Scilife

# The smart guide to eQMS selection and implementation

How to choose, validate, and implement quality management software successfully

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# A smarter, faster path to a successful eQMS rollout

Many life sciences teams know they need to move away from paper-based processes, spreadsheets, or disconnected tools.

But once the journey begins, it can quickly feel overwhelming: How do you choose the right system? What does "validation-ready" really mean? How do you migrate historical data without chaos? And how do you get your team to actually adopt the new way of working without grinding operations to a halt?

This guide is here to make the path clear.

Inside, you'll learn what to consider at every stage, from selecting the right eQMS and planning your rollout, to validation, onboarding, and long-term success.

You'll also find practical guidance to help you avoid common pitfalls and make decisions with confidence, whether you're implementing your first eQMS or upgrading from an existing system.

This content is compiled from our eQMS series, featuring insights from QMS consultants, software validation experts, and teams who have already led successful implementations.

Their real-world experience will help you understand what "good" looks like and how to get there faster, with fewer surprises.

Because when you take the right approach, an eQMS doesn't just help you stay compliant, it makes quality visible, scalable, and dramatically easier to manage.

Let's dive in.

# **Choosing the right eQMS** for you

# What is an eQMS?

Before diving into eQMS selection and the technical aspects of implementation, let's start with the fundamental question: what is an eQMS? In simple words, an eQMS is a software solution that ensures compliance with regulatory guidelines.

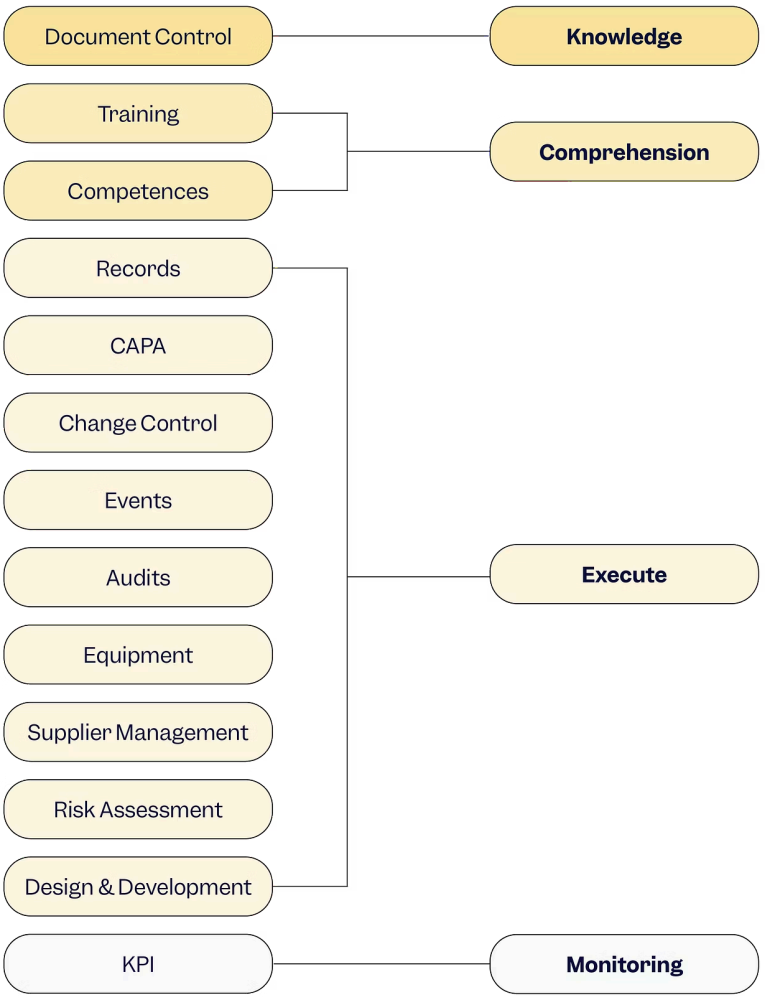
It supports the cross-distribution of data across the value chain via a communications platform that allows collaboration between various levels of the chain. Most current eQMS platforms are web-based and model their approach on core business process management methods.

Market leaders in eQMS like Scilife create software that adopts a broad set of functionalities related to quality management. This includes the range of GxP, quality risk, regulatory compliance, and auditing functionalities.

While document management is foundational, a modern eQMS orchestrates the full quality lifecycle — connecting events, investigations, corrective actions, change control, training, audits, and performance monitoring into one closed-loop system.

A robust eQMS typically manages:

**Platform Simplification**




Instead of isolated quality processes, everything is interconnected. It acts as the central hub of the quality ecosystem — integrating with platforms such as LIMS, ERP, MES, or PLM to ensure data flows seamlessly across the organization.

In this way, the eQMS becomes the operational backbone of quality, not just a repository for procedures, but the system that ensures compliance, traceability, and continuous improvement across the entire value chain.

# How to know when you need an eQMS

Life sciences companies explore eQMS solutions for many different reasons. Do any of these common triggers sound familiar to you?

Upcoming audits or inspections

Audit findings or warning letters

Product launches and market expansion

Company growth

Drive for operational efficiency and cost reduction

Strategic digital transformation initiative

## Upcoming audits or inspections

Many organizations implement an eQMS ahead of regulatory audits to centralize documentation, manage training records, and maintain audit readiness. Adopting an eQMS proactively allows companies to stay in control and take a more proactive approach, rather than reacting under regulatory pressure.

## Audit findings or warning letters

Audit findings related to CAPAs, deviations, or documentation gaps often prompt eQMS adoption. Year after year, **organizations fail to translate their written procedures into consistent daily practice and get an FDA warning letter**. By automating workflows and improving visibility, an eQMS helps organizations regain control and address systemic issues more effectively, avoiding non-compliance fines altogether.

## Product launches and market expansion

New products or expansion into additional regulatory markets increase complexity. An eQMS helps standardize processes, manage multiple regulatory frameworks, and ensure consistent training across global teams. It serves as an "engine" that turns diverse regulatory inputs into consistent, compliant outputs.

> "Implementing an eQMS ahead of an audit gives you control over the plan. Waiting for an audit finding means the plan no longer has your name on it. It has the regulator's." -
> **Rodrigo Nasif**, General Manager at Pharmware

# Company growth

As companies scale, hiring more people and opening manufacturing sites overseas, it can become really hard to manage everything with paper-based systems. Email back and forth across time zones just doesn't cut it. And when you need compliant electronic signatures, especially under 21 CFR Part 11, manual processes simply aren't enough. Training management, in particular, often becomes a risk area. Many generic HR or LMS tools are not validated for regulated environments.

# Drive for operational efficiency and cost reduction

Organizations often feel the impact of poor quality through rising costs, weak KPIs, or increased compliance risk. Digital transformation initiatives are accelerating the shift toward cloud-based, paperless quality systems that enable better data access, interoperability, and decision-making.

# Strategic digital transformation initiative

Beyond immediate cost savings, many organizations are undertaking comprehensive digital transformation to modernize their entire quality system, ensuring long-term competitiveness and future-proofing their operations. This strategic shift involves embracing advanced technologies to streamline processes, foster a culture of quality, and adapt to evolving regulatory landscapes, positioning the company for sustainable growth and innovation.

