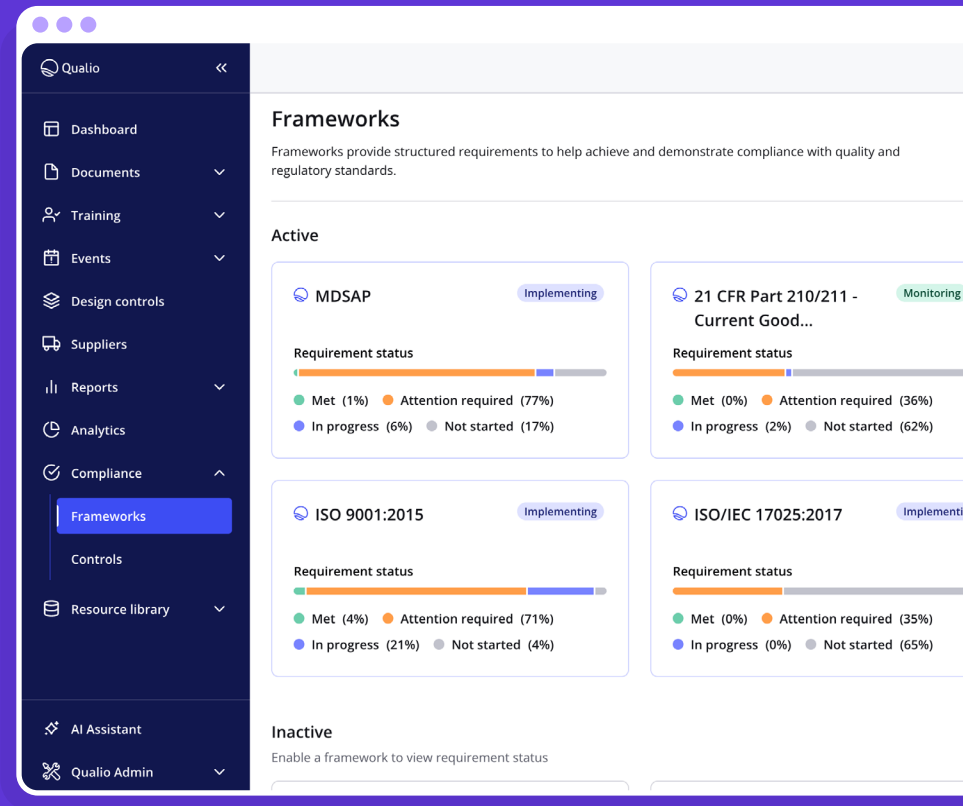
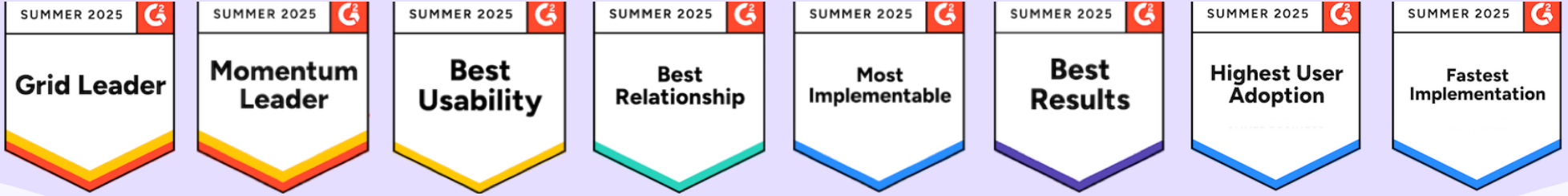
Qualio

QUALIO PRODUCT GUIDE

Qualio Compliance Intelligence

For constant audit readiness and complete compliance visibility





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

Compliance software for modern life science challenges

Compliance Intelligence gives us a 360° view of our QMS and automatically surfaces the gaps.

We resolve issues faster, our team is more productive, and our risk is lower. With the system analyzing our documents and evidence end to end, we know we have full coverage and can walk into audits with total confidence.

See the case study

CHRISTOPHE DOHR

Site Quality Manager
Sentec

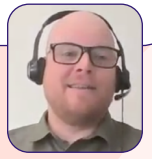
My confidence in being audit-ready is dramatically improved. Feeling like you're not missing anything going into an audit is always a nice thing.

Getting all the pieces in place with evidence and documentation, getting everything ready ahead of time — you just feel good about it.

See the case study

CHRIS RICE

Senior Quality Assurance Manager
AGADA Biosciences



Compliance software for modern life science challenges

With this tool, the painful and time-consuming process of gap analysis is gone. And because you're cutting the risk of audit findings in the first place, the pain of having to resolve things afterwards is gone too.

ALBERT RODRIGUEZ

Ex-FDA inspector

See the case study

This is the ChatGPT of quality.

I wish there'd been something like this when I started my career.

OTTY ANGULO

Senior QA/RA Consultant
RegWeb

See the case study

Compliance Intelligence users enjoy...

