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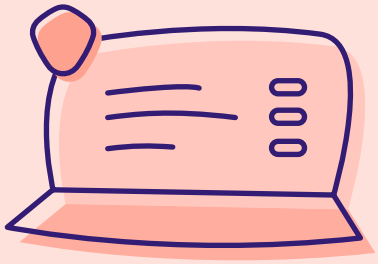

Audit success playbook

Best practice tips for before, after and during the big day

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For life science quality professionals, there are few things as stressful and daunting as an audit.

It's not just your company going under the microscope: it's your work, team and professional value being examined, with your reputation on the line.

But as with most things, careful preparation and a little know-how brings both confidence and success. The Qualio quality team has poured our decades of collective experience into this playbook to give you everything you need for a successful audit experience.

We hope you find it useful, valuable and instructive!

Meg Sinclair
Senior Manager, Quality and Support

What do we mean by 'audit readiness'?

Audit readiness is a spectrum which every company finds itself on, from complete unpreparation to a state of being totally prepared, ready and confident. We can define audit readiness as:

1. Being comfortable and aware of what your auditor will ask you, and how you'll respond.
2. The entire business (not just the quality manager!) is prepared.

When we think of audit readiness, three key elements come into play.

Let's look at each in turn.

People

Building your 'A-team'

You should start by considering who you want by your side during your upcoming audit.

There are 4 key actors you'll need to identify and assign for your audit preparations.

Scribe: takes notes, records pertinent details

Authorized escort: point of contact who escorts the auditor

Runner: brings relevant documents to the auditor

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

- Demonstrate expertise and understanding
- Own their areas and make the right first impression
- Explain without a script

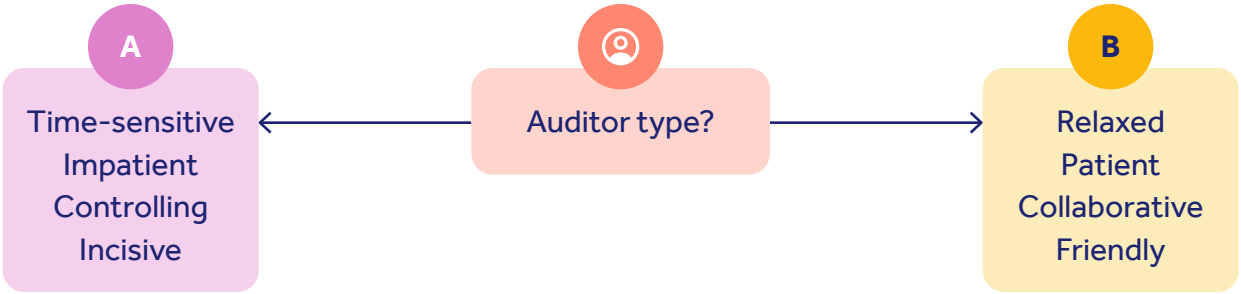
The guiding factor for your people choices should always be **knowledge**. In particular, you should pinpoint the people with the deepest, most confident and 'automatic' knowledge of your business and how their piece of it operates. There are a few things to consider as you assemble your subject matter experts:

- **Find** colleagues with the best knowledge of their individual areas of operation
- As a second priority, **look for** emotionally intelligent people with good interpersonal skills
- **Use** your business leaders to help you find the most confident, competent and authentic subject matter expert for each area (it may be the leader themselves)
- **Don't** let personality type override knowledge as a decision factor. If someone in your team is shy, abrasive or overly talkative, but they have the most confident knowledge of their business area, then they're the right person for the job. A social butterfly unable to answer detailed questions won't cut it

Personality & communication

Of course, in an ideal world you'll be able to have an audit 'A-team' with a perfect balance of personality and operational knowledge. Building rapport and understanding with your auditor and communicating effectively with them is a softer skill, but it's still important on the big day.

This can mean 'reading' the auditor quickly and working to their personality type. Your subject matter experts may be able to do this, but the main point of contact should definitely be able to.



Above all, your audit preparations should be performed with **authenticity** as the guiding light. Nervous, underprepared businesses that know they may not be fully compliant often fall into patterns which experienced auditors can pick up on very quickly.