> "When you're launching a new product across multiple countries or regions — each regulated by different authorities — the complexity increases significantly. That's where an eQMS becomes the engine of your operations. It acts as a smart system that helps you process all those inputs and turn them into standardized, compliant outputs."-
> **Rodrigo Nasif**, General Manager at Pharmware

**Searching for the right eQMS?**
Save hours with clear, unbiased comparisons of features, compliance, and technical fit across top life sciences solutions.
**Go to the eQMS software comparison hub**

# What are the key factors to consider when choosing an eQMS?

**Must-have eQMS features:**

- System that complies with industry regulatory requirements
- Include modules that support key quality processes (Document Control, CAPAs, Audits and Training Management)
- Ensure data integrity and security
- Quick time-to-market
- Feature expandability and scalability
- Customizable to support your company's goals
- Cost-effective solution
- User-friendliness

- ## System that complies with industry regulatory requirements

  Ensure the eQMS aligns with the regulations and standards applicable to your products and markets — such as 21 CFR Part 11, Annex 11, GxP, ISO 13485, ICH Q10, or ISO 9001. Look for true Part 11–compliant electronic signatures, secure audit trails, traceability, and clearly defined vendor responsibilities for maintaining compliance.

- ## Include modules that support key quality processes

  Define the core quality processes you need to manage and confirm the system supports them through connected workflows, not isolated modules. Strong document control, CAPA management, audit tools, training tracking, and change management should work together to create full process visibility and traceability.

- ## Ensure data integrity and security

  Verify that the platform protects your data through role-based access controls, complete audit trails, encryption, and secure infrastructure aligned with standards like ISO 27001. Backup, restore, and disaster recovery capabilities should also be clearly defined to safeguard business continuity.

- ## Quick time-to-market

  Balance system capabilities with implementation effort. Evaluate onboarding timelines, internal resource requirements, and dependency on external consultants. The right solution should deliver value quickly without overwhelming your team or delaying operational improvements.

**QMS software vendor assessment template**
Evaluate systems against your User Requirements Specification (URS) to identify the best solution for your organization.
**Download the template**

- ## Feature expandability and scalability

  Choose a system that grows with your organization. It should support additional users, processes, and sites without requiring major reconfiguration or replacement — both technically and commercially — ensuring long-term sustainability.

- ## Customizable to support your company's goals

  Look for flexibility that allows alignment with your processes and objectives — but avoid excessive customization. Clear processes and ownership typically deliver more long-term value than heavily tailoring the software to every exception.

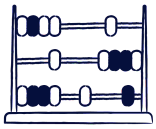
- ## Cost-effective solution

  Assess total cost of ownership, not just subscription price. Factor in validation effort, implementation support, integration needs, maintenance, and scalability to avoid unexpected costs as your organization grows.

- ## User-friendliness

  Adoption across departments is critical. An intuitive interface, logical workflows, and minimal training requirements encourage consistent usage beyond QA — driving real operational efficiency and sustained compliance.

> "I remember a case involving a company receiving a warning letter citing poor CAPA tracking and incomplete deviation records, essentially, weaknesses in their CAPA process and overall quality event management.
>
> To address the compliance gap, they decided to implement an eQMS. The goal was to automate the CAPA workflow, assign clear ownership of tasks, improve visibility across the organization, and strengthen accountability." – **Jordi Ametller, Account Executive at Scilife**.



**Calculate your potential return with Scilife using our ROI calculator**
**Calculate your ROI**

# Defining User Requirements Specifications

Start by clarifying your internal needs and translating them into User Requirement Specifications (URS) by documenting your processes, regulatory obligations, quality goals, and risk profile.

Mapping your processes helps capture real-world workflows and intended use, allowing you to define precise requirements — including documentation, validation support, and service expectations.

With a clear URS, you'll then be able to create a shortlist of eQMS vendors and issue RFIs or RFPs aligned with your timeline and specific pharma, biotech, or medical device needs.

**Key considerations include:**

- **Selection criteria:** Use your URS to define evaluation criteria such as functionality, cost, and usability, and clearly distinguish between mandatory, prioritized, and optional capabilities based on operational and regulatory needs.
- **Build requirements:** Define technical expectations from your URS, including hosting model (onsite, web-based, or cloud) and browser compatibility to align with your existing IT infrastructure.

### 1. Why create URSs?

- Ensure a common language to evaluate different vendors
- Centralize and document expectations for vendor comparison

### 2. How to create URSs?

- Define your organization's QMS needs
- Map the different intended use for both users and regulatory bodies

> "A good URS creates a common language and helps you determine whether a vendor is truly aligned with your needs, not just technically compliant.
>
> For me, creating a URS isn't about writing a shopping list. I like to compare it to baking a cake. If everyone here is baking a cake, the shopping list will look pretty similar — flour, sugar, and chocolate. Vendors already know those 'ingredients' such as key regulatory requirements like the 21 CFR Part 11.
>
> But a URS isn't the ingredient list, it's the recipe. It's where you explain how you want the cake to be made. It communicates your specific processes, your way of working, and your expectations."- **Rodrigo Nasif, General Manager at Pharmware**

**URS should explicitly cover:**

Data integrity, regulatory compliance coverage, validation support required.

**Involve CSV experts when defining URS.**

**Avoid copy-pasting generic URS templates that don't reflect real GxP risks.**

**Focus on WHAT the eQMS needs to cover instead of HOW it will do it.**

# eQMS selection process

### Smart selection strategy

- Find a trusted consultant to support the process and help find a technical partner
- Make sure you have an adequate technical supplier that can guarantee QMS success and provide the needed support
- Learn from others: Testimonials emphasize flexibility and vendor support.
- Validate vendor claims with trials or demos, and plan a vendor audit in advance.
- Understand implementation and onboarding timelines
- Involve tech-savvy team members

# Book demos with eQMS vendors

Booking demonstrations with shortlisted eQMS vendors is a critical step in the selection process.

Start by identifying the right partner — ideally with the support of a trusted consultant who can guide the evaluation and help you select an adequate technical supplier capable of guaranteeing QMS success and providing the necessary long-term support.

When scheduling demos, ensure each session is tailored to your organization's specific processes and regulatory requirements. Involve tech-savvy team members from QA, IT, and operations so they can assess functionality in depth.

**Get started with Scilife for free**
Test the platform, explore the experience, and take your first steps toward connected quality.

**Try Scilife for free**

# Evaluate an eQMS through **trials and Freemium programs**

Beyond demonstrations, validate vendor claims through hands-on trials or freemium programs. Testing the system in a real-world environment allows your team to evaluate performance, usability, and alignment with your operational needs.

Involve a selected group of users to gather structured feedback and identify potential gaps early. This stage is about understanding how the solution truly works in practice. At the same time, plan a vendor audit in advance to assess compliance posture, technical infrastructure, validation support, and overall maturity.

This is also the moment to review testimonials and speak with existing customers. Learning from others often reveals valuable insights about vendor flexibility, responsiveness, and the level of ongoing support you can expect.

> "Involve your technical experts early. Cross-functional input ensures that your requirements are realistic, robust, and aligned with operational realities. And finally, validate vendor claims through demos or trials. Not to 'test' the vendor, but to truly understand how their system works, how it's designed, and how they deliver their services. Seeing the system in action provides clarity that no slide deck can." - **Rodrigo Nasif, General Manager at Pharmware**

# Understand implementation and onboarding timelines

Before making a final decision, gain clarity on implementation scope, onboarding timelines, resource requirements, and validation effort. Understand what is included in the vendor's support model and what requires additional investment. A capable technical supplier should offer structured onboarding, clear project planning, and proactive guidance throughout deployment.