30-40 -minute gap analysis of their entire QMS

80% reduction in audit prep time

3x faster new market readiness

$150K+ consultancy spend mitigated

5x faster external audits

Constant audit readiness

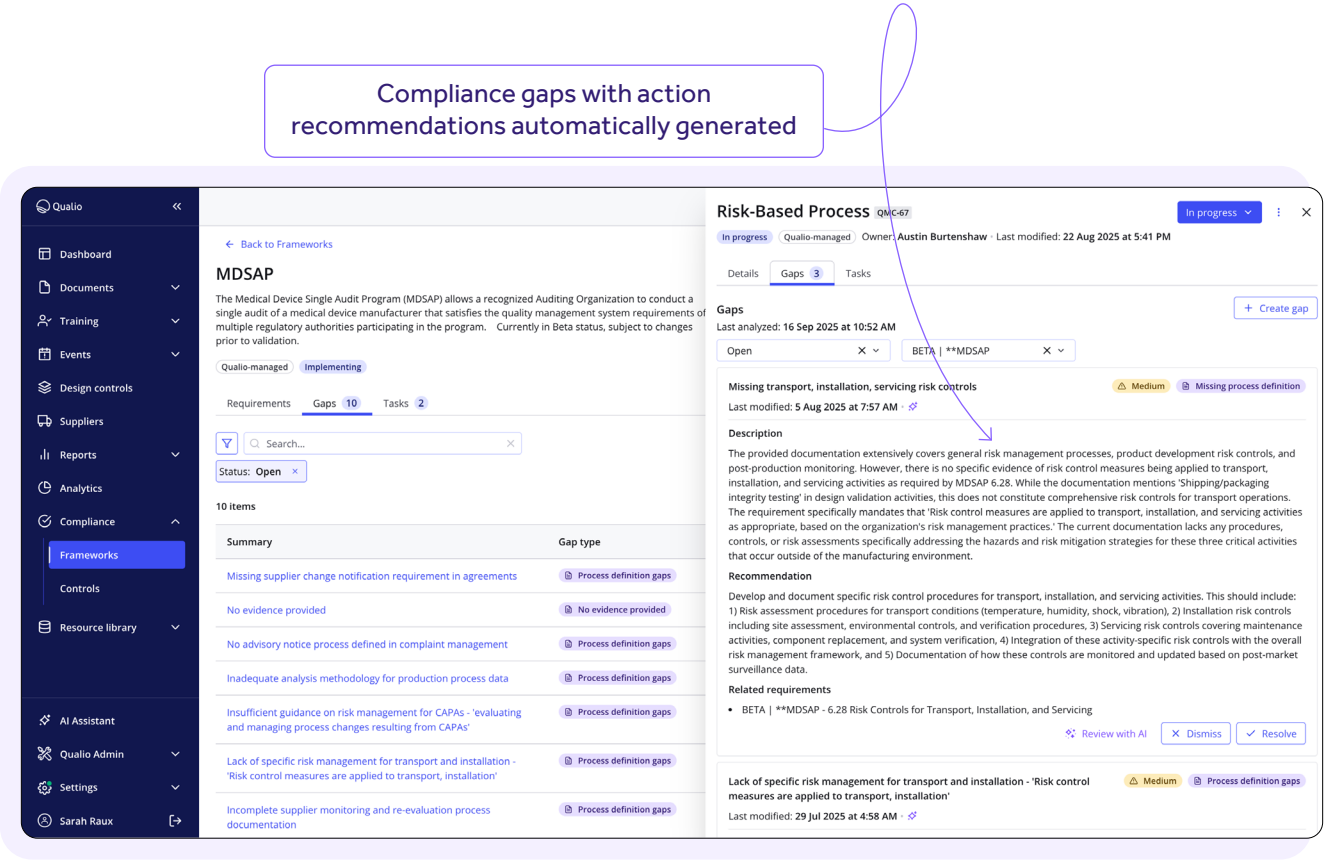
Unshakeable multi-standard confidence

1 AI-powered scanning to find and fix every compliance gap

With modern quality management systems encompassing hundreds of documents, manually checking for compliance gaps before audits is a major time drain for quality and regulatory teams.

In fact, around 30% of their time is typically spent 'policing' the QMS: checking documents and processes against regulatory requirements, pinpointing compliance gaps, then building plans to close them.

Compliance Intelligence scans your entire quality system at the touch of a button, completing end-to-end gap analysis in just 30-40 minutes.

