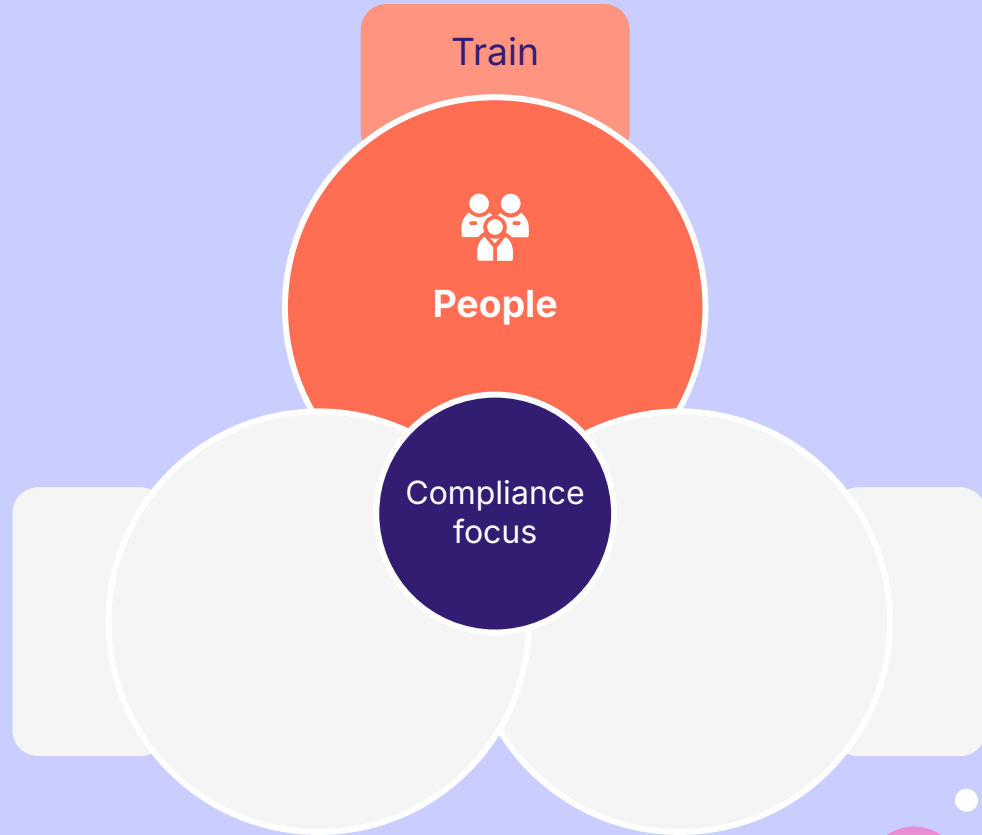


Compliance gaps flagged by quality vs.
by wider business

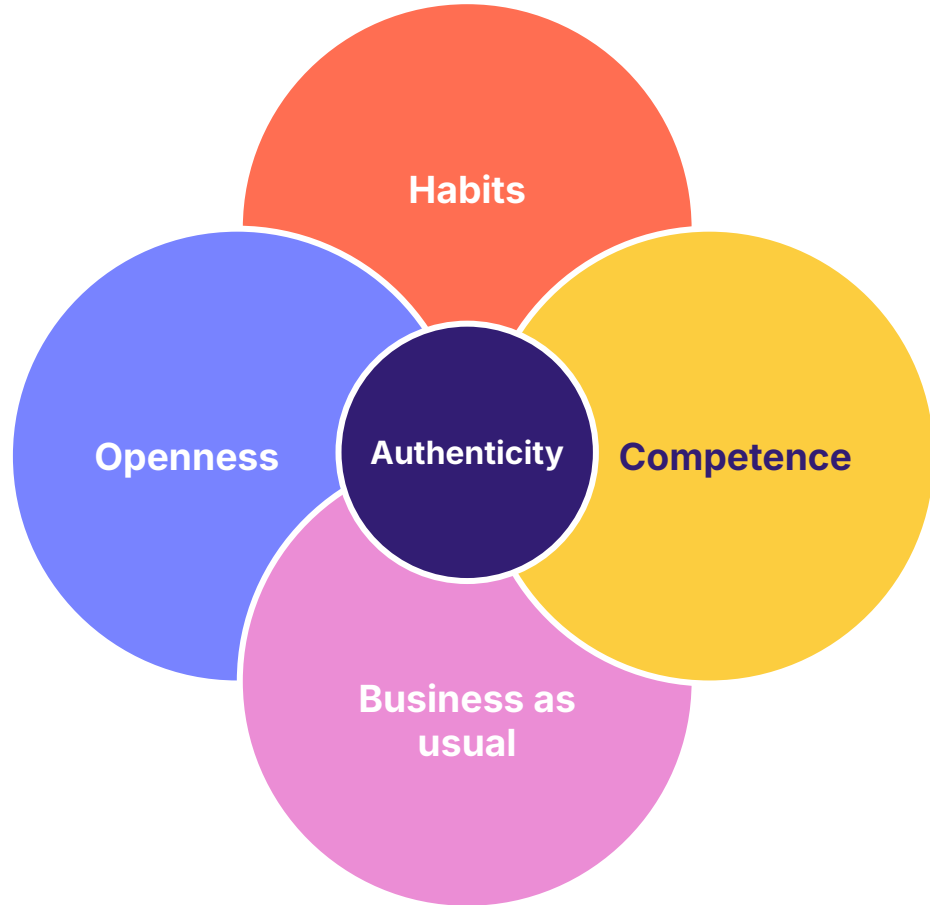


% of actions where assigned
resources exceeded plans

People



**Your culture
needs to be
*authentic***



Assign your SMEs!



Your subject matter experts should...

**Demonstrate
expertise and
understanding**

**Own their areas
and make the
right first
impression**

**Explain without a
script**

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



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?

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

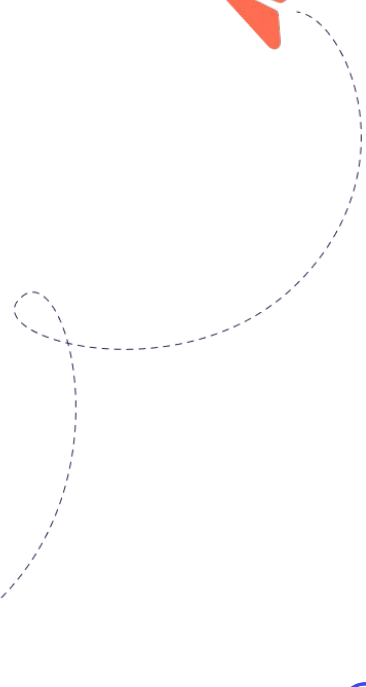
Performance monitoring

4

Time to review, every week

5

Clear, collective corporate culture



From this...

Saying compliance is important

Lots of industry language

Lots of QA/RA conclusions and action points

...to this

Showing *how* compliance is important

Normal language - add some excitement!