Balancing system capabilities with realistic implementation timelines ensures you achieve value quickly without overwhelming internal teams.

# Final decision: Choose your eQMS

After completing demos, trials, and vendor evaluations, assess the overall partnership — not just the software. Evaluate responsiveness, training quality, customer support, and the vendor's commitment to long-term success.

Ultimately, you need to choose an eQMS that offers a complete and tailored solution, facilitating seamless quality management and compliance. The right choice will streamline operations, mitigate risks, and support long-term success.

> You'll need to build an internal business case and secure budget approval, which means coming prepared with solid calculations and clear financial justification.
>
> But value isn't only about numbers. It also includes risk reduction, moving away from paper-based processes, improving compliance, and strengthening operational control. Those qualitative benefits are just as important when making the final decision." - **Jordi Ametller, Account Executive at Scilife**.

**Business case presentation template for eQMS implementation**
Convince your management or board that an eQMS is a strategic and worthwhile investment.
**Download your template**

# How to **migrate your quality system** to an eQMS

# eQMS migration step-by-step

One part of eQMS implementation that overwhelms many companies is transferring all legacy documents into a digital format. In this section, we'll show you that when you take a systematic approach, the process doesn't have to be stressful.

While every vendor has its own implementation approach and support model, in this section, we will focus on the best practices Scilife has developed and refined over the years.

We recommend setting goals and expectations first. For instance:

- **Identify 3–5 recurring pain points** you want the eQMS to kill first.
- **Define success metrics**, e.g., average doc cycle time < 10 business days; 95% on-time training; zero effective outdated SOPs in labs.
- **Set your "non-negotiables"**, e.g., former IDs preserved; read-only access for auditors; monthly KPI pack.

Then you'll need to identify the documents that are truly worth migrating (That obsolete SOP lying unopened for months? Probably not), classify your documents, set up accessibility, check metadata requirements, map out and configure your new system, then import the documents, reconcile and verify, and train teams on how to use the new system.

> I can assure you it's important to let go of very stringent old views and reassess where you can remain compliant, of course. Avoid replicating broken manual processes in a digital format.- **Jeroen Leemen, Software Validation Expert & Lead Auditor at QbD**

Adapting existing processes for successful system implementation

01

## Process mapping and gap analysis

Review current quality processes and map them to eQMS capabilities. Highlight improvement opportunities and remove redundancies. Avoid replicating broken manual processes in a digital format.

02

## Alignment with system architecture

Ensure processes fit within the eQMS structure (e.g., routing, approval hierarchies). Prioritize configuring eQMS for adoption and customize only when necessary, as customization can increase validation efforts, costs and complicate future upgrades.

03

## Stakeholder involvement in redesign

Engage cross-functional teams in process reengineering.

04

## Documentation and SOP updates

Revise SOPs, work instructions, and forms to reflect the new digital processes. Ensure traceability between old and new procedures.

05

## Pilot testing and feedback loop

Use controlled rollouts to test adapted processes. Gather user input for refinement before full deployment.

Let's take a look at each step of the process in detail.

## Step #1: Inventory and classification

As stated above, you can classify all of your documents based on criteria like department, availability needed, etc. You could manage this step by creating a simple tracker:

- Columns: Current ID, Title, Type (SoP/policy/record), Dept, Owner, Lifecycle (Draft/effective/obsolete), Last Reviewed, Retention Category, Must-Import? (Y/N), Former System Path/Link.
- Decision gates:
  - Import approved and in-use docs.
  - Import retention-required docs (regulatory/contractual).
  - Retire obsolete content (keep as an archive if required).
  - Create new process changes that benefit from templates and automation.

> "Don't worry about losing reference to your documents. In the import, there is a field called a former document ID, so there's an easy way to connect new documents with the old ones — you don't lose that reference." - **Juan Carlos Aller, Onboarding Project Manager**

# Step #2: Define metadata

Metadata gives context and meaning to your documents and results, so it is important to keep it always safe and make use of it. Here's an example of metadata that could be useful for your new eQMS:

### Core

Information like Document ID, Title, Type, Owner, Department, Status, Effective Date, Next Review Date, Version, Linked Processes/Products.

### Extended (custom fields)

Site/Location, Product Code, Risk Level (L/M/H), Regulatory Impact (Y/N), Former Document ID, Change Control Reference.

### Rule

If people search/filter by specific information, make it a field.

> Metadata gives context to your documents and results, so don't throw your metadata away. Scilife is very clear about helping you maintain complete traceability of your metadata and even adding extra elements where needed. - **Jeroen Leemen, Software Validation Expert & Lead Auditor at QbD**

# Step #3: Configure your eQMS

Now, it's time to configure your new eQMS so that it all aligns with legacy. For consistency, document templates can be uploaded so that docs adhere to a predefined structure and format. This will also help you manage your templates easily.

Here's an example of how we could logically configure the eQMS:

### Information architecture

Set categories, folders, and tags that mirror how people think, instead of how servers are structured off the shelf.

### Workflows

Author, Reviewer, QA, Approver, Publish; include due dates and escalations.

### Templates

SOP, WI (work instruction), Policy, Report; variables for ID, Title, Version, Effective Date, Owner, Linked Docs, Change Control.

### Groups

Start with Public (core QMS) vs. Private (design/validation/regulatory). You can always expand later, for example, per site (more on that later).

**Computer System Validation (CSV) according to GAMP 5**

**Download Handbook**

# Step #4: Migrate legacy documents into eQMS

It's show time, document importation!

There are two different ways you can import documents into Scilife, depending on the amount of documentation that needs to be imported:

### Manual import

Here, you will handle most of the effort. This is the best approach for small volumes (up to ca. 200 documents). Through the user interface, you simply click 'Import', fill in the document metadata, and click Save. It's quick, practical, and requires no support from us, meaning full autonomy.

### Assisted

As the number of documents increases, we recommend using the assisted method. Instead of entering data one by one, you complete a structured Excel template. We validate and process this to minimize errors and speed up the import. This method is optimized for bulk uploads of 2000–10000+ documents.

> One big best practice is to keep it simple. Work with the system, not against it, because if you try to bring your old ways exactly as they were, you're most likely going to face conflicts due to how each system works.
>
> Take advantage of Scilife's functionality — we have tags, folders, and ways to connect documents to products, services, and contacts. There are many ways to structure your documentation easily, so take advantage of what the system is offering you." - **Juan Carlos Aller, Onboarding Project Manager**

# The PIV framework (Preparation, Import, Validation)

To go about importing all of your documents, we use the PIV framework (preparation, import, validation):

## Import preparation

- **Train up with Scilife Academy** (Core course + Document Control).
- Try before you fly in a test environment, like a "flight simulator".
- Get materials ready:
  - Manual: Simply organize your files.
  - Assisted: Fill the Excel template (we give you a 16-page guide + a 45-minute video), and share a .zip with us.

## Import

- Dry runs (assisted only): Like a "dress rehearsal." We process your materials end-to-end without touching production, return a report, you tweak, and we repeat. Most teams nail it in ca. 3 iterations.
- Final import: After sign-off, the production import typically takes 3–5 days, depending on volume and data cleanliness.

## Validation

- We validate; you validate: Many teams use a statistical sampling approach (e.g., review ca. 278 of 1000 docs. But we advise you to follow a validation approach based on your risk assessment. We ask you to hold off on making changes in production until validation is complete. Fixes are much faster that way.
- Proof of import: You'll receive an import evidence document signed by our QA manager for your records.