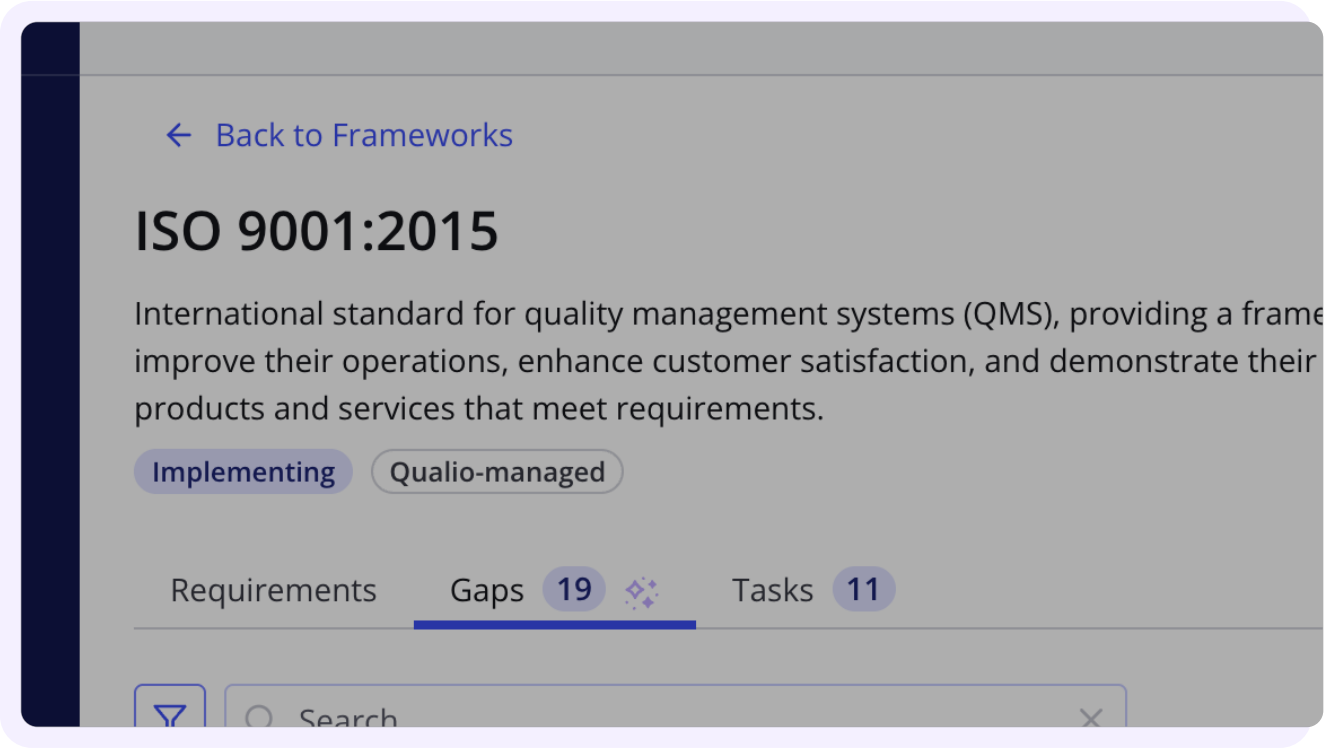


1 AI-powered scanning to find and fix every compliance gap

Compliance gaps are presented by priority, with detailed step-by-step recommendations for closing each gap and getting your company 100% audit-ready.

Best of all?

Compliance Intelligence continuously scans and checks your QMS, giving you peace of mind that nothing's been overlooked as you build and change your documents and processes.