This can include:

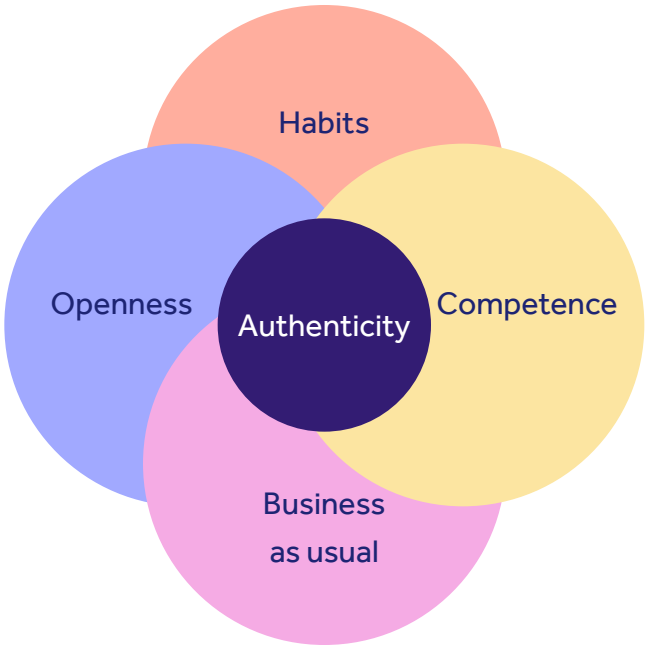
- The quality manager 'stealing the show' and answering everything themselves
- Falling back on the same soundbites and the 'company line' without supporting evidence
- An overly rigid and inflexible approach on the day, with spontaneous auditor questions triggering instant discomfort and panic

As an interrogating government officer says to a watching student in the Oscar-winning film The Lives Of Others:

> "Do you notice anything about his statement?"
>
> "It's the same as at the beginning."
>
> "Exactly the same. Word for word. People who tell the truth can re-formulate things, and they do. A liar has prepared sentences which he falls back on when under pressure. We now have two important indicators, and can increase the intensity."

Of course, we should never treat an audit as an interrogation – but the principle remains the same.

Authenticity stems from combining several ingredients. Get them in place on the day and your audit will flow smoothly and confidently, and your auditor will 'feel' that you know what you're doing.

