Scigeniq™

10 QUESTIONS TO ASK BEFORE BUYING A QUALITY MANAGEMENT SYSTEM

INTRO

You're ready to take the next step and purchase a quality management system (QMS) to improve compliance and speed up decision-making.

But there's a catch: you aren't sure what you need or what a modern QMS provides.

That's where we can help. Read on to learn the 10 questions you need to ask when researching and talking to QMS vendors.

QUESTION 1

Is the QMS a "Cloud-Native" Solution?

Check out the history of the QMS you are considering. Find out when it was built and whether it was built as a cloud-first, cloud-native application because you should not invest in a solution built on technologies that became obsolete a decade or more ago.

- Easier to use (less training and on boarding time
- Easier to deploy and configure, reducing startup time and effort

Cloud-Native

QUESTION 2

Does the application include a dashboard view of all incidents, their current stage, and their timeline?

That means a modern QMS must collect, consolidate and report on all the activities it tracks. Look for a dashboard-style interface that allows you to select key performance indicators (KPIs), set targets for each, and choose from graphic options (bar chart, pie chart, donut, etc...) to present the results.

One of the hallmarks of Pharma 4.0 is the "datafication" of every aspect of the manufacturing operation.

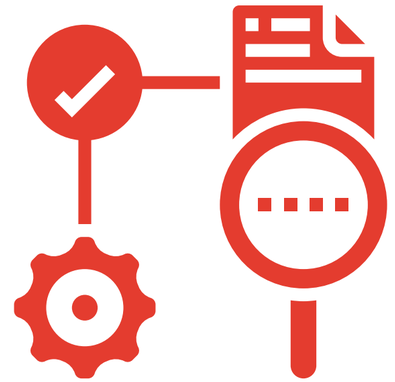
Look for the ability to configure individual dashboards for different users so that each user sees the KPIs and other information most relevant to their role.

QUESTION 3

How long does validating and putting the QMS into production usually take?

Longer timeframes waste tremendous resources and increase the possibility that the implementation will fail.

Older systems are more "hard coded," and changes to address your processes will dramatically slow implementation. A modern QMS should be able to be in production within 6 to 8 weeks at most. The system you want will be pre-configured with standard processes that can be easily changed to match your needs.



Part of the benefit of cloud-based systems is that they are typically "pre-validated," meaning the base system has gone through the complete validation process, leaving only a final set of user acceptance tests to complete the validation.

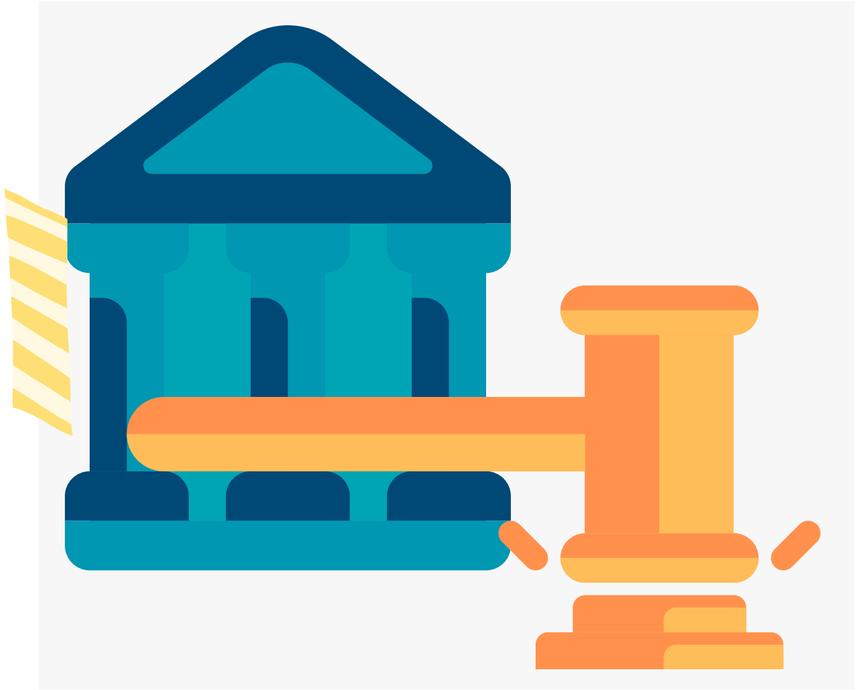
QUESTION 4

Can the forms used in this system be easily used to generate well-formatted records?

