CHECKLIST · BUYING AN EQMS

eQMS Evaluation Checklist

Critical questions to ask any eQMS sales team

Sales calls can be overwhelming — especially if it's your first time buying an electronic quality management platform. That's why we put together this eQMS Evaluation Checklist. It's full of the important questions you should ask during your next eQMS sales call or demo to make sure you're getting the right tool with the right functionality for your team.

01 Configurability
02 Ease-of-use
03 Support
04 Account cancellation
05 AI features

01 Questions to ask about configurability

- [ ] How would my existing paper process work in your system? Can you create a mock-up of my current process live on this demo?
- [ ] What steps in your modules are absolutely required? What can I not take out?
- [ ] Can I easily configure my own categories of documents or are they predetermined?
- [ ] How are permissions managed around each process? Are they global permissions or specific to each process?
- [ ] Can I change the fields of each process once they're locked?
- [ ] Does a user have to retrain on a document multiple times if that document is in multiple courses, or can I change those settings?
- [ ] Does an author of a document need to train on the document they authored?
- [ ] Can I be selective about which documents I share with auditors?
- [ ] What are the different user access levels? How easy is it to adjust these permissions?

02 Questions to ask about ease-of-use

- [ ] What does the experience look like for the general user?
- [ ] How easy is it to train a general user? How long does it take?
- [ ] What's the percentage of time I should expect an admin to spend on managing a system?
- [ ] Can I access a quick overview of company-wide training compliance from the home screen?
- [ ] Can I easily delegate required items to other employees if I am out on leave/holiday?
- [ ] Can outside training certifications/credits easily be added on the dossier in the system?
- [ ] Can I upload as many documents as I want into the system?
- [ ] Can you upload a document live on this demo?
- [ ] Can any type of document be uploaded into the system?
- [ ] How do I export my documents from the system?
- [ ] Are there differences between general/"lite" users and full/"super" users? What are the limitations and costs?

03 Questions to ask about support

- [ ] What are the hours of the help desk? Can it support staff in other time zones?
- [ ] Can the company provide any metrics from helpdesk (resolution time, satisfaction scores)?
- [ ] What are the average response times?
- [ ] Does the company provide a Service Level Agreement (SLA) for response times and escalations?
- [ ] What costs are associated with implementation? How is it staffed? What is the plan?
- [ ] What are the costs for ongoing support for different kinds of requests? Be specific:
  - Small vs. 'large' tickets
  - Document or data import requests
  - Configuration changes (e.g. adding a new CAPA process)
- [ ] Is the software knowledge base updated, organized, and easy to navigate?

04 Questions to ask about account cancellation

- [ ] What is the cancellation policy and where is it documented?
- [ ] What are the fees associated with cancellation?
- [ ] How much advance notice is needed for account cancellation?
- [ ] What is the transition process and how can I ensure data continuity?
- [ ] In what form will I receive my metadata and exported, signed documents?

05 Questions to ask about AI features

- [ ] What AI features are included in your platform, and what specific problems do they solve?
- [ ] Which AI features are considered low-risk (e.g., drafting, summarization) vs. high-risk (e.g., investigations, risk scoring, decision support)?
- [ ] Is the AI functionality opt-in or enabled by default?
- [ ] Can I control which users or roles have access to AI features?
- [ ] Will my data be used to train your AI models?
- [ ] What data protections are in place?
- [ ] Can I clearly distinguish between AI-generated content and human-authored content in the system?
- [ ] How is AI use captured in the audit trail?
- [ ] Can AI-assisted actions (e.g., suggested CAPAs, document edits) be reviewed, edited, and approved before being finalized?
- [ ] What controls are in place to prevent or detect incorrect outputs or "hallucinations"?
- [ ] Do you provide validation support for the AI features?
- [ ] How does your AI functionality align with GxP expectations for validation, documentation, and change control?

Ready to put ZenQMS to the test? Bring these questions to a demo.