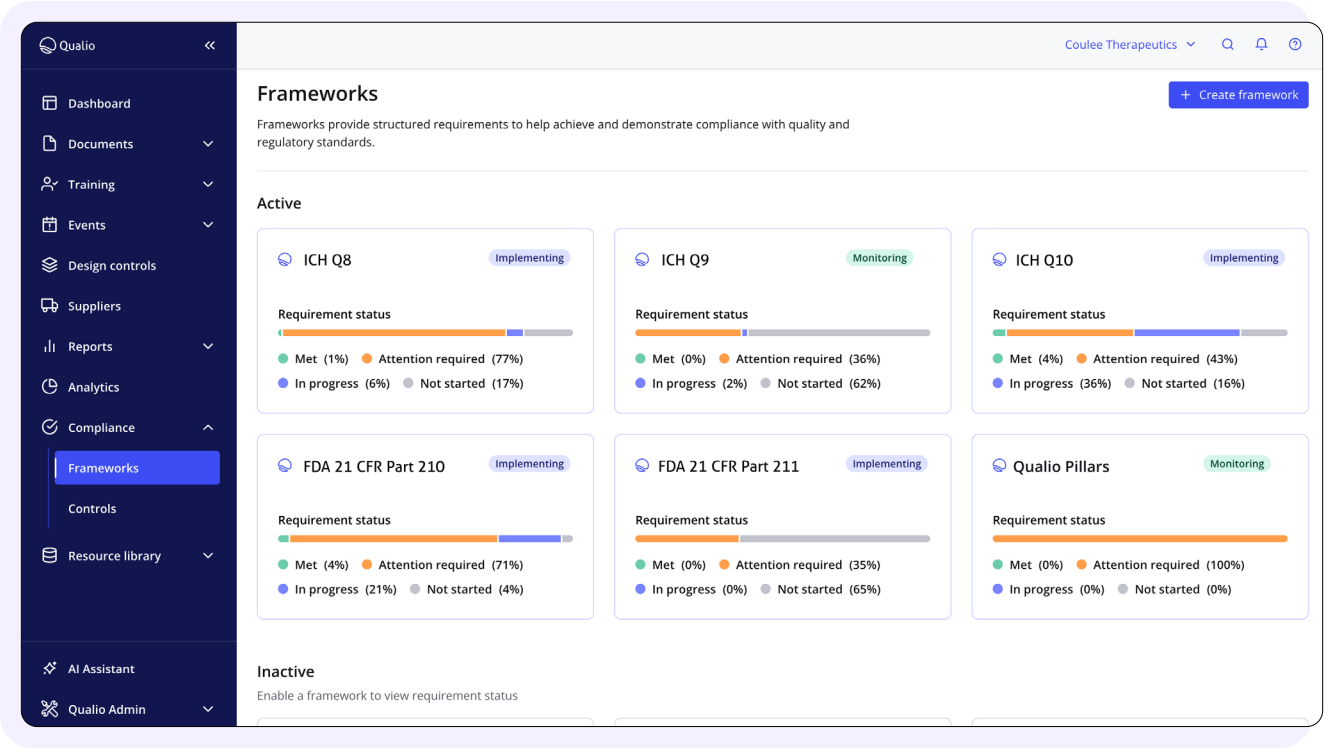


2 Frameworks and controls for easy auditability

Compliance Intelligence is built around a library of frameworks: expert-built, pre-validated, clause-by-clause maps of the standards and regulations that matter to you.

From FDA 21 CFR Part 11 to ICH Q10 and ISO 13485, just turn on a framework and Compliance Intelligence assesses your level of compliance with its requirements — so you can see at a glance which you've met, and what you still need to do.

Compliance Intelligence's AI brings regulatory expertise in-house, dramatically lowering your need for expensive consultancy support.



2 Frameworks and controls for easy auditability

Controls are how you meet the requirements of a given framework.

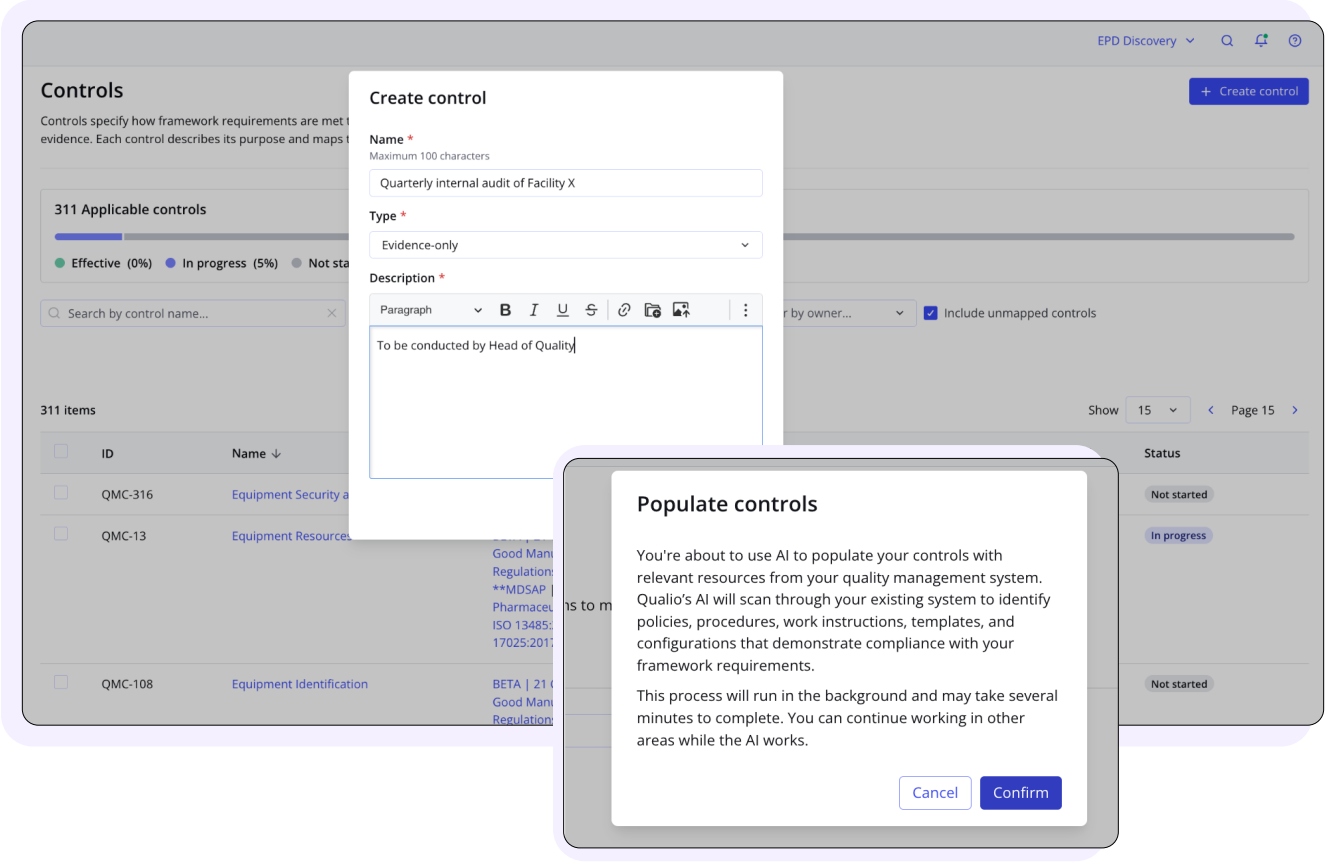
Controls are comprised of:

1) Process definitions: the documented policies and procedures that establish how you work

2) Objective evidence: the day-to-day records and reports which prove you're following those policies and procedures

Compliance Intelligence automatically fetches, assesses and organizes this control information for you as it scans, saving you hundreds of hours of manual evidence gathering and mapping.