## Best practices

IMPORT PREPARATION

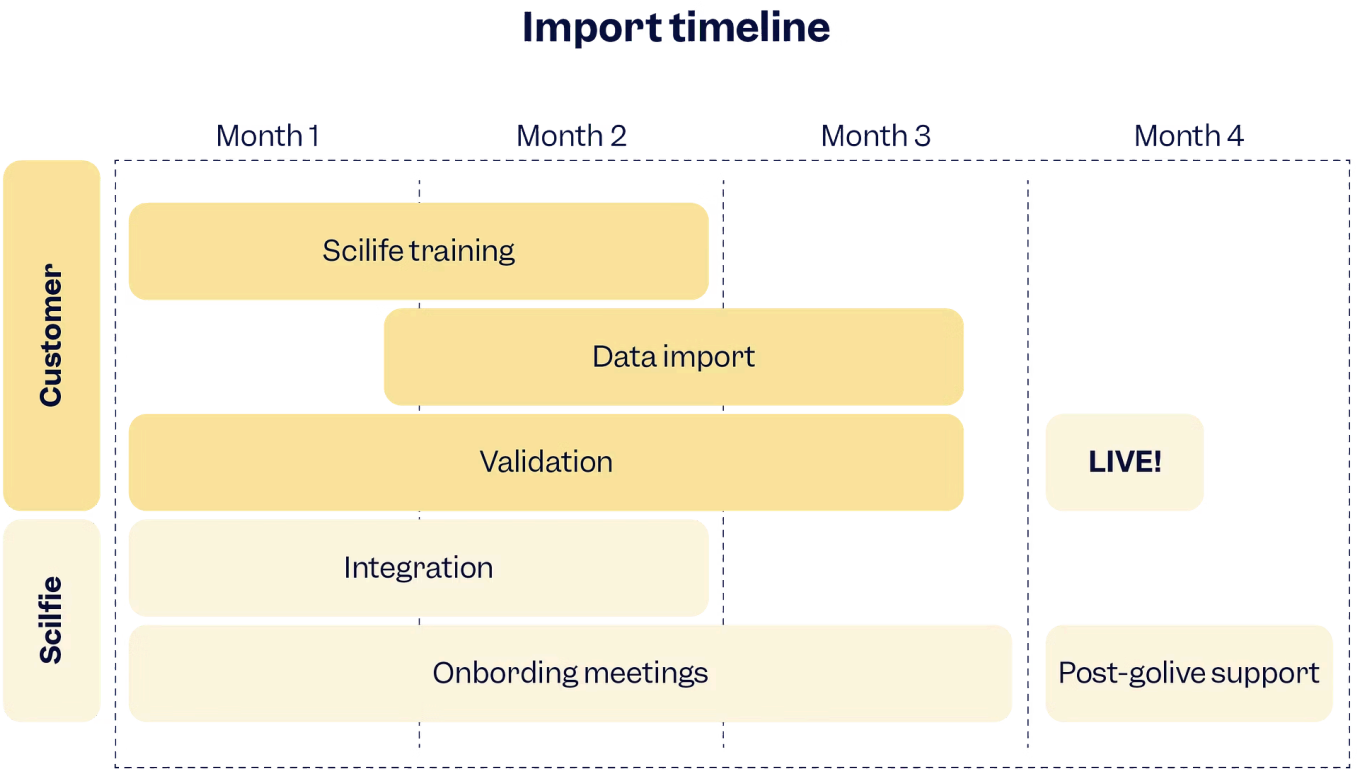
1. Keep it simple
2. Work with the system, not against it
3. Document organization before import
4. Don't rush

IMPORT WINDOW

1. Have a clear owner of the import material delivery (Import Lead)
2. Attention to details is key
3. Don't assume, ask questions

IMPORT VALIDATION

1. No changes in production before import validation is complete
2. Import validation before system validation
3. Validation approach based on your risk assessment




# Step #5: Review and reconcile

As stated by the PIV method above, after we assist you with your upload, we will run the scripts to import everything you require and start a review cycle of the uploaded documents so that we are sure that we are still accurate and complete.

ALCOA+ is integrated into Scilife's eQMS. So here we verify that your documents are unaltered. And at that point, we also confirm metadata, version history, document approvals, etc, to make sure we applied everything correctly.

- Spot-check metadata correctness, version history, approvals present, and links resolve.
- Confirm controlled copy rules (print watermarks, download permissions).

After all is reviewed and approved, it is time to train your teams.

# Step #6: Training and onboarding

It is now time to train the team on how to use their new system, and how it will affect their new daily workflows, new roles and responsibilities per user group, etc. There will, of course, be a structured training program that includes:

Role-based sessions, e.g., read-only vs. full users.

Step-by-step guides with videos, screenshots, and other resources.

Real case demos, e.g., how to author a doc, route it, approve it, and train on it.

There will also be micro-demo videos (2–3 min) embedded in your internal SOPs.

QA should be trained first, followed by other teams. Our onboarding managers will be there to answer any questions you may have, catch red flags, and guide big business decisions.

You will also have access to the **Scilife Academy** to acquire more certification courses by role and module, backed by knowledge-based articles, templates, and live sessions.

# How medical device company Subiton successfully migrated 1,500 legacy documents in 60 days

# Subiton's back story and challenges

When Subiton approached Scilife in late 2023, they were struggling with a paper-based quality system that involved manually stamping controlled documents, maintaining cumbersome logbooks, fragmented audit trails, and complex tracking procedures.

These manual processes caused substantial operational stress and regulatory pressure, particularly during audits.

Subiton identified several critical challenges during the early stages of their eQMS implementation, including:

- Resistance from the team due to concerns over added bureaucracy
- Complexities around migrating and standardizing legacy documents
- Defining clear metadata and document coding systems
- Effectively managing user access

To overcome these issues, we helped Subiton take a strategic approach to implementing its eQMS.

> "At the beginning, the people were frightened, or maybe concerned that this change would bring more bureaucracy into the process.
>
> But in practice, the opposite happened. We saw greater engagement from people in the system, and this led to quicker and better document updates.
>
> Today, we have 2,500 documents in the system — so we've added 1,000 more since the initial import phase." - **Santiago Ibañez, Head of Quality Assurance at Subiton.**

# Subiton's migration plan

Here's an overview of how their migration plan went:

- They needed to move **ca. 1500 documents in 2 months** with low resources.
- They also needed to **adapt existing processes** (especially document control and change control) to the capabilities of the eQMS.
- Initially, they were a bit **concerned about the added bureaucracy.**

## How they rewired their documentation system

To start the transition, they came up with a new document coding system:

- 2 letters for the document type
- 2 letters for the responsible sector
- They created IDs for design, validation, and regulatory documents

For legacy traceability, they kept former document IDs in the system so users can search by new or old ID. They also enabled admin roles to import missing docs and delete or replace when needed.

For templates and formatting, they did the following:

- They created templates for core QMS docs with locked sections to prevent unauthorized edits.
- They approached the import in phases, importing legacy docs as they were, then applied new templates when documents were updated.
- Later on, they created more complex templates for design, validation, and regulatory docs.

They initially disabled periodic reviews to avoid reviewing 100% overnight and later enabled them gradually as documents changed. This feature is now key for keeping documents current.