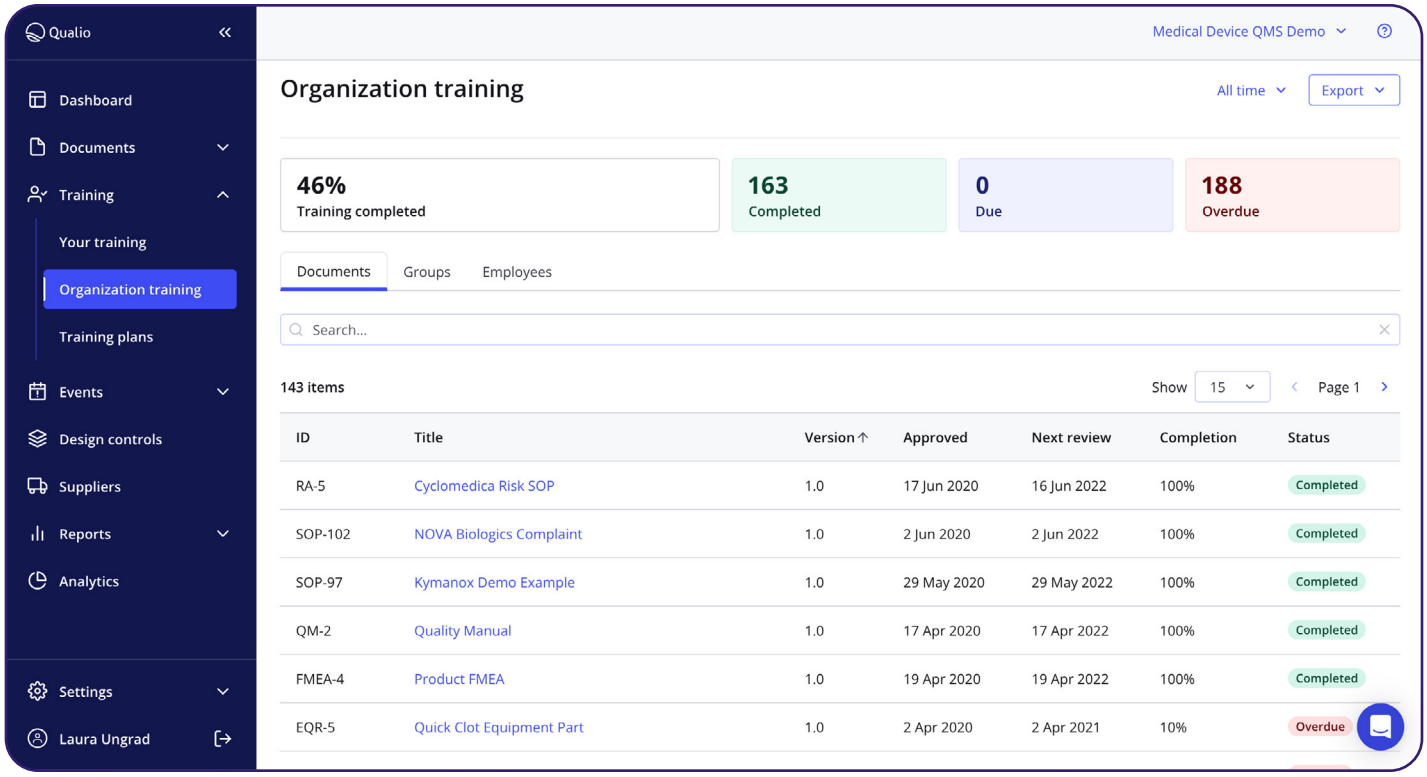


The key to all four elements? Training.

Get a mechanism in place for training staff on new processes and confirming understanding.

Check the training completion rate for each and every process.

And actively capture feedback on new processes as you train: if people don't like them, they won't follow them!



Process

Pre-audit

Internal practice audits to pinpoint improvement opportunities are an indispensable part of your audit prep. Just as you'd revise your course and perform a mock exam before a real one, internal audits are the best way to prepare for your upcoming external audit.

What?

- Quality data
- Customer feedback
- Product conformity
- Characteristics/trends of corrective action
- Suppliers
- Past decisions

Why?

- Drive CAPAs & continual improvement
- Pinpoint operational issues
- Improve processes
- Evaluate effectiveness of QMS
- Ensure supply chain integrity
- Determine reasoning, track goals, show improvement

Your audit process itself should be clear, logical and well-run for maximum effectiveness. Be on the lookout for 'danger' signs, such as:

1. Too many systems

Are you recording your findings across paper, Dropbox, Excel, email, and so on? Can you easily find the information you need to make improvements?

2. Recurring findings

Are your audits *actually* driving improvements? Are the same things cropping up time and again?

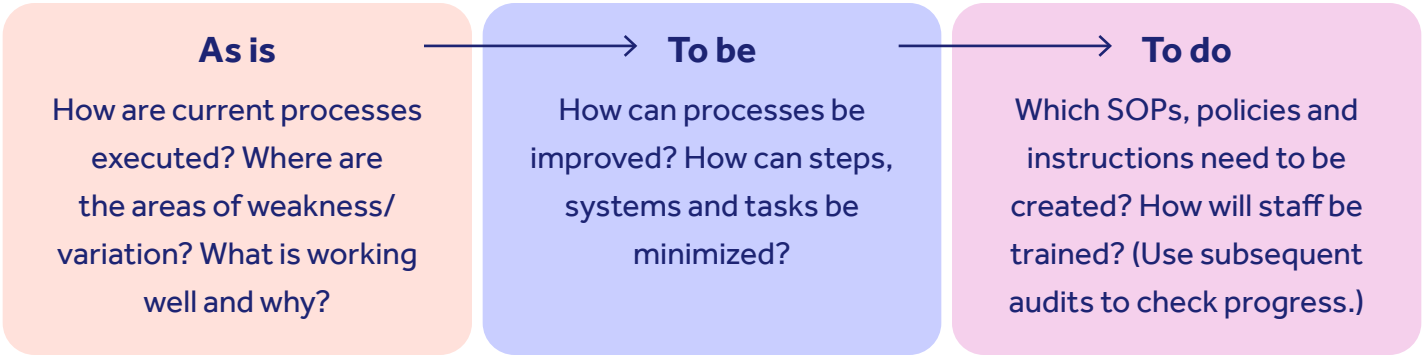
3. Data overload

Are your reports ambiguous, overly complex or unactionable? Less can sometimes be more.