Business-wide conclusions and action points

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



Data



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

External Audit

QR-43

Export



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

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](#)

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

1 Read document

2 Sign-off

Enter your digital signature to confirm you have been trained.

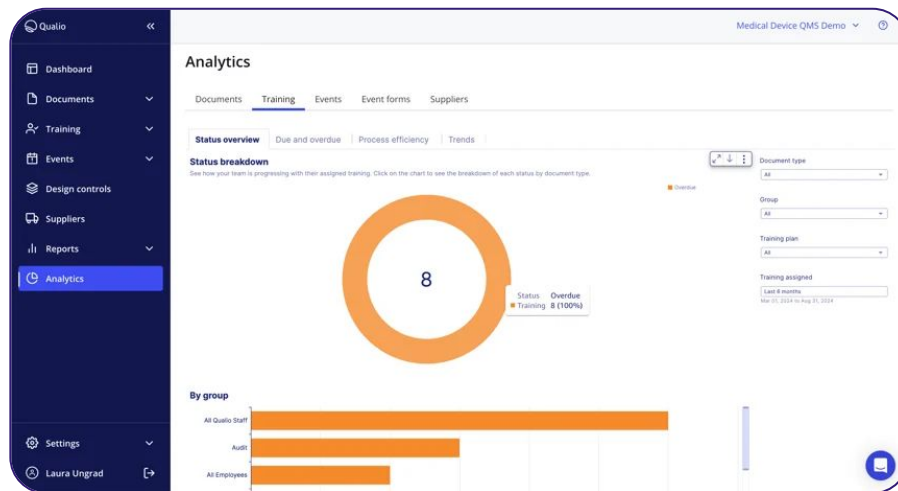
Email djones@qualio.com

Password *****

Sign-off Cancel & go back to the document

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!



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

Demonstrating compliance during an audit



Mid-audit: create the environment

Wi-Fi

Private workspace

Food and drink



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

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?