Plus: controls can be reused *across* requirements and frameworks, letting you tackle multiple standards without duplicate work and effort.



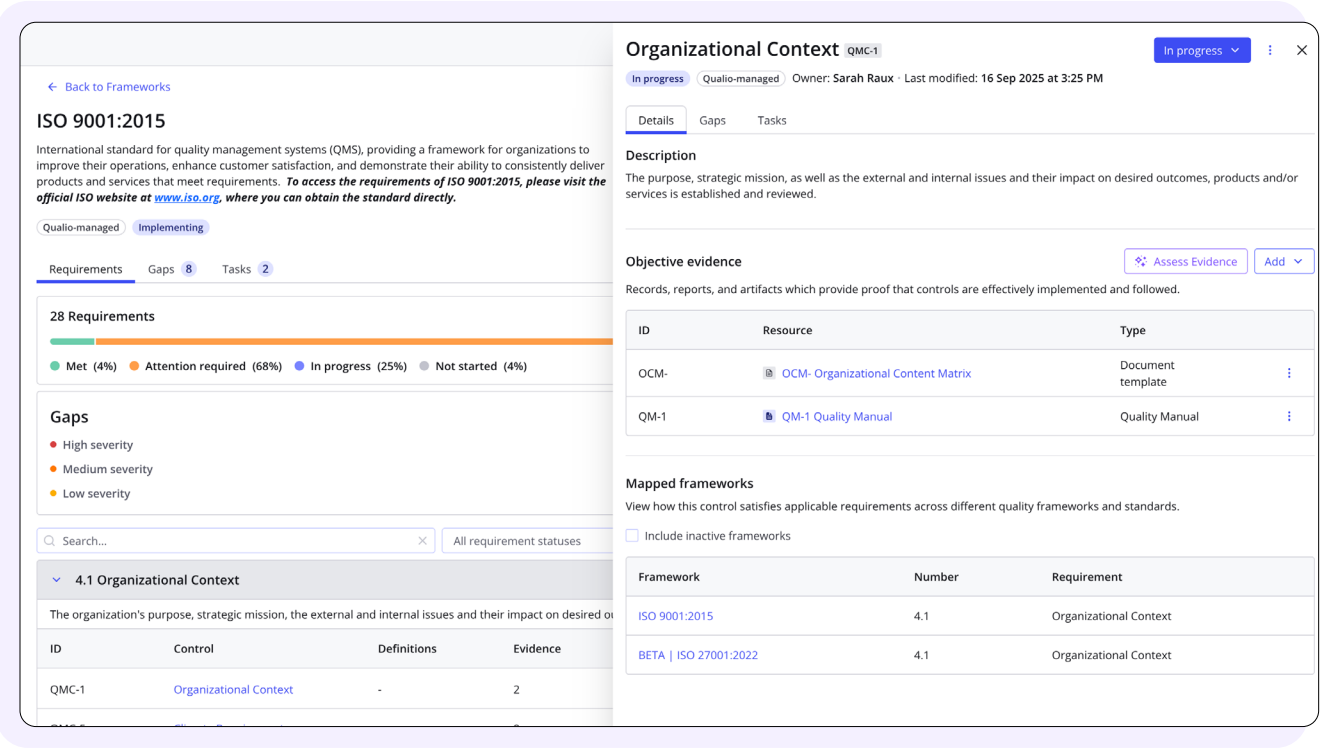
2 Frameworks and controls for easy auditability

The end result?

A connected, visually intuitive representation of your compliance activity, ready for auditors and inspectors to assess.

Explainable, human-in-the-loop AI with full audit trailing ensures you don't sacrifice control or traceability as Compliance Intelligence does the heavy lifting for you.

And our team of quality experts updates Compliance Intelligence's frameworks as new versions of standards and regulations are published, keeping you constantly at the cutting edge of regulatory expectations.