4. Long audits

If you're finding it difficult to audit your processes and pinpoint what you're looking for, an external auditor will find it even harder.

The 'As-Is' method is a helpful way to structure your internal audits and the follow-up activity surrounding them.



3-step process for building audit readiness with internal audits

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. Map subject matter experts onto each process as you go. SMEs can be responsible for multiple processes.

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 processes to think about include product design/development, risk management, incident management, documentation, supplier onboarding, data retention, and so on.

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? Are lines of communication broken at hand-off points?

Support from leadership

Do your leadership team...

- Inform everyone of the importance of audit readiness?
- Actively collect and respond to feedback about processes from SMEs?
- Make themselves available for audits?
- Integrate audit KPIs into management reviews?
- Invest in systems and tools to simplify audit prep?
- Encourage a culture where processes can be challenged and improved?
- Set constant audit readiness as a key operational goal?

Mid-audit

As your auditor arrives for the big day, it's important that the right environment is established.

Has Wi-Fi access been provided to the auditor? Do they have a private, quiet workspace they can retreat to as needed? Are you being a good host and providing food and drink throughout the day?

Once that's been done, you should pay careful attention to how you'll react to the auditor throughout the day.

1. Communicate real-time developments mid-audit to relevant personnel

If you know someone will be called in to answer questions, arm them with as much context and info gleaned from the auditor as you can, so there's no surprise or 'ambush'

2. Plan how to minimize 'catch-out' moments

Have answers and honest explanations ready for past mistakes. Has the auditor spotted something you haven't? Be honest and don't try to hide the fact.

3. Look out for the auditor's preferences in real time and respond accordingly

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

We've already seen how the softer skills of rapport and personality can contribute to a successful audit (even if process knowledge is most important). With this in mind, the 'Goldilocks Approach' should be stuck to throughout the audit to help you balance friendliness and professionalism.

Being 'too hot' means excessive small talk, overly detailed explanations of documents, repeating document contents, and answering questions you weren't asked.

Being 'too cold' means unhelpful answers, not elaborating on something when asked, or being generally evasive or 'shifty'.

For a happy medium, let your objective evidence do the talking and stand by for helpful, concise and friendly elaboration if and where needed.

Post-audit

Your work doesn't end once the auditor's gone. Take some time to reflect on what went well, what can be improved on, and how.

The sharper and stronger your quality approach, the faster and more nimbly you'll be able to get to work at this point. An electronic quality management system (eQMS), for instance, allows you to:

- Enforce action due dates and timelines to ensure you're ready for the next audit
- Assign actions to the right personnel and teams to close out findings in the most efficient and sensible way
- Set system action reviewer(s) to make sure findings have been properly closed out before your next audit
- Build an audit-trailed and fully traceable set of CAPA actions to prove at your next audit how you've progressed from the previous

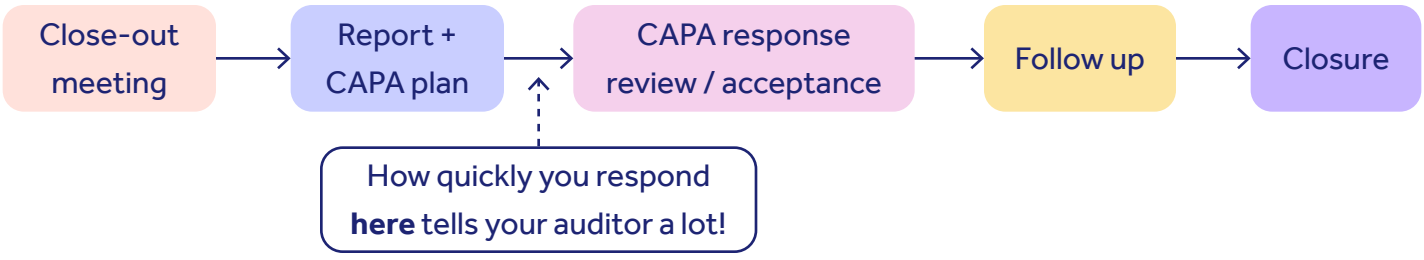
Three post-audit tips

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

Acting on audit findings *quickly* (without compromising effectiveness!) is crucial too.