There are two distinct use cases in a QMS.

1. When the incident is active and being tracked.
2. When you create records of the incident on paper or for export from the system

Choose a QMS that addresses both use cases effectively so that users don't have barriers while the incident or issue is active. Then, effective documents can be generated to meet reporting needs when needed.



The QMS should address pharma processes such as CAPA (incident change control process), documenting supplier qualifications, managing out-of-specification issues, and handling internal and external audits.

QUESTION 5

Is the QMS designed for life sciences, and does the system meet all pharma regulatory requirements?

A QMS for life sciences must meet requirements related to managing electronic records. That includes, among other things, a full audit trail of every action and the ability to leverage electronic signatures as part of approvals.

Generic systems require more time to configure to address the specific requirements of a pharma company and may have gaps in the features necessary to meet pharma regulations.

QUESTION 6

Does this QMS support "dynamic workflows"?

1. After an initial deviation or out-of-specification is created in a QMS, the answer to "what happens next" is it depends.
2. It depends on the incident type, processes, and departments involved.
3. An overly rigid or simplistic workflow model will frustrate you when you try to implement it with real-life processes.

The QMS needs to determine the next step – and each step -- in the process based on various parameters that are collected as the scenario evolves. And you must be able to configure the system based on your processes, whether sending a notification, starting a new investigation, or initiating a corrective action.

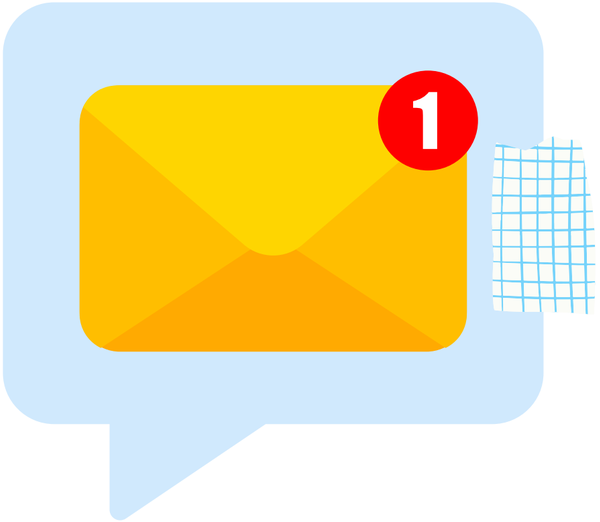
It is essential to ensure that the system you are considering includes the ability to execute a variety of workflow patterns and that the "next" step in a flow can always be based on the actions taken in "this step."

QUESTION 7

Does the QMS generate automatic email notifications triggered by key events and actions?

A quality management system's fundamental purpose is to ensure that a consistent series of steps is followed from beginning to end for every issue, incident, complaint, or finding. Notifications are critical because they make the required participants aware that an item is awaiting an action required by them.

