eBook

The Complete Guide to Quality Management Goal Setting

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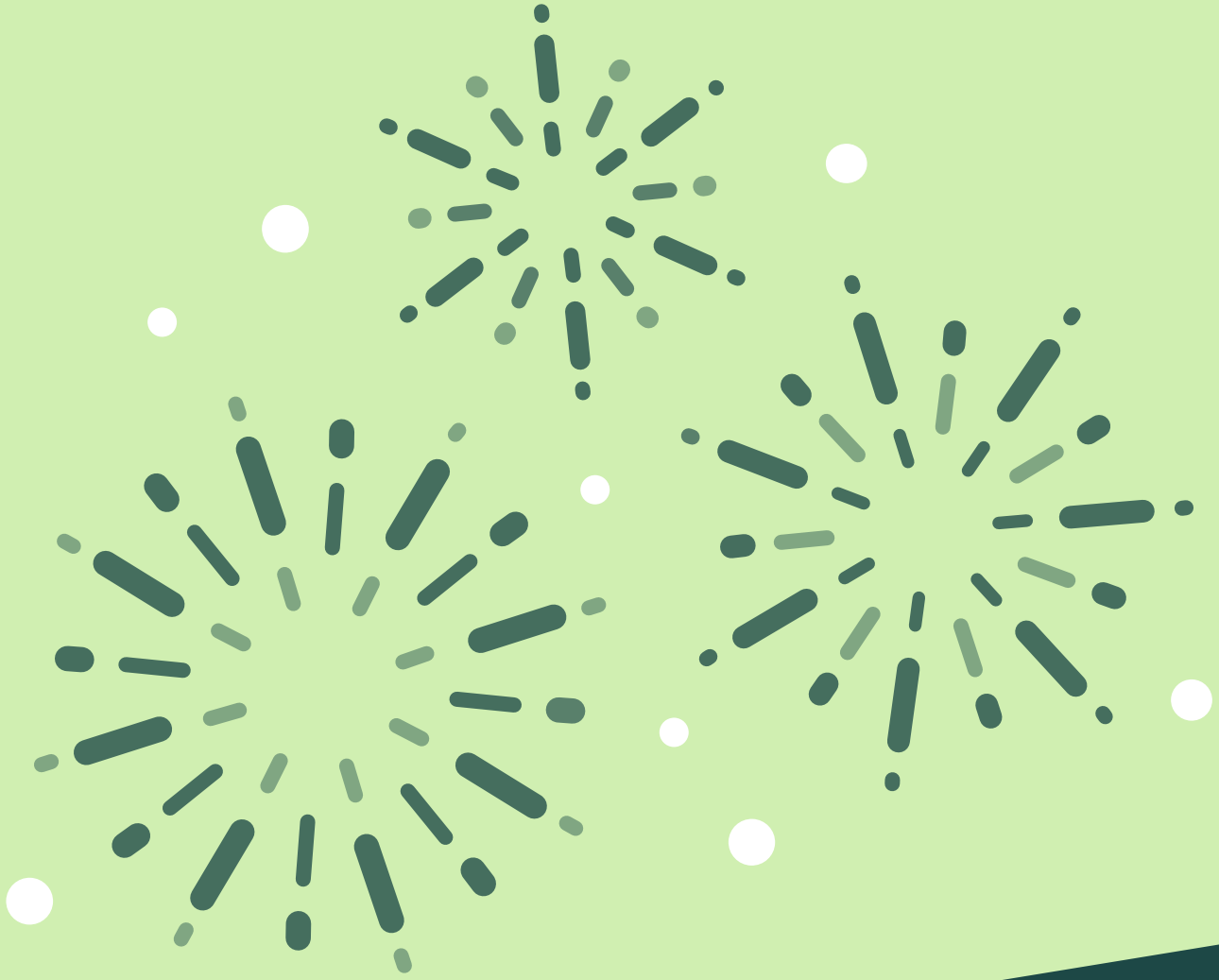


Section 1

3 New Year Resolutions for Quality Management Professionals

New year, new quality management goals!

But while you're setting document approval time objectives and other KPIs for the Quality department, don't forget to focus on your team's professional development and overall success too.

Need some inspiration to get started? Check out these three goals for quality management professionals looking to grow their networks, resources, and knowledge.

1. Get involved in quality management events

Even if you don't grow your Quality team this year, you *can* grow your Quality network. Commit to creating valuable connections in the life sciences space by making time for quality conferences and networking events. There are plenty of opportunities for quality pros to come together, but these are a few organizations that host our favorite events.

- **RAPS Conference:** RAPS (Regulatory Affairs Professional Society) offers a variety of events for leaders in professionals in medical devices/IVD and pharmaceuticals to connect on key regulatory affairs topics.
- **KENX:** KENX hosts events on a variety of key quality topics, including compliance, validation, GxP data security, AI, and more.
- **SQA Annual Meeting & Quality College:** SQA's Annual Meetings are dedicated to promoting and advancing the principles of quality assurance essential to human, animal and environmental health worldwide.
- **ASQ:** From annual meetings to community events, ASQ offers a variety of opportunities for Quality professionals to come together and chat about the latest best practices.
- **Quality Leaders Forum | Ongoing | United States:** Our ongoing QLF series brings together quality leaders from biopharma, CMOs, CROs, and more for networking, workshops, and panel discussions around the latest quality management challenges and emerging trends. Get more details, plus learn when we'll be in your city here.

2. Get better quality management tools

Do you really want to continue using spreadsheets, disconnected programs, and overstuffed folders?

This is the year to get the quality management tools your team deserves. Check out these guides to help figure out which quality management software is right for your organization, plus how to convince leadership to invest in your team:

- **eQMS Cost Comparison Calculator:** Use this calculator to help uncover and track the real cost of each eQMS in your search.
- **eQMS Buyer's Guide:** Find the QMS software that fits your needs AND your budget with tips to compare eQMS functionality and pre-drafted questions to ask during a demo.
- **eQMS ROI Calculator:** Calculate what your current quality processes cost in time and dollars, then compare it to the cost of an eQMS to see just how much your organization could save.
- **Vanguard Clinical | How the Associate Director of Quality made the financial case for a better QMS software:** See how a fellow Quality leader worked with both the CFO and CEO to secure budget for the right eQMS.
- **Quality Q&A: What's the real ROI of an eQMS?:** How much impact does an eQMS really have on GxP-regulated organizations? Hear from a VP of Quality and Regulatory Affairs.

3. Seek out continuing education opportunities for quality management

You can't have continuous improvement without continued learning. Whether you resolve to earn a new certification this year or simply set aside more time to tune into webinars and read through industry reports, it's always a good idea to stay current with quality management best practices. Here are a few resources to consider:

- **ASQ Quality Auditor Certification:** Why should Quality professionals earn an auditor certification? The better you understand what an auditor is looking for, the better you can prepare when your own organization is up for review. Plus, you'll find ways to improve your own vendor evaluations and even your internal quality audits.
- **eQMS University - Reporting on Quality KPIs and Metrics:** Learn which quality metrics your team should track, plus the best ways to report on quality management data to leadership in this educational webinar with VP of Quality & Regulatory Affairs Sandy Hedberg.
- **Six Sigma Black Belt Certification:** This certification proves an individual is an expert in the Six Sigma methodology, a formalized approach used to improve quality processes in organizations.
- **Quality Engineer Certification (CQE):** The CQE recognizes a professional's expertise in managing quality systems, diagnosing quality issues, maintaining quality standards, and more. This certification is especially helpful for anyone aiming for a leadership role in the near future.

Section 2

How to Create Achievable Quality Management Goals

As Quality professionals, we love goal setting season.

It's the perfect time to get aspirational and embrace the idea of continuous improvement that fuels GxP organizations.

But that doesn't mean it's not also a little daunting. You want quality management goals that are both impactful, yet realistic. Inspirational, yet actionable. How do you strike the right balance to create meaningful QA goals that are actually *achievable?*

It's all about thinking SMART.

What are SMART quality management goals?

SMART is a framework for goal setting and it stands for Specific, Measurable, Achievable, Relevant, and Time-bound. There are a lot of goals you *could* chase after, but following the SMART framework makes it more likely the goals you set are worthy of pursuing.