Data

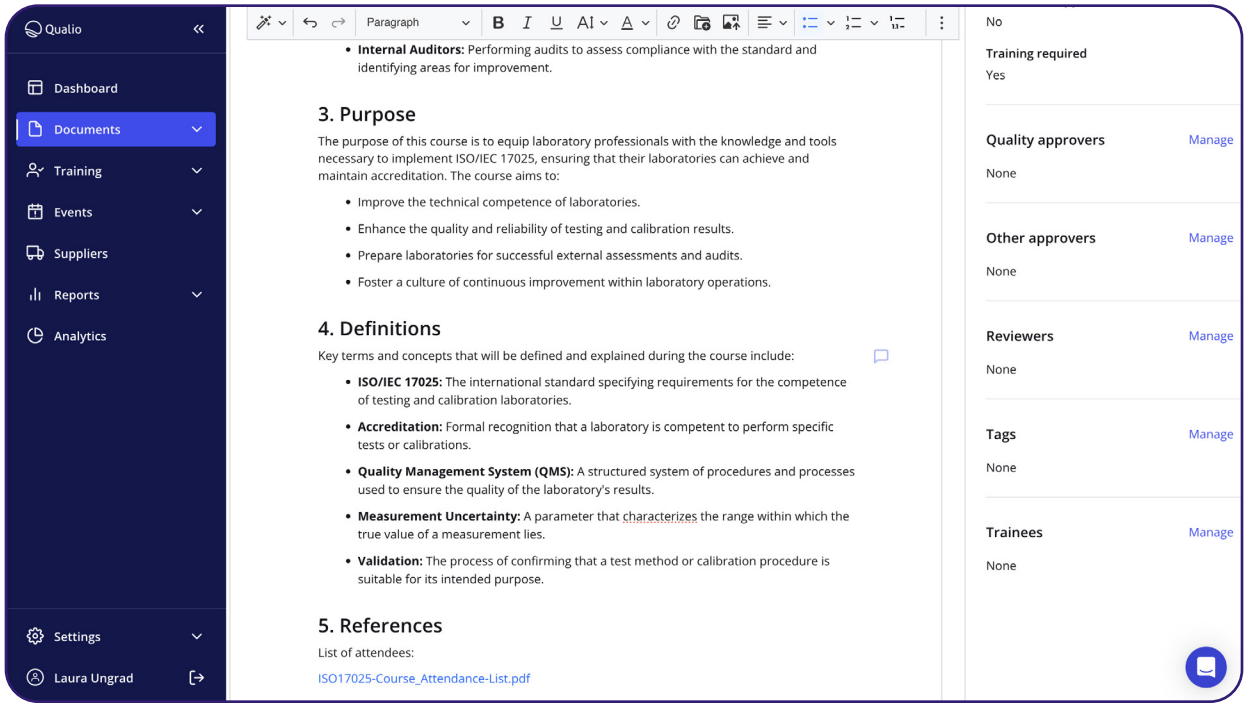
The final component to consider for real audit readiness is your access to, and control of, your key quality information and data – and how you respond to the findings data provided by your auditor.

As with the 'Goldilocks Approach' above, it's a matter of balance:

Information underload	**Information overload**
Can't locate requested documents	Irrelevant/inappropriate information
Information gaps	No clear narrative
Awkward time-consuming trips to dig out info	Wasted time and effort

A stable, logical core of objective evidence is absolutely essential for audit success. Give yourself a mechanism for securely and confidently controlling, reviewing and distributing SOPs, quality manuals, objectives, and so on. Don't forget the basics like ALCOA+ and GDocP, and ensure information can be quickly exported and shared as required.

As your auditor requests information from you before or during the audit session, ensure you provide it in their preferred format. Since more and more auditors expect digital quality management systems, most will be well-used to interacting with an eQMS platform. If you do use an eQMS, prepare a document ahead of time containing links to all other requested information, to make it easier for the auditor to source what they're looking for.