> "When making the switch to an eQMS, it's the perfect opportunity for customers to continue doing what works well and to streamline what doesn't.
>
> Here at Scilife, we collaborate closely with customers to guide them in setting up a system that truly works for them. This enables them to focus on the core aspects of their roles, while allowing the system to handle those routine, repetitive tasks." - **Catherine Kolar, Onboarding Project Manager at Scilife**

## Metadata, custom fields, control copies, and audit trails

To manage their metadata, they created fields for product types, product codes, and company areas. They used parent–child links to relate forms with parent documents or processes to boost searchability and auto-populate templates.

- They moved away from stamps and manual logs, leaving the system to manage copies end-to-end.
- They enabled audit trails across documents, CAPA, change control, etc., to gain visibility over who printed, downloaded, or changed and investigate history.

## Roles, groups, and access model

To manage access controls, they split users into two categories: read-only and full users.

- When it comes to document visibility, they classified docs as public (e.g., core QMS) vs private (e.g., design/regulatory/validation).
- They created two main groups: Public and private, and assigned items and users accordingly.

## Training rollout and adoption

Santiago's team trained first with the onboarding project manager, using the Scilife Knowledge Base and Scilife Academy to build deep system understanding. Then, they ran company-wide trainings and trained ca. 70 people over 2 weeks.

- They had separate training paths for read-only vs full users.
- They also included platform demonstrations and tests to document compliance.
- Ongoing training and support continued to run to drive adoption and proper use.

> The audit trail in Scilife is a very powerful tool, and we usually use it to investigate the history of that element or item in the system. It's not just documents, but every element in the system has its own audit trail — change controls, CAPAs, etc.
>
> It's very useful in your daily work because you have the opportunity to look into the audit trail and search for everything that has happened there. If you want to see who printed or downloaded a document, what happened to it, whether it was removed from a change control, all of that is captured. - **Santiago Ibañez, Head of Quality Assurance at Subiton.**

## Subiton results

**Automating previously manual tasks eliminated repetitive work**, significantly reduced errors, and freed up valuable time for higher-impact activities.

**Instant access to critical data** — including open CAPAs — replaced hours of searching through paper files, dramatically boosting audit readiness and productivity.

**Audit preparation timelines were shortened**, and change request reviews and approvals moved faster than ever, accelerating overall quality operations.

**Employee satisfaction increased substantially**, fueled by intuitive workflows and a streamlined user experience that made quality processes easier to manage.

Subiton's journey proves that a well-executed eQMS migration with Scilife delivers real operational impact, from efficiency gains to stronger compliance!

# **Setting up** your digital QMS

# How to use your new eQMS effectively

There are a few practicalities you need to get right to use your new eQMS effectively. Let's dive into the key aspects below.

## Document structure and metadata

Document structure in an eQMS starts with metadata. Although metadata can seem overwhelming, it is simply the information captured along the way:

- Document IDs
- Effective dates
- Training dates
- Owners
- Tags, etc.

Using it in templates and folder structures makes documents searchable, traceable, and easier to manage.

Legacy IDs can be preserved, mapping them into a dedicated field so compliance continuity is never lost, or even creating custom ones to capture additional details like product codes, departments, or regulatory categories.

> An initial concern for many of our customers who switch from paper to electronic systems, especially those looking to simplify and scale their structure, is how to meet regulatory requirements to retain their old document IDs while implementing a new, streamlined ID structure.
>
> Scilife already has that covered. We even map it for you. When importing a document, whether manually or with assistance, you simply provide the former document ID, and it is automatically associated with the document in its own dedicated column on our document listing page. - **Catherine Kolar, Onboarding Project Manager at Scilife.**

## E-signatures

E-signatures in Scilife are fully compliant with 21 CFR Part 11 and Annex 11. Each signature is unique to the user, requires re-authentication at signing, and is permanently bound to the document.

Once signed, records cannot be altered without triggering re-signing, ensuring authenticity and integrity while meeting strict regulatory requirements.

## Audit trails

Audit trails provide full visibility, tracking who did what, when, and to which document or record, whether it's a CAPA, a change control, or a training item. Logs capture everything from edits and approvals to print and download actions.

Trails are immutable, always active, human-readable, and exportable for audits, making it easy to prove compliance and investigate issues.

> Sometimes an audit trail can feel overwhelming because, technically speaking, it is a log. But once we can search within those logs, we can extract a very specific part of the log — and that effectively becomes its own trail, which makes document review much easier.
>
> An audit trail also needs to be exportable and printable. And it needs to be — not preferably, but as a requirement from the regulatory authorities — in a human-readable format. - **Jeroen Leemen, Software Validation Expert & Lead Auditor at QbD**

## Setting user roles and access control

User roles and access control are critical for protecting content in an eQMS, ensuring only people with a justified need can view or edit documents.

Scilife applies role-based access control, ensuring rights are based on job responsibilities.

Roles can be assigned at different levels:

- Modules
- Document types
- Events
- Entities

Users inherit permissions from their roles, and some may hold more than one role if they work across departments. For example, someone in both Chemistry and Microbiology can be part of both groups.

Workflow-specific roles, such as author, reviewer, or approver, are also clearly defined to maintain accountability.

Scilife supports two main user types:

- Full users can create, edit, and participate in workflows.
- Read-only users can view content and complete training.

Full users can be administrators, managers, or regular users, with additional permissions like QA authority or training coordinator assigned as needed. Managers also get visibility into their team's outstanding tasks, ensuring nothing slips through the cracks.

You can also set groups. Users can only interact with documents belonging to the group they're a part of.

Content can be set up as public (core QMS documents, visible to all) or private (sensitive design, validation, or regulatory documents). This structure keeps information secure while giving teams the right level of access to do their work efficiently.

## Archiving and retention policies

Archiving and retention policies are a big chapter in the GAMP guidelines, and have their own appendix. Archiving is a process of moving records and data from the computerized system to a different location or system, often protecting them against further changes.

Archived records should be readily retrievable for business or regulatory purposes.

Use of cloud storage solutions for archived records is acceptable, and archiving and retrieval should not be confused with backup and restore, as this is really a separate process.

Your new eQMS can be configured to retain archived data for a mandated period in alignment with regulatory and business continuity requirements. Archived data, along with its metadata, is protected against unauthorized changes throughout retention periods.

Archived documents remain searchable and accessible to authorized users. And the eQMS differentiates between active, archived, and obsolete documents.

## Integrations

By connecting your eQMS to systems like ERP, CRM, or training platforms, you ensure that all relevant data for audits and regulatory reporting is automatically captured and easily traceable. This proactive approach simplifies compliance efforts and reduces audit readiness burden.

# All you need to know about **eQMS validation**

# When does a SaaS eQMS need to be validated?

The first thing to consider about SaaS eQMS validation is which applicable regulations and standards apply to a company. This is important to revisit regularly, especially for startups or rapidly growing organizations, because regulations can change and new eQMS validation requirements can become relevant over time.

Examples include requirements associated with laboratory, clinical, manufacturing, and distribution practices, medical device requirements, and privacy considerations.

Once the regulatory context is understood, a good practice is to create and perform a criticality assessment. A criticality assessment functions like a basic questionnaire to list the standards and requirements that could impact the selection and implementation of the system.

It helps clarify which regulations are in scope for the system and how the system needs to reflect those requirements. The end result of that assessment helps determine whether validation is required and, if it is, what level of effort is appropriate.