How to use the SMART framework to set better quality management goals

The SMART framework is useful no matter what kind of goals you're setting, but it's especially helpful for Quality teams. Often, Quality departments are short on resources, operating with small teams and budgets. It's easy to set goals that are either too broad or too ambitious. The SMART approach keeps your objectives grounded in reality while still pushing your organization toward improvement.

Here's how the SMART goal framework can shape your quality management goals:

Specific

Ambiguity is the enemy of improvement.

You'd never write an SOP that simply said "keep all equipment maintained." To be actionable, an SOP has to be clear and specific with its expectations and instructions.

The same is true of your goals.

For example, instead of "make our quality processes more efficient," narrow in on the factors that *influence* efficiency, and be specific about what you'll improve. That could mean focusing on document approval time, total number of errors, the time it takes to find a document, etc.

And the more information you have about your current quality activity performance, the more specific you can be. Maybe you know there's an approval bottleneck during a specific part of your workflow. All of a sudden, the goal "decrease document approval time" becomes "decrease document approval time between workflow stages 2 and 3 by 30%."

Take note of the "by 30%" added to the end. That's an important component of a *specific* goal. It gives us a clear parameter for success.

Without it, speeding up approval by 2 seconds is *technically* hitting our "decrease document approval time" goal... but is that a true win?

Not only does specificity prevent your goals from becoming too broad and overwhelming, it makes each objective immediately actionable.

Measurable

"Build a culture of quality" is an admirable mission. But it's a bad goal.

How do you know when you've built it? Does everyone share your consensus? If at the end of the year you find yourself saying "I *think* we hit our goals," they probably weren't SMART.

Don't let success be up for interpretation. Make your goals **measurable**.

Start by looking at the quality metrics or KPIs you're currently tracking (or maybe the ones you want to start tracking). These could be metrics like:

- The speed at which employees can find the documents they need
- How long it takes to complete an audit
- How long it takes for a document to go from draft to final approval
- The number of major and minor audit observations the company received
- How long it takes to address audit findings
- Company-wide training compliance percentages
- The time taken to implement corrective actions
- The recurrence rate of issues
- The percentage of CAPAs deemed effective

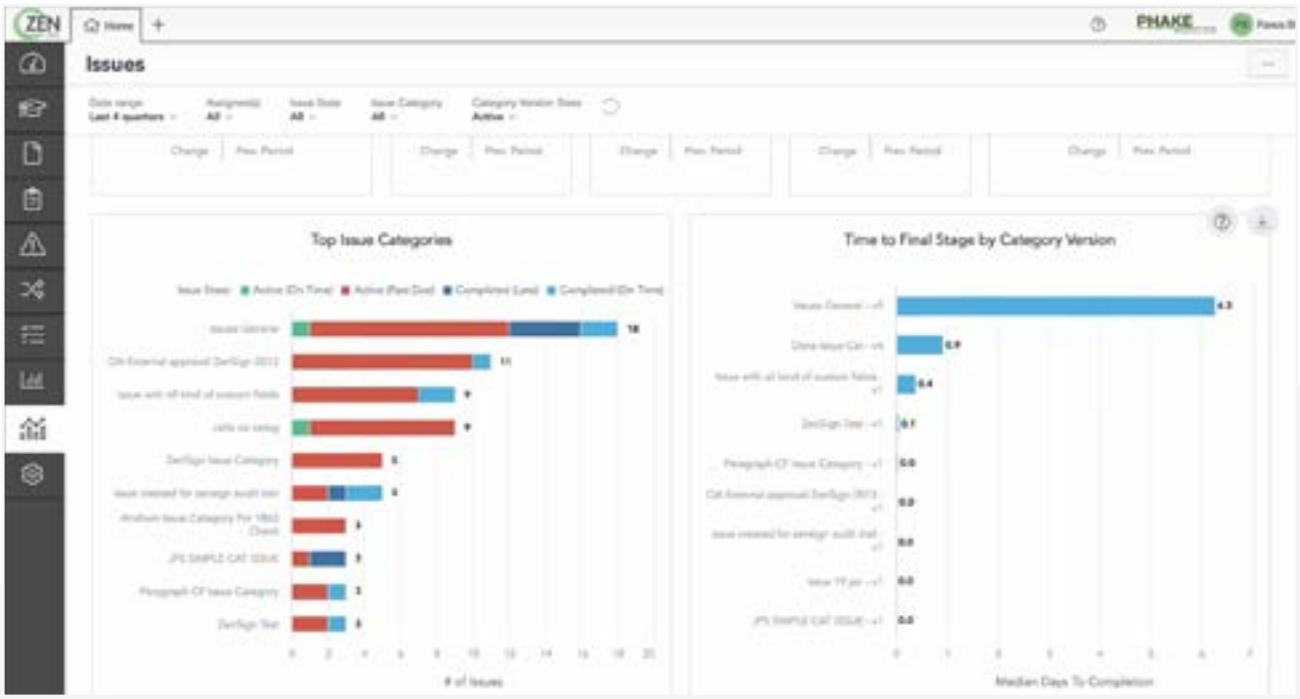
(Check out our longer guide on the right quality metrics to track for continuous improvement here.)

Make sure to give your goals a benchmark value in addition to their goal value. For example, "In 2024, our on-time training completion rate was 70%. In 2025, our goal is to hit an 85% on-time training completion rate." Or even, "We're starting 2025 with 50 SOPs that need to be updated. By the end of Q2, we aim to have 50% of those revised, with 100% revised by the end of Q4."

Keep in mind, the key to meeting your measurable quality goals is... actually being able to measure them.

An eQMS that offers in-depth data analysis for your document management, training management, change controls, issues, and audits will make setting and tracking your goals a lot easier.

The more robust the insights function of your QMS software is, the more specific you can get with measurement. For example, in our Insights module, Quality leaders can even drill down to measure the time to final stage by unique issue category. These metrics can help you determine exactly what's working and what's not, making the path to hit your goals clearer.



An example of the data available within the ZenQMS Insights module.

Achievable

Setting quality management goals is a balance between thinking big and thinking realistically. Yes, you want goals that push your team and your organization to improve, but you don't want them to be so lofty they're unreachable.

The key? Use benchmark data as a guide for reasonable improvement.

Let's say your audit on-time completion increased by 5% last year compared to the year before, even without a concentrated focus on this metric. With more intentional procedures and process updates, it might be reasonable to set a 10% increase goal in 2025.

Don't forget to consider the resources you have at your disposal before setting your team's goals in stone. Do you have enough team members to carry out the activities necessary to meet your goals? Do you have the right QMS tools to support improvement efforts?

Goal-setting season is a great time to advocate for the resources you need for success. Here are a couple of guides to help you do just that:

- How do you get the Quality Management tools you really need?
- Vanguard Clinical: How the Associate Director of Quality made the financial case for a better QMS software
- eQMS University: Getting Leadership Buy-In for the Quality Tool You Need

Relevant

The first half of the SMART formula explains how to make your goals stronger. But how do you know *which* quality management goals to set in the first place?

Above all, prioritize goals that are most **relevant** to your organization and will make the biggest impact.

Start by uncovering the clearest areas for improvement. Examine your problem log and make note of any patterns or consistent issues. Some common problem areas might be:

- A specific action (like a signature) is frequently delayed
- Access controls are incorrect
- Documents take too long to find during an audit
- Users are referencing outdated documents
- Corrective actions take too long to implement

Take a close look at any part of your QMS that has a high risk of human error, as well as practices that haven't scaled or adapted as your organization has evolved. (If you haven't already, this is a great time to set the habit of pulse-checking your QMS health).

Goals that address these issues are bound to be relevant and worthy of pursuing.

Time-bound

This one is pretty straightforward: Your goals need a deadline.

Since you're likely setting your yearly goals, a pretty standard deadline would be... the end of the year. That said, quarterly milestones are great to add to your goal plan.

This allows you to check in on your team's progress and course-correct before it's too late. Maybe that means a new process isn't working as planned, or is less efficient than hoped. Or maybe the quality management software you slotted to invest in next year bumps up in the priority list.

The QMS software that makes goal tracking easier

Good data is critical for good goals.

Whether you're identifying improvement areas, setting benchmarks, or tracking progress throughout the year, you *need* a complete view of your quality activity data.

The easiest way to get this data? Choose an eQMS that incorporates in-depth quality data reporting.