Compliance culture can't be faked



Stage-managed

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

Compliance culture can't be faked



Authentic

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

The Goldilocks approach

Too hot 🥵

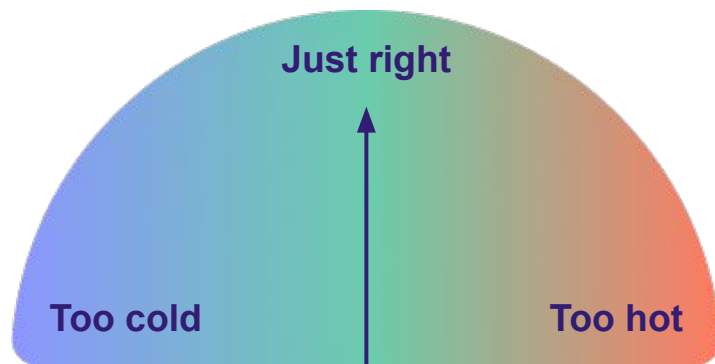
- Small talk (after first 5 minutes of auditor arriving)
- Detailed explanation of documents/repeating contents
- Answering questions you weren't asked

Too cold 🥶

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

Just right 🤝

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



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

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?**

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



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

The world has changed.

Compliance is holding innovation back.



Regulatory trust

Market access

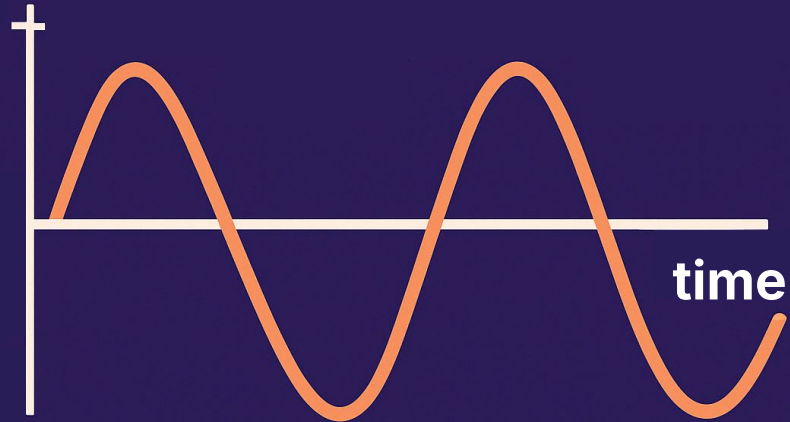
Expansion

Compliance

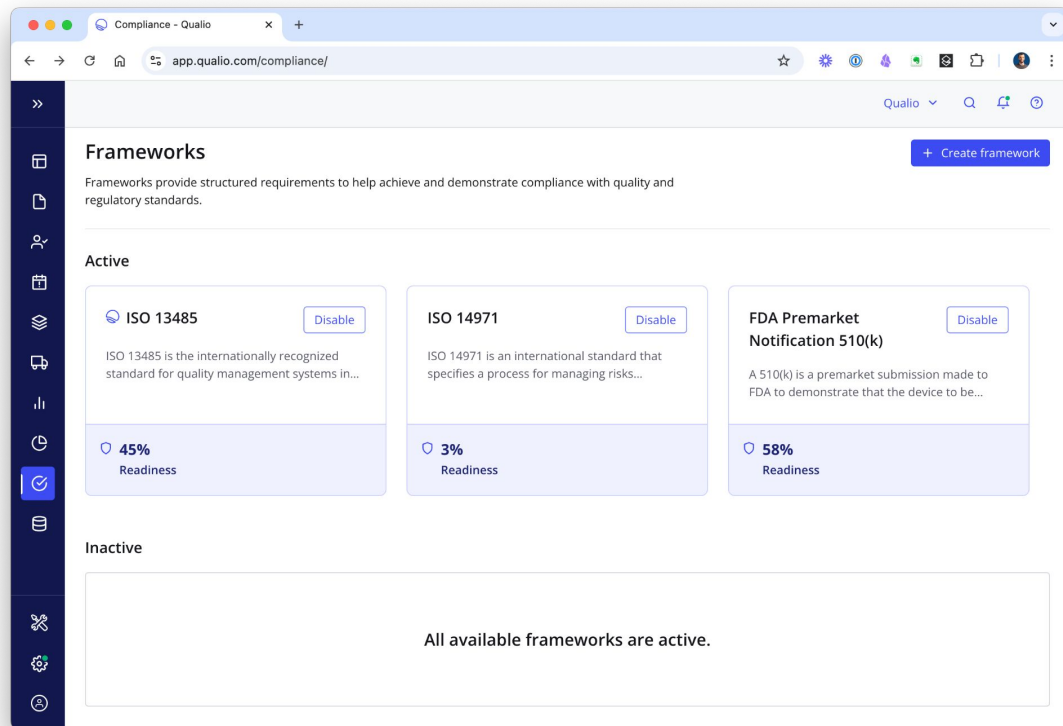
Fines

Recalls

Extra scrutiny



Introducing: our new compliance solution



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!