> I would advise every company to perform a criticality assessment for any system where regulations and standards may apply.
>
> SaaS solutions are preferred over building a system yourself because, from a GAMP perspective, the higher the category, the more validation work you will have. If you build and host your own system, you move into a higher category and significantly increase your validation effort. - **Yves Dène, Senior CSV Specialist**

| Scilife | Customer |
| --- | --- |
| _ Validates the platform using a GAMP 5/CSV approach on AWS.<br>_ Tests standard workflows in an environment separate from customer instances.<br>_ Provides a signed validation package plus release notes and change documentation.<br>_ Maintains a validated state | _ Ensures their validation methodology explicitly supports SaaS.<br>_ Qualifies Scilife as a supplier using the documentation provided.<br>_ Defines intended use and documents configuration with verification evidence.<br>_ Updates SOPs/work instructions, trains users, goes live, and closes the change request. |

The same steps are repeated for new features or when the customer changes configuration.

# How to determine if newly acquired **Software as a Service needs** to be validated

Know your applicable predicate rules and standards to be adhered to (e.g. GxP, Data Privacy, ISO standards) keeping in mind changing business scope and new/updated requirements

Perform a Criticality Assessment

Key assessment questions include:

- Identifying applicable regulations
- Determining which regulation sections are in scope of new system processes,
- Understanding specific requirements for system reflection

Determine need for validation depending on outcome assessment

# Regulatory expectations for SaaS eQMS validation

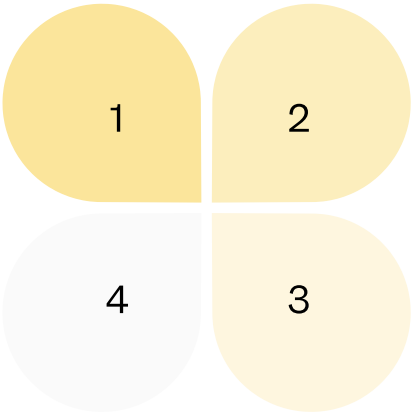
Auditors and inspectors do not expect a single rigid validation methodology. Instead, they look for a structured, risk-based validation approach that demonstrates control over the system throughout its lifecycle.

**Key expectations include:**

- **Risk-based validation, lifecycle approach:** validation activities should be scaled according to risk. Higher-risk functionality requires more controls and testing, while lower-risk areas require less. Validation must continue after go-live.
- **Clear ownership of responsibilities:** In a SaaS model, responsibilities are shared. Vendors manage infrastructure and core platform elements; customers validate intended use, configuration, and processes.
- **Supplier oversight and vendor qualification:** organizations must assess and **qualify SaaS vendors**, ensuring they are capable of supporting regulated use through appropriate documentation, transparency, and contractual controls.
- **Objective evidence of control, including:** Documented intended use, Defined user requirements, A risk assessment appropriate to the system and its use, Testing evidence showing the system performs as required, Change control records for vendor releases and internal changes
- **Ongoing validation, not "validated once":** because SaaS platforms evolve, validation cannot be a one-time exercise. All vendor releases and internal configuration changes must be assessed for impact. Also, avoid retrospective validation at all costs.

# Maintaining the validate state

Validation is a continuous activity




Consider configuration changes versus vendor releases

Emergency changes allow action before documentation completion with quality department approval

Change control must specify levels of change corresponding to vendor minor/intermediate/major release terminology

# How to validate and implement an eQMS SaaS: eQMS validation best practices

Now, let's talk eQMS validation best practices. A practical SaaS eQMS validation approach typically includes:

## 1 Vendor and platform assessment

- Evaluate the vendor's development, testing, and compliance practices
- Perform a risk assessment based on your intended use
- Leverage vendor IQ/OQ documentation where appropriate

## 2 Planning and documentation

- Master Validation Plan (scope, responsibilities, strategy)
- User Requirements Specification (URS)
- Risk-based validation approach rationale

## 3 Execution and testing

- Performance Qualification (PQ) / User Acceptance Testing (UAT)
- Verification of workflows, roles, and configurations
- Data integrity checks

## 4 Analysis and reporting

- Document test results and deviations
- Produce a validation summary confirming fitness for use

## 5 How to stay validated with SaaS releases change control

- Manage releases, incidents, backups, and ongoing monitoring

> "Ongoing validation requires a validation methodology, structured change control, and robust IT infrastructure procedures."- **Yves Dène, Senior CSV Specialist**

# Validation for startups or paper-based teams implementing SaaS

For organizations implementing an eQMS for the first time, validation should start with process clarity.

Not all quality processes must be automated at once. Teams should first decide which processes belong in the eQMS and define user requirements based on those processes. These requirements form the foundation of validation.

Cross-functional involvement is essential. Stakeholders may include quality, operations, production, and other departments, depending on system use. Mapping current and future workflows early helps prevent late changes and validation rework.

Off-the-shelf SaaS solutions are generally preferred over custom-built systems, as customization significantly increases validation effort and risk.

> "Never forget: many teams are startups, regulations change, and new requirements can become relevant over time. You have to stay up to date."- **Yves Dène, Senior CSV Specialist**

# How to validate an eQMS in a SaaS model with existing validation methodology

For organizations with established internal validation practices, the key is ensuring that their validation methodology, policies, procedures, templates, and overall approach explicitly support SaaS models.

As seen above, a critical difference in SaaS is that the infrastructure and part of the software lifecycle are managed by the vendor. However, the customer still must ensure these meet regulatory expectations, and everything must be documented.

Supplier qualification becomes especially important. Vendors should demonstrate compliance maturity and provide documentation that customers can leverage, not recreate.

# Shared responsibility in SaaS eQMS validation

No vendor can deliver a "100% validated system". As stated above, SaaS eQMS validation requires objective evidence that software specifications conform to user needs and intended use.

These are never the same across companies.

Even with the same platform, organizations may have different document types, CAPA categories, and configurations. Because of that, customers must be able to demonstrate that the system is validated for their specific use.

## Vendors promising **100% validated systems**

- Be careful with 100% validation statements, do they understand compliance? False sales argument?
- Creates wrong customer expectations
- Validation for "OWN INTENDED USE" is mandatory!
- Pre-validated system is better terminology
- Up to 95% of validation effort/deliverables can be provided by vendor

The FDA's definition of computer software validation (CSV) is establishing, by objective evidence, that software specifications conform to user needs and intenged uses, and that the software consistently fulfills those requirements

> "We tell our customers and prospects that with the proper leveraging of our validation package, Scilife is 95% validated, leaving just 5% of the burden on them. Of course, customers are responsible for validating their intended use and this can vary slightly depending on the level of configuration and integration needed" - **Catherine Kolar, Onboarding Project Manager**

# SaaS eQMS validation of the Scilife platform: GAMP 5 and Computer System Validation

Scilife uses a GAMP 5 and Computer System Validation approach for validating the system on the Amazon Web Services (AWS) platform.

As part of the validation phase, the Scilife platform is validated for, e.g., standard functionality and workflows in an environment independent of customers. This validated environment for standard functionalities and workflows can be used as-is by our customers if their business process is aligned with the Scilife platform default workflow.

Our validation package includes a drafted, executed, and signed-off validation documentation set that customers can use as the basis for the validation of Scilife on their end. All showcased options are risk-based approaches.

This document effectively eliminates most of the costs and resources needed for validation by our customers.

**Comparing eQMS options?**

**Try one for free**

# Scilife's customer validation package

1

### Validation Plan

This plan outlines the validation approach, activities, responsibilities, and deliverables for validating the Scilife platform.