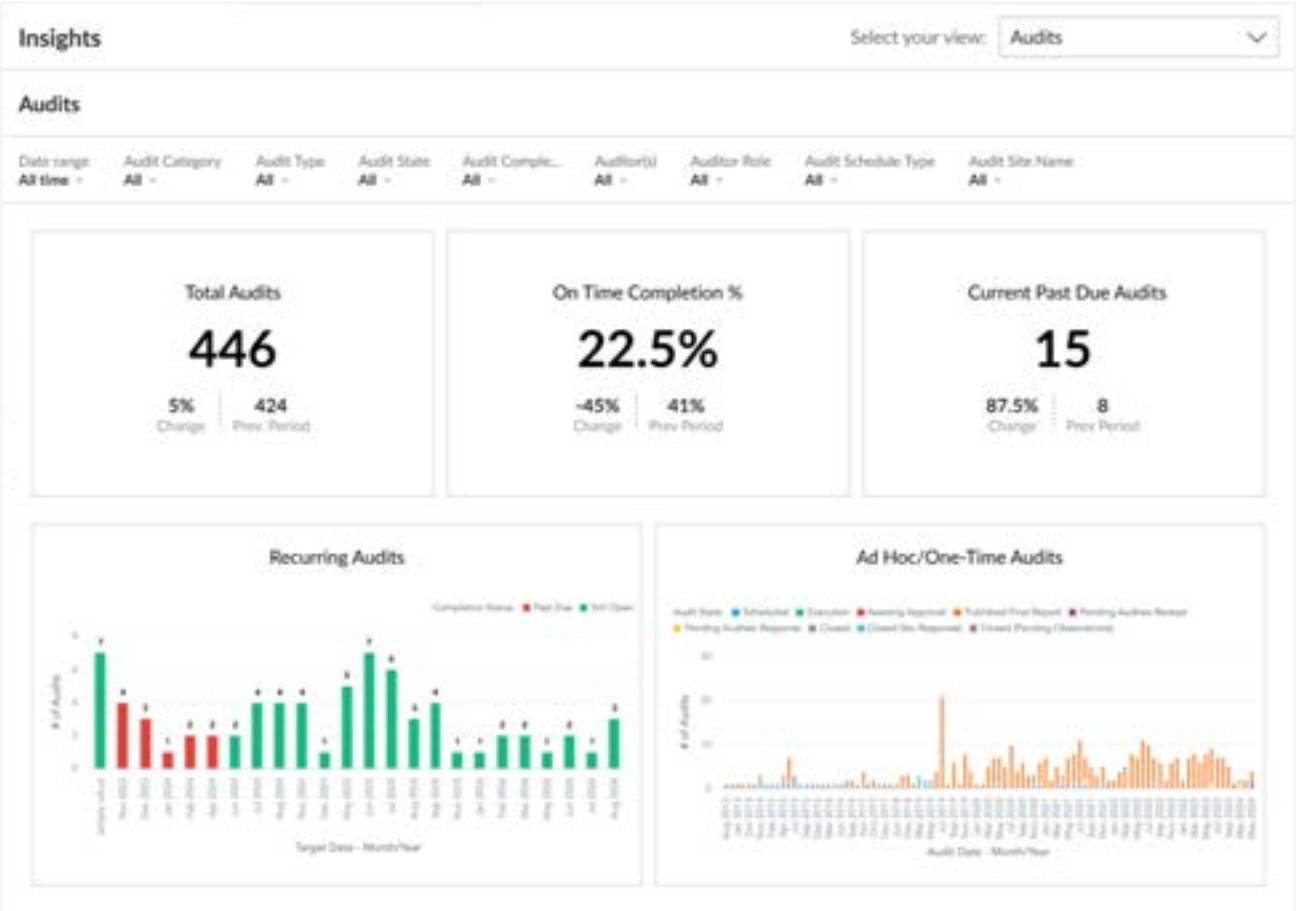
At ZenQMS, we've done this via the Insights module.

With the Insights module, users get access to data across all of their quality activities, including document management, training management, audits, change controls, and issues. Plus, our dashboard makes reporting on quality management quick and easy with interactive charts.

Through the Insights module, quality leaders can:

- Identify and analyze trend data on compliance, training, risks, and more
- Provide leadership with actionable insight to fuel improvement and growth
- Prove the impact and value of quality management
- Export dashboards to PDF for easy sharing
- Export data from visualizations to CSV and XLSX formats

Want to see the Insights module in action? See the 3-minute demo here. Then, reach out to our team to get an overview of how it can impact your unique GxP-regulated organization.



A snapshot of the Insight module, featuring just some of the audit data available for users.

Section 3

5 Tips to Help Quality Teams Hit Their Training Management Goals

Training compliance is critical for life sciences organizations regulated by GCP, GMP, and other GxP standards.

That means training management should probably appear somewhere on your Quality team's annual goals.

But while training is one of the most important functions for Quality teams to manage, it's also one of the trickiest categories to tackle during goal setting season.

That said, setting – and more importantly, achieving – impactful training management goals is possible. There are just a few tips Quality Management teams need to follow.

1. Get buy-in on training management goals from other departments

Though training *management* falls under the remit of the Quality department, training *completion* is a company-wide responsibility. The Quality team can set clear completion goals, but meeting those goals ultimately relies on others actually doing the assignments.

Ideally, you wouldn't set goals where success rides on forces outside of your control. But when it comes to training management goals, it's pretty unavoidable. The key is getting outside support.

Start by collaborating with other department leaders within your organization to review your training compliance goals. Work together to understand the *reason* behind the goal, what's required from a regulatory standpoint, what's realistic, and the role they can play in enforcement.

It can be hard to get others to dedicate time to training, especially when they see it as a distraction from their own lengthy to-do lists. But when other leaders in the organization feel like they have a real stake in training – and that it's not just another box to check – you'll find it much easier to hit your training goals.

2. Create a process for accountability

Yes, it's ultimately up to each individual employee to press "submit" on their training assignments, but there's still a lot the Quality team can do to make it more likely training goals are met.

Most importantly, make sure you have a process in place for compliance check-ins and training reminders before assignments are overdue. (Sounds tedious? Well, it usually is... unless you have an eQMS that automates the reminder process and sends notifications directly to email.)

Don't forget to also set an escalation policy for non-compliance. For example, after 3 days past due, they get a personal reminder from the Quality team. After 5 days past due, perhaps the relevant department head gets notified. In extreme cases, consistent, repetitive training non-compliance may even be an HR issue.

Training is truly a non-negotiable in life sciences organizations. Regulatory bodies require it *because of* the incredible role it plays in consumer safety, so don't be afraid to hold your teams accountable.

3. Use a quality management tool to more easily track training

Measurement is a critical part of goal setting. You have to check in on your goal progress often to ensure your efforts are actually paying off. But if your training matrix is housed in an overloaded spreadsheet and/or your training data is spread across different files in multiple locations, those check-ins are easier said than done.