The screenshot displays the Qualio software interface, which is organized into a sidebar on the left and a main content area on the right.

Sidebar:

- Qualio logo
- Dashboard
- Documents
- Training
- Events
- Suppliers
- Compliance
 - Frameworks (highlighted)
 - Controls
- Resource library

Main Content Area:

Frameworks Section:

Frameworks provide structured requirements to help achieve and demonstrate compliance with quality and regulatory standards.

Active Frameworks:

- ISO 13485:2016** (8% Readiness): International standard for quality management systems to meet regulatory requirements for...
- ISO 9001:2015** (8% Readiness): International standard for quality management systems (QMS), providing a framework for...
- Qualio Pillars** (0% Readiness): The six essential pillars of a Quality Management System.

Inactive Frameworks:

- 21 CFR** (0% Readiness): U.S. Food and drug regulations, o...

Risk Management Detail View:

5.3 Roles & Responsibilities (Next ready)

| ID | Control | Def |
|-------|--------------------------|-----|
| QMC-8 | Roles & Responsibilities | - |

6.1 Risk & Opportunity Management (Next ready)

| ID | Control | Def |
|-------|-----------------|-----|
| QMC-9 | Risk Management | 1 |

6.2 Quality Objectives (Next ready)

| ID | Control | Def |
|--------|--------------------|-----|
| QMC-10 | Quality Objectives | - |

6.3 Planning Changes (Next ready)

| ID | Control | Def |
|--------|-------------------|-----|
| QMC-11 | Change Management | 0 |

7.1 Resource Management (Next ready)

| ID | Control | Def |
|--------|----------------------------------|-----|
| QMC-12 | Environmental & People Resources | 0 |
| QMC-13 | Equipment Resources | 0 |

Risk Management (QMC-9) (Next ready) (Last modified: 2 Apr 2025 at 9:11 AM)

Description: Processes for management of risk and opportunities is established to appropriately address risks and opportunities that may have an impact on the company and its products or services in order to ensure that the management system achieves its intended results (prevent or reduce undesirable effects, enhance desirable effects and improvements).

Process definitions: Policies, procedures, work instructions, templates, and configurations that establish what needs to be done.

Resource: SOP-587 Risk Management Document

Objective evidence: Records, reports, and artifacts which provide proof that controls are effectively implemented and followed.

| Resource | Gaps | Recs |
|----------------------------|------|------|
| RISK-2 testing123 Document | 2 | 2 |
| CAPA-103 Risk Test, Test | 2 | 2 |

Mapped frameworks: View how this control satisfies requirements across different quality frameworks and standards.

☐ Include inactive frameworks

| Framework | Number | Requirement |
|---------------|--------|-------------------------------|
| ISO 9001:2015 | 6.1 | Risk & Opportunity Management |

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

Risk Management QMC-9

Not ready

Qualio-managed

Last modified: 2 Apr 2025 at 9:11 AM

Def

Description

Processes for management of risk and opportunities is established to appropriately address risks and opportunities that may have an impact on the company and its products or services in order to: Ensure that the management system achieves its intended results Prevent or reduce undesirable effects Enhance desirable effects and improvements

Def

Process definitions

Fetch

View assessment

Manage

Policies, procedures, work instructions, templates, and configurations that establish what needs to be done.

Def

Resource

SOP-587 Risk Management Document

Def

Objective evidence

Manage

Records, reports, and artifacts which provide proof that controls are effectively implemented and followed.

Def

Resource

Gaps

Recs

RISK1-2 testing123 Document

2

2

CAPA-103 Risk Test Event

2

2

Def

Mapped frameworks

View how this control satisfies requirements across different quality frameworks and standards.