3 Tasks and workflows for collaborative compliance

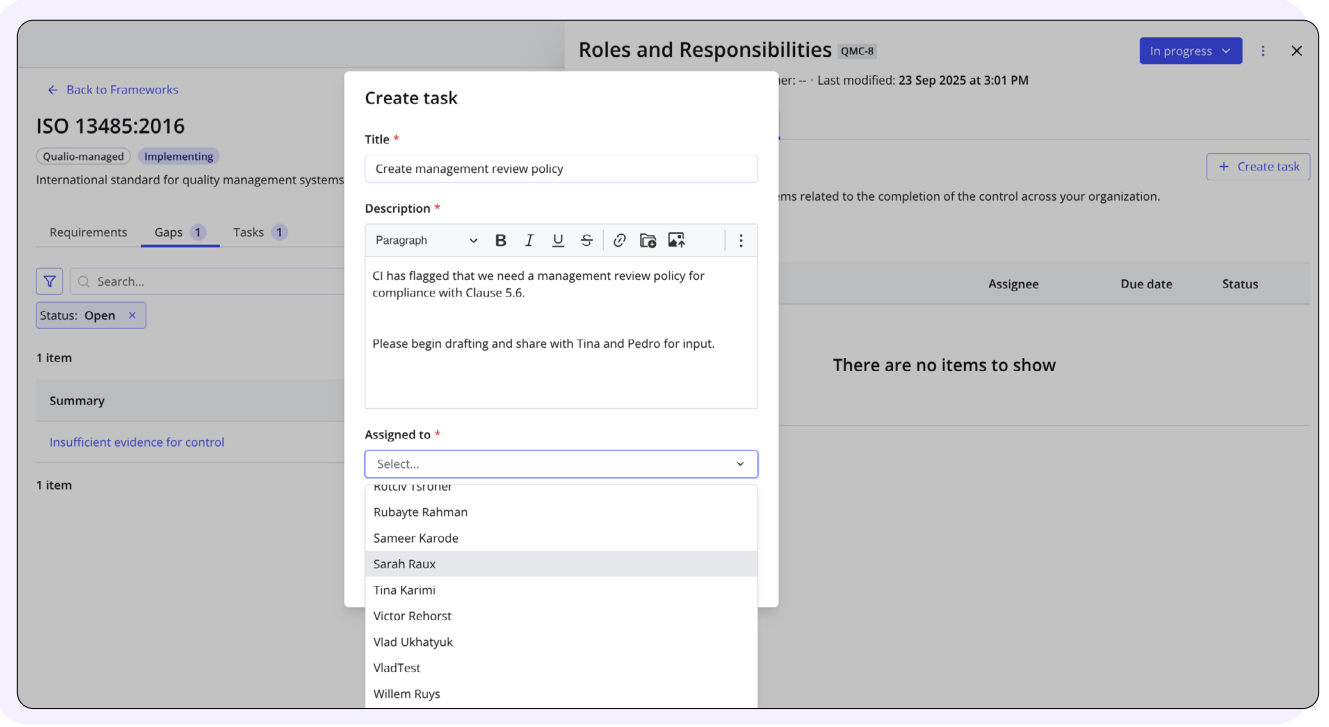
Airtight compliance requires coordination and shared information.

Compliance Intelligence connects your team to a single source of truth for all of your compliance activity.

Once the tool has uncovered your compliance gaps, system tasks are used to close them and continuously improve your quality and compliance processes.

From tweaking terminology to building a new policy from scratch, Compliance Intelligence pinpoints the exact action you need to take to perfect your regulatory compliance.

These actions can then be assigned to Qualio users as fully traceable tasks.

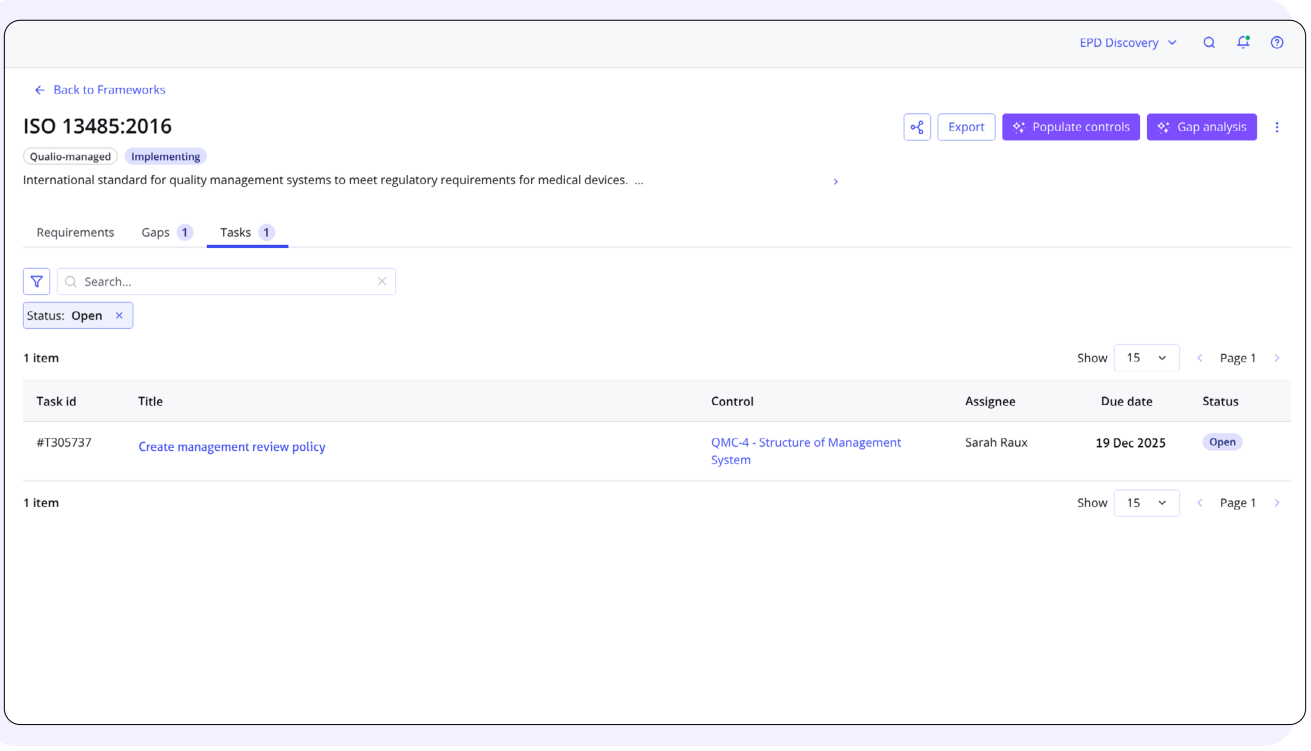


3 Tasks and workflows for collaborative compliance

Once tasks are built and assigned, assigned personnel see them in their Qualio Dashboard, while prompts and reminders keep them on track to completion.