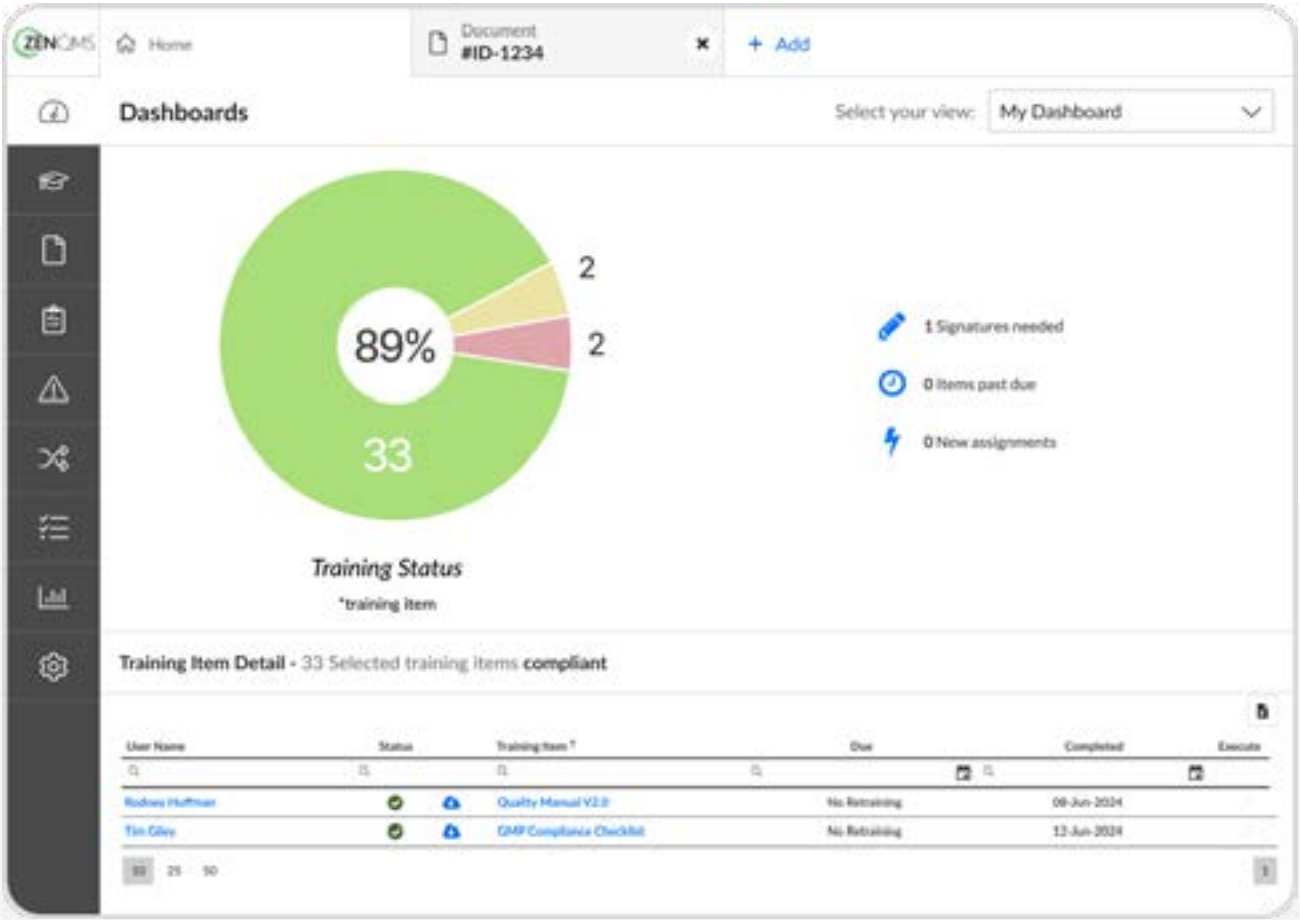
That's where an eQMS can help.

If you're struggling to meet your training goals – or simply spending too much time pulling training reports – prioritize a QMS software platform that provides easy-to-read dashboards.

For example, the ZenQMS platform allows you to pull training reports by individual, course, or group, making it easy to see who's compliant and who's behind without sifting through stacks of dossiers.

As an added bonus, these at-a-glance dashboards can actually encourage on-time training completion from your employees by putting upcoming and past-due assignments front and center immediately after login.

Another key feature to prioritize when picking a quality management software to track training? The capability to log on-the-job training. Without this feature, you're still stuck storing training information in separate locations, which defeats the purpose of moving to an eQMS all together.



An example of an easy-to-read training dashboard within the ZenQMS platform.

4. Get more in-depth training data

With better data, you can set better goals – which is why you may want to look beyond the "read and understand" training model.

To get more in-depth information and to exert more control over training, the SCORM (Sharable Content Object Reference Model) training model is a useful standard. SCORM allows you to incorporate a wider range of training content and track stats beyond "complete/not complete."

If you utilize an eQMS with SCORM capabilities, your training courses can actually include interactive videos, fill-in-the-blank responses, multiple choice selections, etc. Not only do these types of quizzes truly test a user's comprehension of the content, it also gives you data like pass/fail status, test score percentage, number of attempts made, time spent on a given assignment, and more. This kind of detailed data is invaluable for knowing if your training courses are actually working, allowing you to set more impactful improvement goals in the future.

5. Dive into the "why" behind training noncompliance

It's unlikely you'll always have a 100% on-time training completion rate, but if a significant portion of your organization is often non-compliant, it's time to figure out why. It could be they simply don't understand the importance of on-time training completion... or it could be something deeper.

This is where a training effectiveness survey could come in handy. To find the root cause of the issue, ask your employees questions like:

- Do you feel like your required training is relevant to your job?
- Are training materials clear, accurate, and easy to understand?
- How easy is it to find your required training assignments?
- Do you feel confident logging into the training management system?
- Do you receive training reminders from your supervisor?
- Do you feel you have a reasonable amount of time to complete your required training?

Based on the responses, you may find areas to improve within your training management process that could ultimately boost compliance – and help you hit your goals.

Training Management Goal Setting FAQ

What are examples of training management goals in life sciences?

Different organizations will have different training priorities (a CROs training goals will likely be different than those at a biopharma organization) but there are some common training goals many life sciences organizations may share, such as:

- **Maintain a benchmark training completion rate:** For example, "Maintain a 90% or higher training rate at all times."
- **Create an annual training material review plan:** If you don't have one already, it's important to create an annual review process for the training materials you define as "critical." This review should check if the material is still effective, if format updates are needed, if it's still relevant to your organization and the standards required, etc.
- **All staff passes training at or above a specific competency threshold:** If you're using a tool like SCORM that allows you to see training scores, set a target pass score percentage threshold.

What tools can quality management leaders use to track training?

An eLMS and eQMS are the most common tools to track training within life sciences organizations.

- **eLMS:** An eLMS (electronic learning management system) is a platform specifically designed to assign, track, and manage employee training. It automates much of the process and helps quality teams keep employees accountable and compliant.
- **eQMS:** An eQMS (electronic quality management system) typically includes all of the training management capabilities of an eLMS. The key difference is its ability to connect training to your other quality activities, keeping everything streamlined and in a single source of truth. With an eQMS, you can update SOPs, request signatures, retire old versions, assign training on the latest version, and report out on compliance all within the same platform.

What features should a training management tool have?

- **Easy-to-read dashboards:** With clear charts and dashboards, Quality leaders can see training status at a glance and pull detailed reports for stakeholders in minutes.
- **Ability to assign training by group:** Some training management platforms require you to individually assign training materials to every single employee. To save time and reduce the risk of error, look for an eQMS that allows you to assign training materials to preset employee groups.
- **SCORM capabilities:** With SCORM capabilities, Quality leaders can get a better understanding of training effectiveness and get added assurance that employees have fully absorbed the necessary knowledge for their role.

Section 4

Improve Quality Audit Management with These 6 Goals

Is "improve quality audit performance" on your list of goals this year?

If so, you're not alone. Between regulatory bodies, clients, and Sponsors, GxP-regulated life sciences organizations get audited a lot. It's understandable for Quality teams to want those audits to be as positive, smooth, and stress free as possible. But while your goal is on the right track, it's not quite specific enough to actually help you navigate a year of quality audits. (Remember, quality management goals need to follow the SMART formula.)

Instead, break your audit management improvement plan into three key target areas – preparedness, efficiency, and effectiveness – and then set specific, measurable goals for each.

Keep reading and learn:

- How to better prepare for audits, improve their efficiency, and measure their effectiveness
- Examples of quality audit management goals
- The audit goal-setting mistakes to avoid

How to better prepare for quality audits

Logically, you know the auditor is there to confirm the safety of your organization and point out areas for improvement – *not* to scare you. But that doesn't stop the process from being stressful for you and your team. It's never fun to be scrutinized, no matter how necessary it is.

To combat the inevitable audit anxiety, double down on preparation. The more your team knows about what to expect, what to do, and what to say, the more successful – and less nerve-wracking – your audits will be.

With this in mind, your audit goals should help you:

Gain a deeper understanding of your organization.

The Quality team leads the way during audits, which means they *have* to understand how the organization operates at every level. Which SMEs know what information? Why are certain processes carried out a particular way? What quality standards does each department need to meet and more importantly, how do they meet them?

Without this understanding, you'll struggle to provide auditors with the right information at the right time and potentially fail to provide evidence of compliance.

Because of this, at least one of your goals should focus on expanding your knowledge of your organization and the departments within it. For example, this might look like:

- **Audit Example Goal #1:** "Conduct in-depth discovery meetings to uncover each department's roles and responsibilities, as well as how their work aligns with regulatory requirements by the end of Q2."
- **Audit Example Goal #2:** "All Quality team members pass a training assessment covering the roles and responsibilities of each department within the organization."