☐ Include inactive frameworks

Def

Framework

Number

Requirement

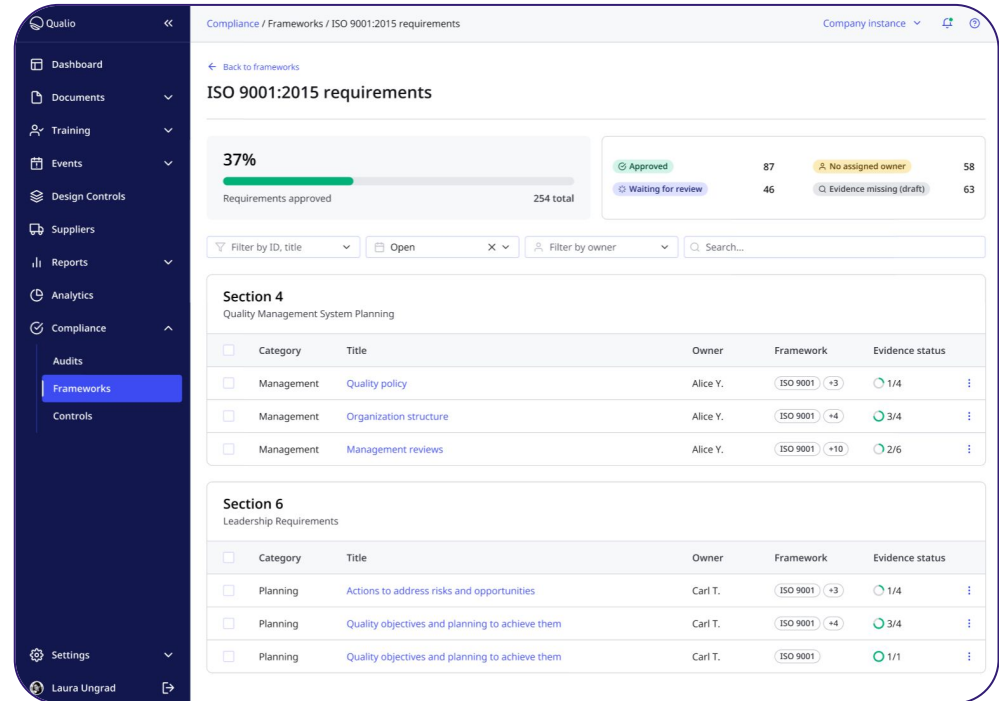
ISO 9001:2015

6.1

Risk & Opportunity Management

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



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

| ID | Control |
|--|--|
| QMC-8 | Roles & Responsibilities |
| 6.1 Risk & Opportunity Management Not ready | |
| ID | Control |
| QMC-9 | Risk Management |
| 6.2 Quality Objectives Not ready | |
| ID | Control |
| QMC-10 | Quality Objectives |
| 6.3 Planning Changes Not ready | |
| ID | Control |
| QMC-11 | Change Management |
| 7.1 Resource Management Not ready | |
| ID | Control |
| QMC-12 | Environmental & People Resources |
| QMC-13 | Equipment Resources |
| 7.2 Competence Not ready | |
| ID | Control |

Assessment results

Summary

The provided documentation appears to be incomplete and lacks sufficient detail to fully assess compliance with the Risk Management control and mapped regulatory requirements. While a risk management procedure (SOP-587) is referenced, the content is largely missing or redacted. Additional information is needed to evaluate the robustness of the risk management processes and their alignment with regulatory expectations.

Improvement opportunities

Enhance Risk Management Procedure Documentation

The current SOP-587 Risk Management procedure lacks substantive content detailing the processes for identifying, assessing, mitigating, and reviewing risks. Comprehensive documentation is needed to demonstrate a robust risk management program.

Impacted requirements:

- ISO 9001:2015 - 6.1 Risk & Opportunity Management
- Qualio Pillars - 1 Risk Management

Recommendations:

Enhance the Risk Management procedure (SOP-587) to provide detailed instructions on the processes for risk identification, analysis, evaluation, treatment, monitoring, and review. Ensure alignment with industry best practices and regulatory expectations, such as ICH Q9 Quality Risk Management.

- SOP-587 - Risk Management: Expand the Purpose section to clearly define the objectives and scope of the risk management program.
- SOP-587 - Risk Management: Provide clear definitions for risk-related terminology in the Terms and Definitions section.
- SOP-587 - Risk Management: Outline specific roles and responsibilities for risk management activities in the Responsibilities section.
- SOP-587 - Risk Management: Describe the step-by-step processes for risk identification, analysis, evaluation, treatment, monitoring, and review in the Procedure section.
- SOP-587 - Risk Management: Reference relevant industry guidance documents and regulatory requirements in the References section.
- SOP-587 - Risk Management: Include templates, tools, and examples as attachments to support the implementation of the risk management processes.

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

Register your interest

qualio.typeform.com/compliance-ai





Thank you!