All tasks can be examined from within a framework screen, with filters for status, assignee and control.

And automatic AI prioritization ensures your biggest compliance gaps get the most attention, giving your team a proactive compliance approach that ends unwelcome audit surprises for good.



4 Compliance health snapshots for full executive visibility

How prepared is your company for that big ISO audit next quarter?

How aligned are you with FDA cGMP requirements as you prepare for that US expansion next year?

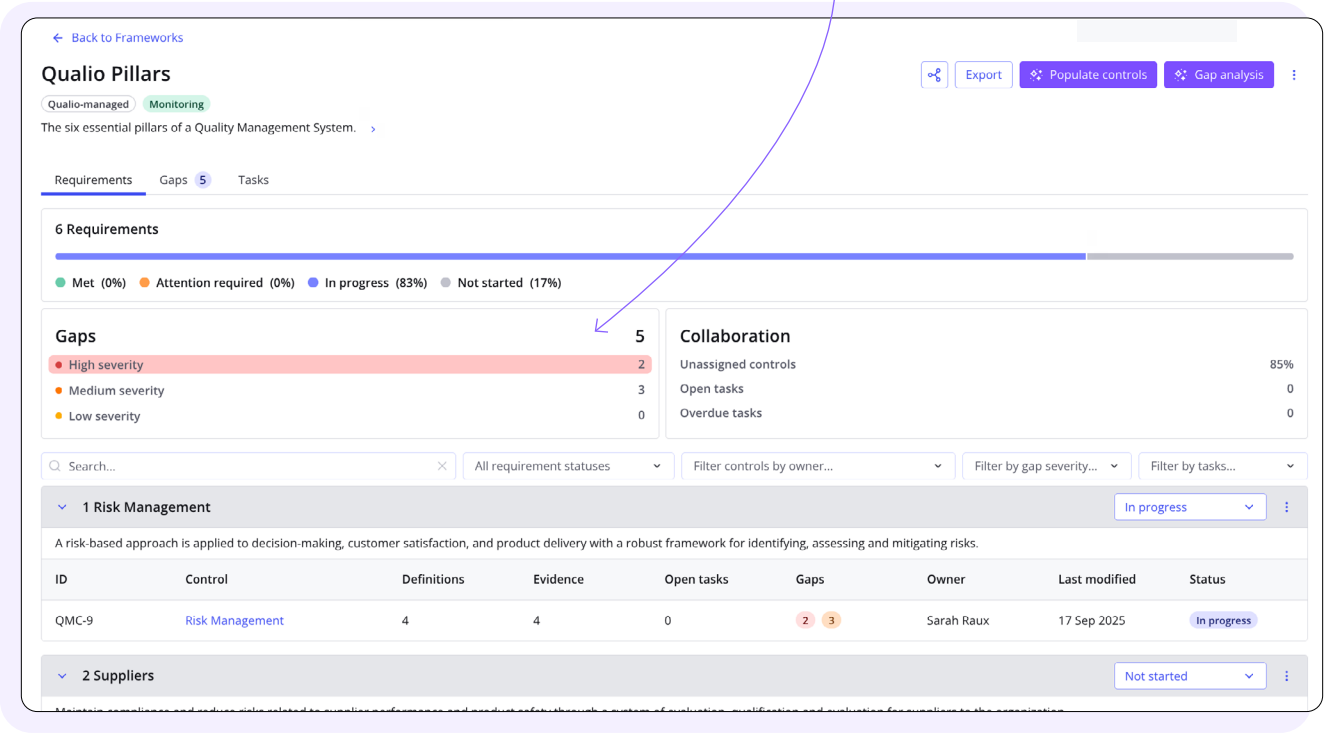
If a customer was to inspect you next week, would they leave happy?

For life science company leaders, these questions are difficult or impossible to answer with legacy compliance tools.

That's why audit observations, warning letters, market delays and recalls happen.

Compliance Intelligence unlocks total visibility of your compliance landscape, giving you at-a-glance insights of where to allocate your resources.