Understand exactly how audits work.

Sometimes, it's fun to be surprised. An audit is not one of those times.

It's better to know what the inspector is looking for, what they expect to see, and what questions they're most likely to ask.

Thankfully, you don't need a crystal ball to predict the auditor's process. Instead, a program like ASQ's Quality Auditor Certification can help your team learn to think like an auditor. Not only is this helpful as you prepare for audits, it also sets your team up for more effective *internal* audits and vendor inspections.

In this case, the example goal could be:

- **Audit Example Goal #3:** "At least one member of the Quality department achieves a quality auditor certification by the end of the year."

How to improve quality audit efficiency

No matter how prepared your team is, if your QMS isn't organized and efficient, your audits are going to be exponentially more difficult. Hence the next audit goal focus...

Get the best audit management tools for your quality team.

Unless your Quality team enjoys pulling all-nighters to prepare for an audit, you have to invest in the right quality management tools to streamline the process. An eQMS (electronic quality management system) is usually the right way to go and can make a world of difference.

There are a lot of benefits to an eQMS, but there are a few key features that are particularly useful for quality audits:

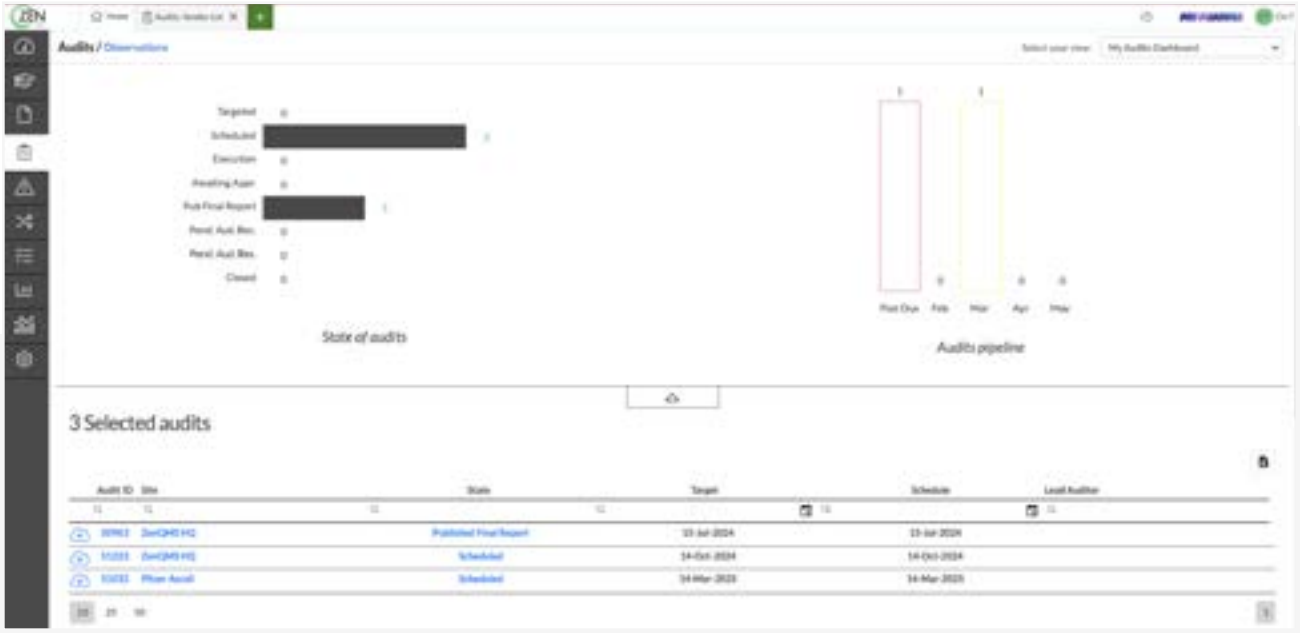
- **Documents Management:** The Documents module of an eQMS lets you store and organize all of your quality documents in one easy-to-search central hub. When the auditor asks to see a specific SOP and a complete list of its version updates, the Documents module should make it easy to find – and showcase – what you need in a matter of seconds. And that adds up. Just ask Jason Bissey, Senior Director of QA at Xerimis: "We've been able to **reduce on-site audit time by more than 50%** because we are able to provide auditors access to review documents in ZenQMS."
- **Audit Management:** An inspector may want to know when you were last audited, the results of that audit, and the steps taken to mitigate any findings. With a robust Audits module, you can track and report on that information quickly. Plus, you can keep tabs on upcoming audit due dates for all of the certifications and standards you need to maintain (such as a ISO 9001 certification).

The Audits module can also seriously improve your supplier management. For example, with the ZenQMS Audits module, you can easily see your complete vendor/supplier list at a glance, immediately pull up Q sheets for each vendor listed with just a click, and set their next inspection dates. Plus, you can create custom fields to track the vendor requirements most relevant to your organization, like GDPR compliance.

The audit goal here is simple:

- **Audit Example Goal #4:** "Evaluate and select an effective quality management tool to support audit management by the end of the year."

This may not be a flashy goal, but it is *critical* for audit readiness.



An example of the overview dashboard from the ZenQMS Audits module.

"The main quantifiable benefit is audit-readiness. I want to be able to find my records in one system, not four or five different places. I don't have to worry about that because I know ZenQMS is my single source of truth."

Kirsten Westrate,
Senior Director of QA, SQ Innovation

(P.S. Sometimes quality leaders run into pushback when they ask for the tools they need. To prep yourself for the conversation, check out these resources to prove the ROI of an eQMS and get the tools you need.)

The audit goal-setting mistake to avoid

You'll notice so far we haven't mentioned "reduce the number of quality audit observations" or "prevent recurring quality audit observations" in our list of goals.

That's because these should be *organizational* goals, not goals and KPIs that are solely the Quality department's responsibility.

It might sound counterintuitive. After all, if your QMS is effective and followed, it should mean your organization sees fewer audit observations. But don't get caught in this trap. "Followed" is the key word here. It's everyone's responsibility to learn, understand, and follow quality best practices within your organization. The Quality department can't do it alone.

More importantly, attaching your Quality team's goals (and ultimately, their measure of success) to the number of observations found actually *disincentivizes* finding areas for improvement. The objectivity of your Quality Management team could be compromised and you may miss critical opportunities for growth.

Instead, your Quality team's goals should focus on your ability to measure audit effectiveness and your overall audit efficiency, not the observation numbers themselves. Take these goals for example:

- **Audit Example Goal #5:** "Implement a data tracking tool to measure total number of observations, audit response speed, and number of recurring observations."
- **Audit Example Goal #6:** "Conduct 90% of internal and supplier audits on or before their scheduled due date."

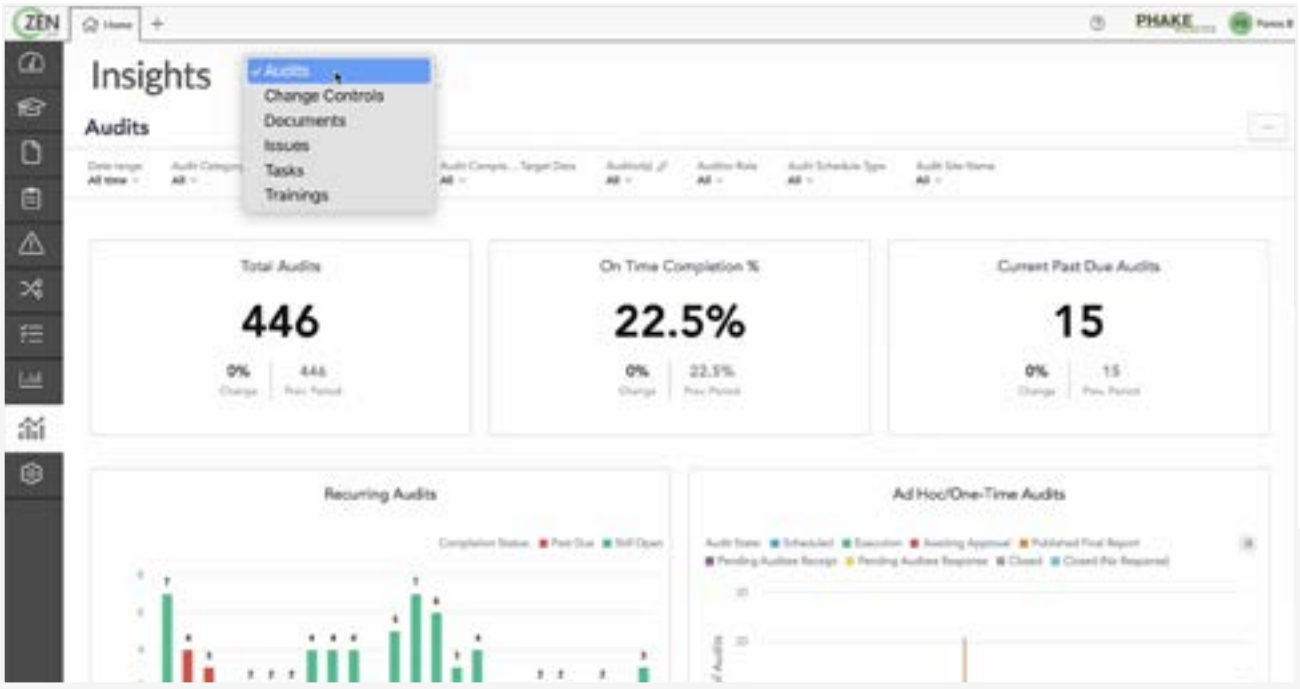
How to measure the effectiveness of your audit management