Look for a QMS that allows users to set how they want to be notified and how often

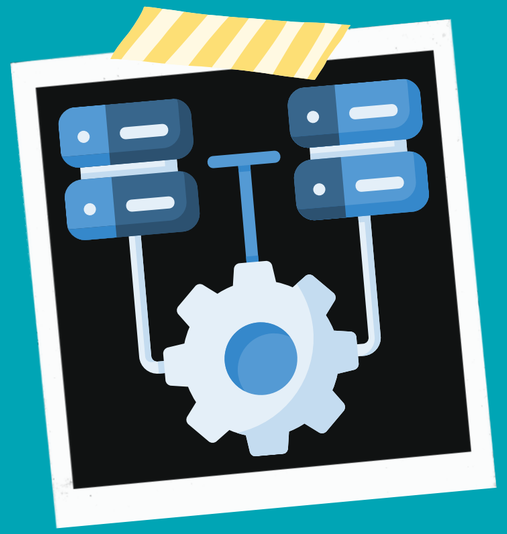


- A queue on the user's application homepage
- An email
- A Text-Message
- A daily summary of all required actions

QUESTION 8

Can data from other systems and equipment be integrated into this QMS?

In the world of Pharma 4.0, systems and equipment are integrated and exchanging information. That means that the QMS you want today has to be able to connect to other systems and devices, collect data from them and share information back.



Must provide a Rest API (Application Programming Interface), the current technology for interconnecting disparate systems.

QUESTION 9

Does the system include support for audit activities?

The system should be able to specify the type of audit as well, for example, internal or external, and the scope of the audit.

Audits and inspections are a fundamental part of the quality process in every pharma company, so your QMS should have specific functionality to support them. That includes:

- scheduling an audit,
- building an audit work plan,
- recording findings and follow-on actions, and
- preparing a polished audit report.

QUESTION 10

Can the QMS manage and track SOPs and related quality documents?

Another critical element of managing quality in a pharma company is managing a complete set of quality documents.

1. Flexibility to manage all documents, including:

- SOPs
- Work Instructions
- Vendor Documents

2. Essential features include:

- Creating new quality documents from templates,
- Controlled access to the documents based on roles,
- Review and approval workflow,
- Version management of each item as it progresses from draft to final version.

ACTION ITEMS

Next steps in your QMS selection process

OUTLINE YOUR REQUIREMENTS

RESARCH VENDORS & UNDERSTAND THEIR SYSTEM CAPABILITIES

SHORTLIST 2-3 QUALIFIED VENDORS

RUN A PILOT ON YOUR SELECTED VENDOR

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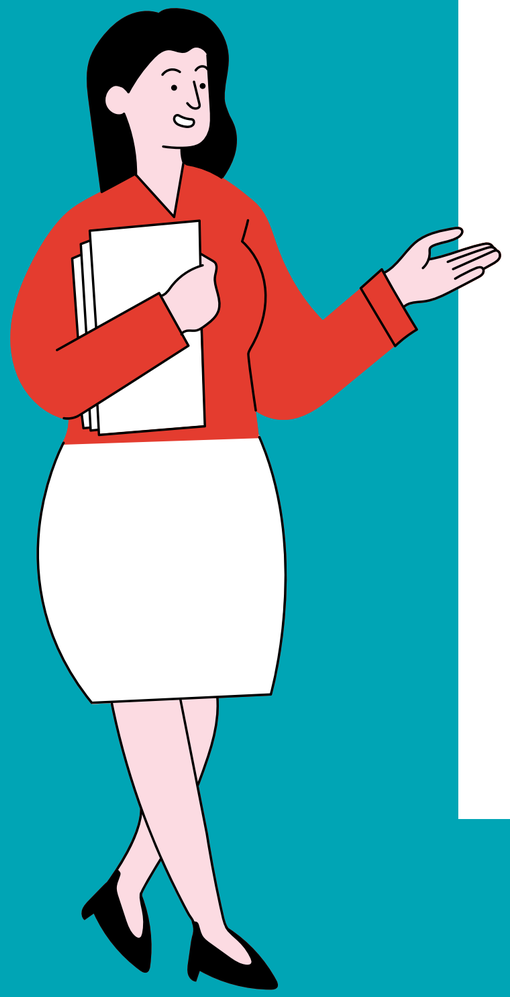

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Sign up for a demo of Sciqeniq QMS to see how a modern quality management system can support your company.

Request Your Demo

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