See where you're compliant — and where you aren't — at a glance



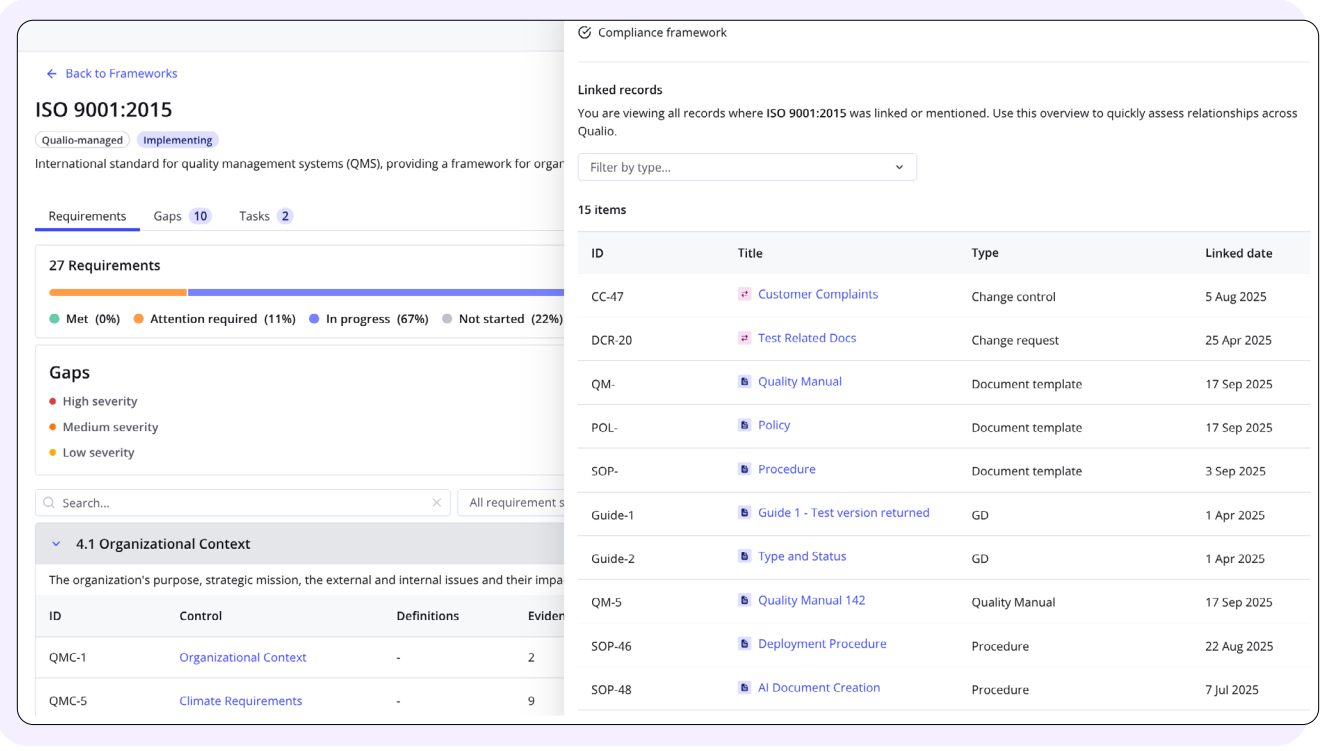
4 Compliance health snapshots for full executive visibility

Compliance Intelligence simplifies complex regulations into clear, understandable, step-by-step components reviewed by independent industry experts, so it's always clear what your teams need to do next.

Simple, data-driven visibility of compliance health informs your company strategy and gives you a real-time, business-wide view of market readiness.

And with your quality and regulatory teams freed from time-consuming gap analysis work, they get more time and energy for actually implementing compliance improvements.

That means faster product approvals, lower compliance costs, and the confidence to scale into new markets without surprises.



The ROI of Compliance Intelligence

Legacy compliance systems aren't just time-consuming and inefficient.

They also increase your organizational exposure to the risks of compliance failure: market delay, fines, recalls, reputational damage and more.

Compliance Intelligence offers a fast, light and scalable way to manage compliance that shields you from risk and provides total stress-free confidence every time your auditor knocks.

Manual compliance costs take up:

- **20%** of R&D budget
- **30%** of IT implementation costs
- **75%** of product submission costs

10% average share price drop from a major compliance failure event

7 months average market delay for pioneer medical devices

- **$ 150-300k** spent every year on compliance consultancy
- **$ 100-200k** average cost of a Form 483 observation
- **$ 50-250m** average cost of a warning letter
- **$ 150-500m** average cost of an import alert

12 reasons to manage your compliance with Compliance Intelligence

See Compliance Intelligence in action
Sign up for a mini-demo webinar session >

1. Slice audit preparation time from 20–24 weeks to about 4
2. Access expert-built, pre-validated frameworks for the regulations that matter to you
3. Fix compliance gaps earlier to reduce costly CAPAs, enforcement actions and recall exposure
4. Reuse evidence across standards to end duplication
5. Uncover every compliance gap in 30-40 minutes
6. Avoid market entry delays from missing or incomplete evidence and keep investor confidence high
7. Cut consultant spend by bringing AI compliance expertise in-house
8. Catch compliance issues before auditors do with dashboards and alerts
9. Apply constant monitoring for constant audit readiness
10. Remove hundreds of hours of manual evidence collection
11. Automate remediation with CAPA workflow generation
12. Expand into new markets 3x faster

Qualio

Stay audit-ready forever.

Ready to see Compliance Intelligence for yourself and to take the first step to best-in-class compliance?

Schedule a demo with us