The Quality team shouldn't tie their success metrics around audit performance, but they should still be tracking this data. Some overarching organization audit goals might include:

- "Reduce the number of quality audit observations by X% compared to the previous year."
- "Reduce the number of observations around [a recurring problem area for your organization] by X% compared to the previous year."
- "Respond to all audit observations within X days."

Technically, you can track this data manually, but it's much easier if you have the right QMS software in place. An eQMS with a robust Insights module, like the one shown above, makes it possible to manage these metrics, pull reports, and set benchmarks without spending hours wading through massive spreadsheets.

If you're curious to see what other quality management data you can see with an Insights module, check out this 3-minute overview video here.



An example of the audit data that can be found in the ZenQMS Insights module.

Section 5

4 Steps to Improve Document Management + Document Control Goals for Quality Teams

Key Takeaways

- Good document management means current, error-free documents, on-time approvals, tight data security, and regular reviews.
- Key changes to approval timelines, workflows, user access rights, and periodic reviews can improve document management.
- The best document management software systems all share four critical features.

What is "good" document management?

Document management is the process of creating, storing, maintaining, and retrieving all of the documents your organization needs to function – and it's a huge piece of a Quality Manager's role. The entire document lifecycle managed by the Quality team usually includes:

- **Drafting:** Creating new documents (such as SOPs), sometimes with the help of SMEs.
- **Review/approval:** Getting the right stakeholders to review drafts and managing the document through the required approval workflows.
- **Version control:** Revising documents as necessary, tracking changes, and making sure only the most up-to-date versions are accessible.
- **Storage and distribution:** Keeping documents organized, secure, and available to the people who need them (and *only* to the people who need them).
- **Document retiring:** Archiving old/outdated documents so they're no longer in circulation, but still accessible for audit trails and regulatory inspections.

Document management takes *a lot* of time and effort, especially for GxP-regulated organizations which often have hundreds or even thousands of documents to maintain. That's a tall order for small Quality teams, and even just one missing document or inappropriate user access permission could lead to major regulatory consequences.

That's why it's so important to have a solid document management and document control foundation.

Good document control means:

- Your documents are up-to-date and error-free
- Only the most current, relevant documents are accessible
- User access is limited so only the right documents are accessible by the right people
- There are no duplicate documents
- There are no overdue document approvals or revisions

> Good document management matters – and not just to the Quality department. See how quality management can impact ROI and how to get the best QMS software for your GxP organization in this guide.

How can Quality departments improve document management?

It's not unusual to struggle with GxP document management, but there are steps Quality teams can take to improve overall document control and prevent issues before they happen.

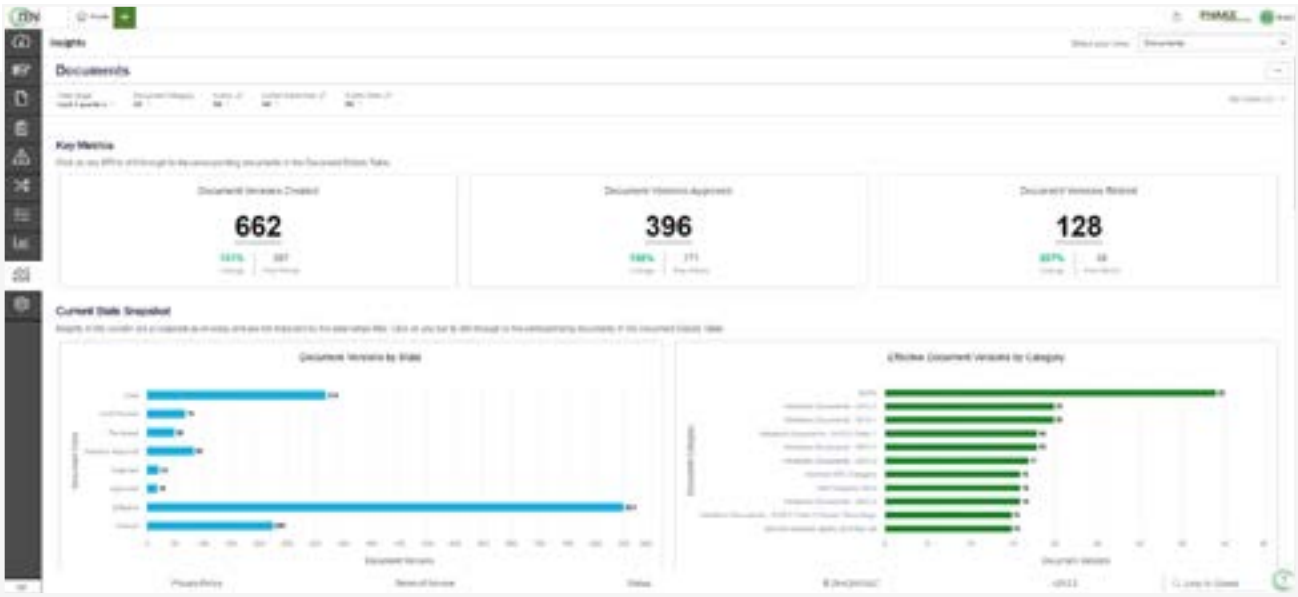
Set a standard document approval timeline

One of the simplest ways to improve document management is to introduce a clear, consistent document approval timeline. For example, a policy that states every Standard Operating Procedure (SOP) will be approved within 14 days.

Why does this matter? Documents are updated for a reason, whether to address an issue or implement a better process, and you don't want them to stay in limbo.

Delayed approval means delayed training. Delayed training means a delayed effective date. And *that* means more time for an issue to spiral out of control.

There is no industry-wide standard document approval timeline – it all depends on your organization's needs and the complexity of your workflows. A critical SOP update may require sign-offs from multiple stakeholders (e.g. Quality, Regulatory, maybe even the CEO), and therefore require a longer approval window. Smaller organizations or minor version updates may mean a workflow that only needs one or two signatures, and the approval timeline can shorten significantly.



Just a small portion of the document lifecycle data available via the Insights module in ZenQMS.

Review your document control workflows

Your document control workflows define who approves what, which steps are required for which document categories, how major and minor revisions are handled, and how to retire a document. If you haven't reviewed your workflows in a while, it's likely there's more than a few opportunities to simplify and streamline your process.

While reviewing, ask yourself:

- **Do your workflows match the needs of your document categories?** If you have one workflow that handles all document categories and all revision types, you're probably adding unnecessary complexity to your process. Use the severity of revisions, the importance of the content, and the ultimate goal of the document to inform how many steps are actually needed.
- **Do you have the right people approving the right documents?** Make sure each document category routes only to the stakeholders who truly need to sign off. Redundant or unnecessary approvals can slow things down *a lot*.

The goal here is to comply with GxP regulations while keeping things as simple as possible. Above all, your workflows should be consistent, clear, and compliant – three building blocks of good document management.

Stick to your periodic review schedule

Even the best documents need periodic review to stay relevant. Regulatory environments change, internal processes evolve, and what worked a year ago might not be the best practice now. That's why **periodic reviews are required** for GxP-regulated organizations.