2

### User Requirement Specifications (URS)

The **URS identifies end-user requirements for the system**. This document defines what the system should do to satisfy business needs and how the system should function to comply with all applicable regulations.

3

### Risk Analysis

This document is directly related to the URS document. It is important to identify and mitigate risks that come with the various URS items. Each URS item is analyzed to identify potential risks that specific functionality may pose from a GxP or a business requirement perspective. Once identified, these risks are classified according to their severity and probability, after which mitigation of the risks is described to assign a risk priority.

4

### Configuration Specifications (CS)

The CS contains configuration requirements in terms of preconfigured settings in the system. The objective here is to explain the configuration options of the Scilife platform and to document the details of user roles and their permissions/accessibility.

5

### Test Plan

The Test Plan lists the procedures needed to verify the proper installation, configuration, and operation of this platform in the validation and production environments.

6

### Installation and Operational Qualification (IO/OQ)

IQ/OQ provides assurance that the application and its supporting infrastructure have been correctly installed and configured, and that the complete integrated system functions as specified before executing the Performance Qualification.

7

### Performance Qualification

This test evaluates the application by users in conjunction with their knowledge of the business processes required to perform certain tasks. It involves the execution and documentation of specific tests designed to demonstrate that the application performs as expected and meets the users' specified requirements.

8

### Traceability Matrix

This tool ultimately ensures that all specified requirements are met. The matrix establishes the relationship between requirements and testing activities that demonstrate the requirement is satisfied. It also provides a cross-reference between requirements and procedures or external controls to satisfy a specific requirement.

9

### Test Summary report

This report summarizes the activities that verify the testing process/test results for the Installation Qualification, Operational, and Performance Qualification testing.

10

### Validation Summary report

This document summarizes the results of all activities and the status of the deliverables identified in the Validation Plan. It helps to determine if the Scilife platform was properly implemented according to the predefined specifications and operates as intended.

## Initial implementation approach for customers

- Initiate a change request to explain the change from a manual to an electronic process using the Scilife SaaS platform, along with the reason, impact, and risk assessment.
- Document the configuration changes you plan to do in your system, along with how you will verify those configuration changes. Attach verification screens with the change request.
- Develop any SOPs/WIs where applicable as per your business for all different modules, or simply refer to the Scilife Knowledge Base.
- Go live in the production environment.
- Close the change request.

After going live, all changes to the customer environment will be driven by the change management process to ensure that all changes to the customer environment are documented.

## Managing SaaS releases and staying validated

How to handle various releases from Scilife:

- **Minor releases/Hot fixes:** Since minor releases do not involve any change in features and processes, no additional effort is required from customers. Customers can review the change request and the release notes provided by Scilife to understand the minimum changes released. If customers identify any change that impacts configurations they have already carried out, then they can follow the process as documented below for Major and Medium releases.
- **Major/Medium releases:** Initiate change requests to document the impact of changes released on current configurations. If the new release has an impact, document the configuration changes you plan to do in your system, along with how you will verify those configuration changes. Attach verification screens with the change request.
- Update any SOP/WI if the new release has an impact on these documents.
- Close change request.

The Scilife SaaS platform is maintained in a validated state by ensuring these listed procedures are followed:

- Operational and maintenance SOPs/policies/WIs
- Change management information
- Incident management
- Disaster recovery
- Data backup and recovery
- Personnel (including qualifications and training)

# Common mistakes in SaaS eQMS validation

1. Planning issues and scope creep
2. Relying on vendor suggested User Requirements only
3. Discrepancy between system configuration and desired process
4. Inadequate risk assessment
5. Too limited acceptance testing effort
6. Poor migration preparation
7. Incorrect, missing and/or late procedural documents

> "Choose your vendor wisely, and qualify your vendor. In pharma and medical devices, a vendor must understand their customers and must know compliance — I can assure you, I've done many supplier audits.
>
> If they don't, they won't be able to give you the necessary confidence in how they work, how they develop, and how they safeguard their SaaS.
>
> And from that perspective, it's essential to have a quality service level agreement — an SLA and/or contracts — that meets all your requirements."- **Yves Dène, Senior CSV Specialist**

# What **eQMS implementation** really looks like

# How to make sure your eQMS implementation goes right

Here are a few top tips from our onboarding team:

- **Ensure key internal end users are included in the sales process**. This includes: Head of QA, Other people who aid in choosing eQMS
- **Have a clear idea about**:
  - Why you need an eQMS and which outcomes you would like to see internally,
  - What processes and documentation will you move to the new system,
  - How will you measure the success of this change
- **Pick a Scilife plan that fits** the time you currently have
- **Ensure you have the internal resources** to dedicate to the implementation of a new system

> "After personally onboarding nearly a hundred customers here at Scilife, I can tell you that the most common challenges aren't usually technical; they're organizational. Gaining internal acceptance outside of the quality department is often the biggest hurdle.
>
> Many teams also feel overwhelmed at the start, unsure of where to begin. There's the initial learning curve, adapting internal processes to fit a new eQMS, deciding who should be involved in onboarding, and determining how much time to realistically dedicate to it." - **Catherine Kolar, Onboarding Project Manager at Scilife**

# You bought an eQMS... now what?

## 1. Start with Document Control

Almost all Scilife customers begin their eQMS journey with Document Control, and for good reason. Document Control is the foundation of the system. Its workflows mirror the logic used across other modules, making it the ideal starting point and significantly reducing the learning curve for future implementations. Once your documents are structured and controlled, you're only a few decisions away from activating related processes such as Training. It also provides the framework for report templates and structured workflows that later support modules like CAPA, Events, and Change Control.

> While the package you end up going for will have multiple modules, 99% of all of our customers start their journey by implementing document control. In fact, we encourage them to. Its workflow mirrors the logic used across other modules, which significantly reduces the learning curve later on. More importantly, it lays the foundation for success when implementing additional tools within the system." - **Catherine Kolar, Onboarding Project Manager at Scilife**

## 2. Go for a phased implementation approach

Implementing an entire eQMS at once can overwhelm teams and strain resources. A phased approach allows organizations to roll out modules step by step, aligning implementation with internal capacity and business priorities. This approach increases user acceptance, supports better resource management, and allows lessons learned from early modules to improve later ones. Rather than extending effort, phasing often reduces total workload by improving efficiency over time. It also allows organizations to prioritize modules based on strategic needs.

## 3. Leverage the test environment

A dedicated test environment is a powerful advantage during implementation. It allows teams to experiment, configure, and plan future modules while already operating live in production with others. This means onboarding doesn't need to be linear or restrictive. Teams can validate processes, test workflows, and prepare upcoming phases without disrupting daily operations. It supports smarter planning and smoother rollouts.

## 4. Customer Success adoption plans and follow-up

Onboarding doesn't end once Document Control goes live. A structured adoption plan ensures your implementation roadmap continues to align with evolving business needs. The most successful organizations treat implementation as a collaborative, cross-functional project. Core teams define processes, while reference users provide feedback. With continued support and phased planning, each new module builds on the last, driving stronger adoption and long-term success.

> "Onboarding isn't the end of the journey. We don't simply go live with Document Control and step away. We continue working alongside you to ensure your evolving business needs stay aligned with your implementation roadmap, supporting you every step of the way." - **Trine Michelson, VP of Customer Success**

## 5. Set expectations, needs, and goals for the first year

Clear internal alignment is critical. Define early on what success looks like, which modules will be prioritized, and how progress will be measured. When organizations think through their processes and requirements upfront, they naturally create a roadmap for phased implementation. This clarity improves decision-making, strengthens user buy-in, and ensures that the eQMS evolves in step with business growth.