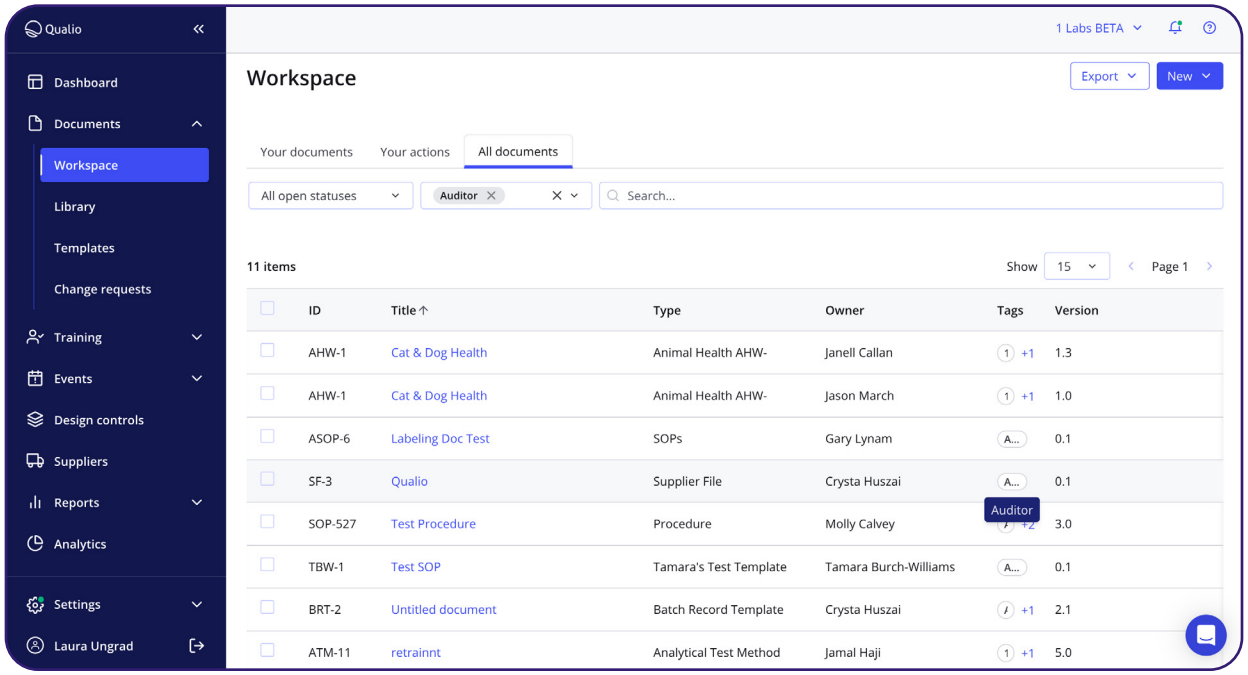
An eQMS can also accelerate your access to information on the day and help build a picture of controlled competence to any arriving auditor. Three Qualio customers recount their experience of using our software to achieve this:

> *Our auditor was really impressed and thought it'd take much longer to retrieve the information they asked for during the audit.*
>
> *Most auditors aren't happy if you have to go off for 30+ minutes to look for things!*
>
> **— Hanna Fanous,**
> Quality Assurance Supervisor, Kazmira

> *We have a rule.*
>
> *Within 30 minutes of an inspector ringing our doorbell, they should be sitting in our boardroom reviewing the first set of documents.*
>
> **— Karen Hue,**
> Head of Quality & GxP Compliance, 30 Technology

> *Our auditor let us know she was really unhappy with how we were managing everything.*
>
> *It took us a long time to get the documents she wanted.*
>
> *It took 6 days. Now we have Qualio, it'd take half a day.*
>
> **— Ami Anderson,**
> Director of Ops & Quality, NeuFit

An eQMS like Qualio can help you present a simple, digestible view of your quality management system to your auditor. A tagging system, for example, can let you segment your eQMS into an auditor-specific view so they aren't overwhelmed, and can enjoy a clean and easy interface with your quality system.



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See how Qualio gets you confident and fighting fit for audits

Schedule a demo with us