But the real key is completing your periodic reviews *on time*. Quality teams have more than their fair share of deadlines to keep track of, and it's not hard for dates to accidentally slip by. This is where a good document management software comes in.

The right tool will keep track of your periodic review schedule and provide easy-to-read charts so you can see what's overdue – and *how long* it's been overdue – at a glance.

Review your user access rights

Maybe the most critical part of GxP document control is user access management. You don't want just anyone downloading, editing, or even seeing certain documents. Not only does this protect PHI and PII, it also makes sure only the most accurate, effective SOPs are referenced. Granular access controls are essential.

As part of your document management process improvement, review your user access controls by:

- **Assigning permissions carefully:** Be specific and critical when setting user access rights. For instance, someone on the lab floor may only need to view certain SOPs and not have the ability to edit or retire them.
- **Restricting downloads:** Restrict or disable downloads where possible. If it's not necessary for someone to have a local copy, don't let them download it. This makes it easier to confirm all retired documents are out of circulation and only the most up-to-date SOPs are used.
- **Conducting regular access rights audits:** Set up regular access rights audits – such as one every six months – to check that all roles and document permissions are correct. If you spot discrepancies (like an employee who has left the company but still has system access) you can correct them before the situation gets catastrophic.

Example document management goals

How do you make sure you're on the right path to improve document management?

You set goals and track KPIs, of course. Here are a few examples of document management goals your Quality Management team may want to define:

- **X% of documents approved on time:** Hold yourself – and the other departments – accountable for document approvals with a set on-time approval goal. Adjust the percentage based on your historical data and the improvement you want to see.
- **Complete X% of periodic reviews on time:** If you don't already have one, develop a system to remind your team when periodic reviews are approaching – or better yet, get a document management system (like an eQMS) that can keep track and send reminders for you.
- **Have no more than X% of periodic reviews more than 29 days past due:** Delays happen. But if you can't conduct a periodic review by the exact due date, limit how long it stays open. Setting a limit means you still catch and correct overdue documents relatively quickly.
- **Conduct a user access rights audit every 6 months:** If you don't already have a user access audit schedule in place, make it a goal to create one this year.

The best document management software for GxP organizations

No matter how well-defined workflows and goals are, Quality teams still rely on individual stakeholders to follow through. Ultimately, it's up to everyone in the organization to approve documents on time, train when necessary, and keep to established processes. That's why the right document management software can be a game changer. It helps automate, streamline, and enforce the workflows you've worked so hard to design.

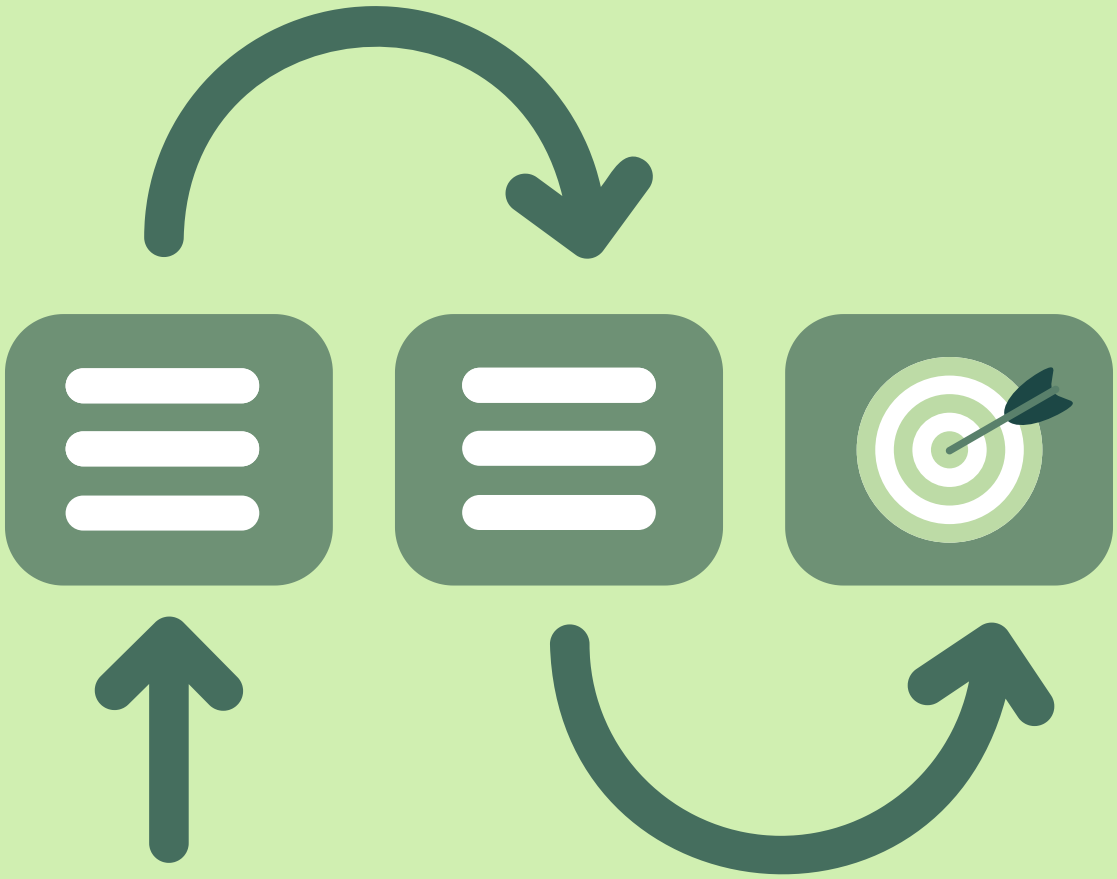
When it comes to document management software, Quality teams have options. For the most compliant, secure, and effective solution, most choose either an eDMS (electronic document management system) or an eQMS (electronic quality management system).

- **eDMS:** An eDMS is a software platform specifically for document management – and only document management. With an eDMS, you can create, revise, and store important documents like SOPs, work instructions, and training manuals, but other quality functions like training or CAPA management will need a separate system.
- **eQMS:** An eQMS is a one-stop shop for everything from document control and training records to managing audits and change controls. If your Quality department oversees anything beyond document management, you'll likely want an eQMS to help integrate your processes.

Whichever you choose, the best document management software for GxP organizations will have these features:

- **Granular Access Controls:** Not all software platforms approach access controls the same way. Pick a platform that allows you to limit access by user role, department, or even specific documents.
- **Automated Notifications:** Built-in reminders for approvals, periodic reviews, and training tasks help eliminate the human error factor. Bonus tip: Look for a system where these notifications can't simply be turned off by the end user.
- **Flexible Workflows & Document Categories:** Some platforms have preset document categories and rigid workflows. This means you have to adjust your tried-and-true processes to match the system – not ideal. Instead, find a document management tool that lets you configure categories and adapt workflows to meet your needs.
- **Insights & Reporting Capabilities:** You can only improve what you can measure, so be sure your document management software has the ability to track and report on critical data. This helps you monitor approval timelines, detect overdue reviews, and pinpoint the areas where bottlenecks are frequent.

> Not sure which quality metrics to track and report? Check out our guide to measuring the right quality management data.



Section 6

6 Goals to Help Improve Quality Issues and Change Control Management

Key Takeaways

- Learn the meaning of change controls and quality issues
- Find out which change control and quality issue resolution metrics to track for success
- See examples of quality issue and change control improvement goals
- Learn how to find the best GxP compliant issue & change control management software

What are quality issues and change controls?

Issues and change controls are usually talked about simultaneously, often because good issue management requires good change management. But issue workflows and change control workflows aren't always connected, so it's important to understand the difference.

What is an Issue in Quality Management?

Quality issues are quality deficiencies, defects, or deviations from an expected outcome. Issues get classified based on their frequency and severity, typically into categories like Critical, Major, and Minor. But no matter their severity, all issues require a root cause analysis to get to the source of the problem, a risk assessment to determine the overall impact, and a CAPA to document how the issue was corrected and the steps you're taking to prevent it in the future.

What is a Change Control in Quality Management?

A change control is the official process to request, approve, and document changes to your procedures, equipment, systems, etc.