# Scilife support and resources

At Scilife, we provide you with the following support and resources:

## Scilife Academy

Scilife Academy provides structured, step-by-step training per module and user type. Administrators complete certification training during onboarding, while end users can begin learning early by pairing Academy content with internal SOPs. It also includes expert-led sessions on broader quality topics like data integrity and CSV.

## Knowledge Base

The Knowledge Base offers clear, step-by-step guidance and best practices for using the platform. It can also be leveraged when drafting internal procedures and work instructions, helping teams align system use with documented processes.

## Deep Dives

Deep Dive webinars focus on practical use cases and optimal configuration of each module. Led by Customer Success experts, they help teams understand not just how the system works but how to use it effectively.

## Test environment

Each customer receives a dedicated test environment to configure, experiment, and plan future modules safely. It allows teams to validate decisions without impacting the live system.

## Guided checklists

Guided checklists structure onboarding activities, highlight key discussion points, and ensure important business decisions are documented — keeping implementation organized and aligned.

> "What would you like to do next? What are your expectations and business needs? That's how we continue to support you through the next phase.
>
> We make sure you receive the right support, the right content, and even tailored Deep Dives based on what you tell us you need. It's an ongoing partnership, not a one-time implementation." - **Trine Michelson, VP of Customer Success**

# How CCRM Nordic took on a phased eQMS approach, driving adoption and efficiency

When CCRM began establishing both its GMP facilities and its GMP Quality Management System, the question wasn't whether to implement an eQMS — it was how to build quality the right way from the start.

## Defining requirements before choosing a vendor

Although vendors often offer templates and pre-built requirement specifications, CCRM prioritized developing its own User Requirement Specification (URS).

The team carefully defined:

- Which quality processes needed to be supported
- Whether integration with ERP or manufacturing systems was required
- What their organizational priorities were
- What measurable improvements they expected to achieve

A small, QA-led team initially screened potential suppliers.

After narrowing down options, they presented a structured comparison, including pros, cons, and expected advantages, to executive leadership. The final decision to adopt Scilife was made by management, backed by a clear business case and strategic alignment.

> "By implementing in phases, we were able to adjust the onboarding team as we progressed.
>
> The core team remained consistent, but the end users and reference group evolved depending on the module we were working on.
>
> That flexibility allowed us to capture lessons learned early — what worked well, what needed adjustment and apply those insights to the next phase." - **Anna Rahmqvist, QA Implementation Lead at CCRM Nordic**

## What they did: **Import**

- Manually imported ~120 active QMS documents since they were building the system from scratch.
- Identified early which procedures would be affected by the eQMS implementation (e.g., document control, training, and module-specific workflows).
- Included affected procedures in project planning and updated them during system configuration.
- Integrated updated procedures directly into end-user training before go-live.
- Imported non-affected documents “as is” in PDF format to preserve traceability.
- Used legacy document IDs in the system to maintain references and continuity.
- Set a 12-month periodic review plan for document owners to transition legacy documents into Scilife templates.

> ”Don’t underestimate or under-resource training. The time invested upfront pays off in stronger adoption.
>
> And the good news is that once the first module is in place, training for later modules becomes much easier because the core functionality remains consistent.” - **Anna Rahmqvist, QA Implementation Lead at CCRM Nordic**

## What they did: **Validation**

- Defined their own User Requirements before leveraging vendor documentation.
- Mapped internal requirements to Scilife's URS and traceability matrix to avoid duplicate testing.
- Performed additional UAT only for critical requirements not covered by vendor documentation.
- Created module-specific configuration specifications and verified settings accordingly.
- Conducted process-based UAT with real end users.
- Validated modules phase by phase, aligned with implementation.
- Ran a non-scripted Performance Qualification after go-live to evaluate real-world use.
- Applied a risk-based approach to focus effort where it mattered most.

> "We also chose to validate modules phase by phase, focusing only on those in active use rather than attempting to validate the entire system upfront. The first validation phase required the most effort, particularly in defining our approach and documentation.
>
> However, once that foundation was established, subsequent modules required significantly less time and resources." - **Anna Rahmqvist, QA Implementation Lead at CCRM Nordic**

## What they did: **Post launch**

Following go-live, CCRM held additional check-ins with their Onboarding Project Manager to ensure a smooth transition and quickly resolve any minor issues. This structured follow-up helped stabilize operations and address early questions efficiently.

After this phase, responsibility transitioned to the Customer Success team. While access to the support portal remained available, the focus shifted toward a self-serve enablement model supported by expert guidance when needed.

The test environment continued to play a strategic role — not only for refining existing modules but also for pre-testing future tools before purchase or rollout. Combined with Customer Success optimization support, this allowed CCRM to plan future phases confidently.

Ongoing resources such as the Scilife Academy, Knowledge Base, Deep Dives, guided checklists, and monthly updates became long-term enablers — supporting continuous improvement and practical use of the system beyond initial onboarding.

> "After onboarding, you transition to Customer Success, where we continue tracking progress with you, helping you stay on course with your implementation milestones and ensuring you achieve the value you set out to gain from the system." - **Trine Michelson, VP of Customer Success**

# Top tips from CCRM Nordic for adopting an eQMS

01

**Identify pain points early**

Pinpoint your biggest operational frustrations — whether it's document retrieval, training tracking, or CAPA management — and clearly communicate how the eQMS will solve them. Early clarity builds momentum and internal buy-in.

02

**Communicate continuously**

Keep stakeholders informed throughout the project. Involve end users in shaping processes and position onboarding as a collaborative effort. Engaged users become system ambassadors.

03

**Prepare for launch and expect questions**

Launch day success depends on preparation. Ensure visible local support, anticipate minor issues, and remember: most early challenges are knowledge gaps, not system failures.

04

**Celebrate milestones and follow up**

Recognize go-live as an achievement. Track early questions, adjust where needed, and gather feedback post-launch to measure impact and reinforce value.

05

**Use the test environment strategically**

Don't just test — configure, experiment, showcase solutions, gather feedback, and train users in the test environment before going live.

06

**Formalize administrator training**

Make administrator certification a requirement. Structured training ensures documented competence and strengthens system ownership.

07

**Leverage the Knowledge Base for SOP development**

Use the Knowledge Base not only for system guidance, but also as a foundation when drafting or updating internal procedures.

08

**Invest in end-user training**

Don't underestimate the importance of structured training. Hands-on exercises before go-live significantly improve confidence and adoption.

09

**Define processes before training**

Train users on your finalized internal workflows — not just on system functionality. This prevents confusion and enables confident answers to real-world scenarios.

10

**Expect training to get easier**

The first module requires the most effort. Once users understand core navigation and functionality, subsequent module training becomes faster and more efficient.

# We’re here to help you get it right the first time

Choosing and implementing an eQMS is too important for trial and error.

We’ve guided hundreds of life sciences organizations through successful selection and implementation — navigating validation requirements, change management, regulatory complexity, and everything in between. We know the pitfalls to avoid and the success factors that truly matter.

Industry leaders like **Novartis, Biocartis, Yusen Logistics, Polpharma, and Amnovis** trust Scilife to power their quality operations.

If you're ready to move forward with clarity and confidence, we're here to help you do it right.

**Get in touch with our team**

**www.scilife.io**

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