



Using Qualio for ISO 9001 audit and certification

ISO 9001 is an international standard that sets out the criteria for a QMS

Organizations of all sizes and in all industries can use ISO 9001 to ensure that customers get consistent, good-quality products and services with every transaction.

Whereas [ISO 9001](#) is a more general regulation, [ISO 13845](#) builds upon it and focuses specifically on medical devices.

If you are a biotech, pharmaceuticals, medical device, contract research organization, or other life sciences organization that is facing an audit, Qualio can help. Qualio is the go-to for internal and external audits for FDA, ISO, and more.

To achieve ISO 9001 certification, organizations need to meet these seven [ISO 9001 quality management requirements](#):

1. Customer focus
2. Leadership
3. Engagement and training of people
4. Processes
5. Continual improvement
6. Decisions based on evidence
7. Relationship management

Recently, Qualio conducted an external audit to achieve ISO 9001 certification, using the Qualio platform and test our own product for real-world usage.

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— Kelly Stanton
Director of Quality

What was the external audit like?

The audit was a two-stage process, conducted as an external virtual audit, due to the pandemic.

In the first stage, the Qualio team gathered all the documentation and procedures the auditor would need to complete the audit. In the second, the auditor had access to the system and reviewed all of Qualio's documentation and procedures over the course of four days.

"Everything went really smoothly," says Meg Sinclair, a Quality Specialist at Qualio.

In large part, that's because the team conducted a gap assessment in its own internal audit ahead of the external audit. This preparation included management review meetings that included team members from Quality, Sales, Marketing, Operations, Engineering, and People Ops, getting all documentation in order, and opening CAPAs for gaps they identified, among other things.

"We were very transparent about what we had to work on," Meg continues.

When the audit began, the auditor asked for examples of how the Qualio team followed its own procedures to accomplish

a certain task. Since all of the information was already captured inside Qualio in an intuitive manner, the auditor's job was a piece of cake.

"We had zero errors," says Kelly Stanton, Director of Quality, adding "that's because training is a big piece within Qualio. We made sure to utilize Qualio's dashboard and created training videos to make sure all team members were properly trained on Qualio. All training records were organized and stored within the platform as well."

The Qualio team did a great job of giving the auditor all the evidence and documentation.

"It was very easy for the auditor to go through our system to find everything he needed", says Kelly.

Qualio makes it very easy for non-quality stakeholders to help their organization get ISO ready. Qualio's dashboard and internal training makes it simple for team members to train on documents quickly and efficiently. Storing these training records within Qualio also demonstrates training has been completed and records can show during any audit.

Tips for passing an external audit

Does your organization need to pass an upcoming audit to comply with international standards or regulatory guidelines? Here are a few tips to keep in mind to increase your chances of success.

#1 — Use a purpose-built quality management system

Since Qualio was used to prepare for our audit, it was much easier to make sure we checked every box that needed to be checked. At the same time, it was very straightforward for the auditor to verify our processes and documentation.

Suffice it to say that if you're still relying on a paper-based quality management system, the certification process will become needlessly complex and drawn out.

#2 — Spend a lot of time preparing ahead of time

"You can't be over-prepared for an audit," Meg says. "There's no such thing."

During Qualio's internal audit, the team had multiple findings, but by the time the external audit rolled around, some of those findings were wrapped up and others

weren't — which is fine, too.

"You need to be able to show the auditor that you're using quality systems," Kelly says. "We pointed out nonconformances and CAPAs and showed him the things we were working on and what we wanted to correct."

#3 — Be upfront with the auditor

If your goal is passing an audit, you need to be upfront with your auditor and tell them where the open areas of improvement are. The last thing you want is for the auditor to discover a nonconformance and have to explain it away.

"The more transparent you can be, the better off you are," Kelly continues. "The auditor will find the things you're trying to hide."

If you're a biotech, pharmaceuticals, medical device, contract research organization, or other life sciences organization, that has an upcoming audit and needs to prepare, Qualio can help.

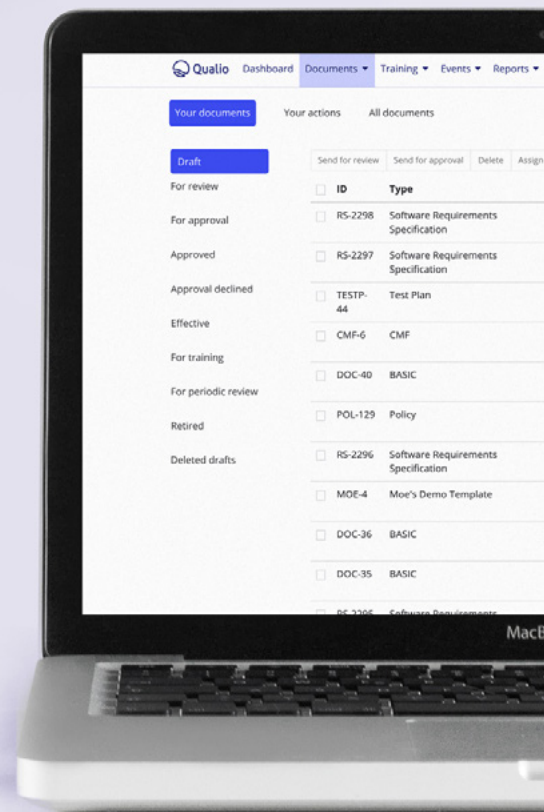
[Request a demo today](#) to learn more about the easiest way to build your organization on an ISO 9001-certified quality management system.



Get your free demo of Qualio QMS.

Qualio is the highest rated eQMS on the market and also the easiest eQMS to use. To learn more about why leading life sciences companies rely on Qualio to improve quality management as they develop medical device products and bring them to market.

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