For example, say you identify an issue with a piece of equipment no longer working the way it was intended. It turns out the equipment is outdated and out of warranty, and third-party maintenance is no longer cutting it. As a result, you find a new supplier and decide to replace your equipment with a new model.

In this instance, you'd launch a change control workflow which would document the need to replace the equipment, details on the new model selected, the procedures that would be impacted, the training needed, etc. – all with controlled signature approvals throughout.

What data should you track for quality issues and change controls?

The ultimate goal of quality issue management is simple: correct the issue and mitigate any risk of it happening again. For change controls, success means your change was applied as intended, was conducted in a timely manner, and ultimately, was effective.

But how do you *prove* the success of your issues and change controls?

It centers around tracking the right data. These are just a few examples of quality issue and change control metrics you should track:

Quality Health Metrics

These metrics help capture the overall health of quality management at your organization:

- **Number of issues logged over time:** You may think zero issues reported is a good thing, but in reality, issues will *always* appear. If you see zero new issues for a long stretch, it might signal a bigger problem (e.g. your employees don't know how to log an issue, they aren't getting logged correctly, etc.) On the other hand, if you see a surge of new issues in a short period of time, that's also cause for high-alert.
- **Severity level of issues:** Track not only the number of issues, but also their severity in order to get a true picture of the health of quality management at your organization.

Completion Time Metrics

These metrics help determine your organization's ability to hit vital quality deadlines:

- **Percentage of issues and change controls closed by the established deadline:** Track how many issues and/or change controls you close on or before the target date in your SOP.
- **Median days to complete:** Determine how long, on average, it takes to complete an issue or change control.
- **Completion time by stage:** Track on-time completion percentage for each stage of any given issue and change control. Are there stages that are consistently delayed? Your issues or change control process probably needs refining.

Effectiveness Metrics

Successful issue and change control management isn't just about being timely. These metrics help determine if your workflows are actually effective:

- **Recurrence of issues:** Recurring problems mean the underlying cause was never truly fixed. Keep tabs on whether the same issues resurface.
- **Root cause categories:** Track and categorize root causes to identify patterns. If a particular root cause keeps showing up, you know exactly where to focus improvement efforts.

Examples of Quality Management Goals for Change Controls & Issues

Once you've set up a system for tracking the right quality management metrics (see the next section for the tools that help with this), it's time to embrace the idea of continuous improvement. Here are some goals quality management leaders can set to help improve change control and issue management:

- **Goal #1:** Close X percent of issues by the established deadline.
- **Goal #2:** Reduce the recurrence rate of issues by X percent over the next year.
- **Goal #3:** Complete root cause analysis of critical issues within X days.
- **Goal #4:** Implement change controls within X days of approval.
- **Goal #5:** Have no more than X percent of over-due change controls.
- **Goal #6:** Complete post-implementation reviews of change controls within X days of completion to evaluate effectiveness.

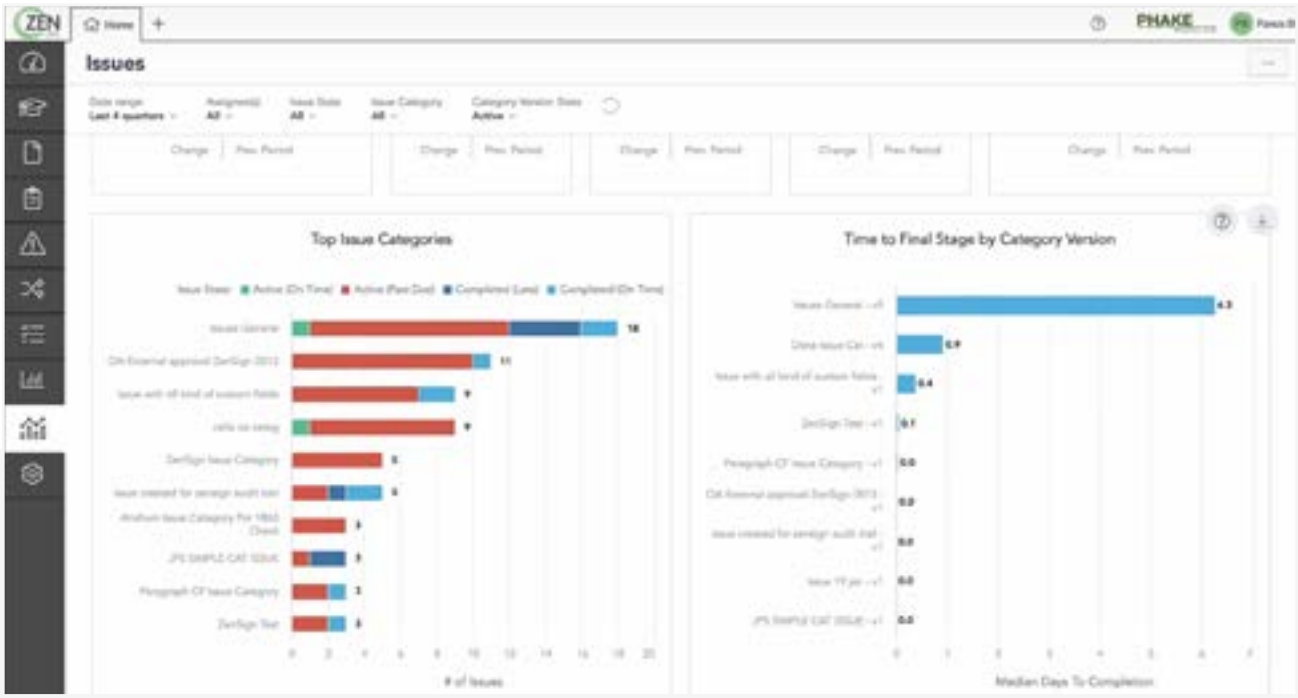
How to find the right issues and change control software

An eQMS is the standard tool for managing issues and change controls, mainly because of its ability to connect all of your workflows, documents, training requirements, etc. You can document CAPAs, initiate change controls, retire an old SOP, assign training on a new SOP, and more without ever having to leave the system.

But keep in mind, if quality issue and change control management are priorities for your organization there are a couple of features your eQMS needs to have:

- **True system configurability:** The best issues and change control software will allow you to configure your categories and stages (this is *especially* important for life sciences organizations). This allows you to still use the vocabulary and procedures you've already established. A rigid eQMS won't give you free rein to change the names, numbering systems, form components, signature requirements, etc., requiring you to adjust your process. Watch out for systems that *say* they're configurable, but really mean they're customizable for a cost. We explain the difference here.
- **Robust data tracking and insights:** You can't set good goals without good data. Choose an eQMS that provides insights reports and real-time data dashboards so you can pull the issues and change control KPIs we mentioned above. See below for an example of the kind of metrics your eQMS should provide.

There are a lot of pros to using an issue and change control management software within your organization. Not only does it make it easier on your quality management team (controlled workflows and automatic reminders are game changers), it also makes life easier for auditors – and we hear they appreciate that.



An example of the quality issues data captured in the ZenQMS Insights module which provides easy-to-read reports and dashboards.

About ZenQMS

ZenQMS is an eQMS platform that empowers Quality teams to control quality and keep their companies compliant from anywhere with less stress, less complexity, and more support.

From early stage to enterprise, over 100,000+ users trust ZenQMS.

Built by Quality leaders who believe Quality teams deserve better, simpler tools, ZenQMS is designed to be easier to use, quicker to validate, and more effective for companies of any size. Here are just a few things that make us different:

- **No seat licenses.** We don't charge by seat licenses, meaning pricing never holds your growth back. All members of your team can have access from day one.
- **Effortlessly configurable.** ZenQMS adapts to match your specific processes, operations, and quality needs. With our system, you get exactly what you need, when you need it, the way you're used to seeing it.
- **Validation made simple.** Validation is required... validation headaches are not. We don't charge for access to our validation materials and our support team guides you through the process from start to finish.
- **Easy to use. Really.** No need to retrain employees on how to use the system every time they sign in. Our dashboard allows everyone to see their compliance status at a glance, quickly find the docs and training they need, and easily complete assigned tasks – without needing an IT degree.
- **Implementation at your speed**. Need to get started ASAP? We can do that. You set the pace of implementation and our team moves to match it so quality never misses a beat.

Want to learn more about ZenQMS?

Find out what makes us different and how we can help. Reach out to hello@zenqms.com or set up a quick chat here!