Ensure Success in Quality Management Software (QMS) Selection

Proven 4-step process for QMS selection
As you embark on QMS selection, start by self-assessing the maturity of your quality organization, and defining the specific challenges to be addressed and strengths to be optimized through technology. Understanding your core competencies in addition to process gaps will support better request for information (RFI)/request for proposal (RFP) documentation and, as a result, more relevant and thorough vendor proposals.

Ask the following questions as you self-assess:

• How do you define the culture of quality in your organization?

• What typical quality issues or events do you face in a given day/week/month/year and during the course of normal work procedures?

• Which specific regulatory mandates influence governance of production and operations?

• What metrics are currently in use to assess the quality organization (e.g., number of customer returns due to defects, number of customer complaints, number of product/system failures)?

• Does your product satisfy functional requirements and levels of reliability that customers prioritize?

• Do you have an existing, commercially available QMS in place, or are you using spreadsheets, etc.?

• What specific needs do end users have? How will the UI/UX impact user adoption?
**Step 2: Understand QMS functionality.**

Before engaging in any type of RFI/RFP process for QMS, first identify business goals, and then thoroughly define the necessary software requirements. Will the “off-the-shelf” capabilities of the QMS suffice? If not, what level of customization is needed?

Based on our surveys of end users and research into QMS vendors, Gartner has identified the most commonly sought QMS functionalities and the questions to ask as you self-assess:

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<th>Functionality</th>
<th>Questions to Ask</th>
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<td>Data migration</td>
<td>Does the system provide tools to import data from multiple systems, mindful of master data management? Does this include migration from legacy systems or from other commercially available software applications?</td>
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<tr>
<td>Document control and management</td>
<td>Does the software support electronic storage, maintenance, version control and retrieval of quality documents, which may include SOPs, work instructions, engineering change orders, etc.?</td>
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<td>Failure modes and effects analysis (FMEA)</td>
<td>Does the software provide a structured approach to discovering potential failures that may exist within the design of a product or process? Does it encompass potential quality-related impacts on safety or environmental risks?</td>
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<td>Robust product design</td>
<td>Does the system provide tools that reduce the unintended variation in finished products, ensuring that consistency in delivered products is maintained when uncontrollable factors have an effect on production processes?</td>
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<td>Corrective and preventive action (CAPA) and incident management</td>
<td>Does the system provide workflows to respond to a nonconforming or unplanned event through investigation, action plan development, implementation of preventative actions and ensure no risk of recurrence?</td>
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<td>Training and qualification</td>
<td>Does the software provide a module(s) for managing responsibilities, training and certification requirements for employees, suppliers and other partners to monitor and ensure compliance with respect to required training and certification?</td>
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<td>Change management</td>
<td>Does the software provide workflows and enforcement of processes for managing changes in quality process, procedures or documents?</td>
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<td>Risk assessment</td>
<td>Does the software facilitate identification, magnitude, frequency or likelihood of quality risks?</td>
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<td>Data submission and reporting</td>
<td>Does the software have the ability to extract information from QMS and other systems and present data in tabular, graphical or other formats?</td>
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<tr>
<td>Internal control systems</td>
<td>Does the software have functionality that helps enforce policies and procedures implemented to assure that reports are viable, operations are efficient and that activities comply with applicable laws and regulations?</td>
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### Functionality | Questions to Ask
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Integration with production equipment | Does the software have the ability to interoperate and share data with equipment used on the production floor?
Integration with business systems | Can the software import data from/post data to other applications within the architecture (including, but not limited to, ERP, MES, PLM and LMS)?
Supplier quality management | Does the software measure and track the cost of poor supplier quality? Will the software support supplier quality audits? Will the software help standardize supplier quality metrics? Does the software have functionality to support supplier collaboration and visibility?

**Step 3: Interview QMS vendors.**

The QMS vendor’s ability to understand your business issues and implement creative problem-solving strategies is paramount. Consider not only the technical capabilities of a QMS vendor but also their strategic direction, product roadmap and competitive differentiation. The strongest vendors can preemptively articulate common issues that occur during QMS deployments and ongoing usage and have a set of processes in place to address these challenges. Have vendors provide sample scenarios and specific examples of how these challenges may be addressed.

Gartner has compiled the following list of sample interview questions to help supply chain leaders with QMS selection:

- What distinguishes your solution’s functionalities from your competition?
- What are the commonalities across your most successful deployments?
- What is your approach to customer conflict resolution? How do you prepare customers to avoid common pitfalls?
- In what ways does your solution address specific challenges in my industry’s regulatory environment?
- What is your approach to continuous improvement?
- What hosting options do you offer? Describe your support model of global deployments.
- Describe your product roadmap. What do your future releases look like? How often should we expect new features and technical updates?
Quality organizations interface and overlap with a variety of other functional disciplines in the organization. Similarly, QMS solutions must interface with other systems in the architecture, which include, but are not limited to: Enterprise resource planning (ERP), manufacturing execution systems (MES), product life cycle management (PLM) and learning management systems (LMS).

Gartner recommends asking the following questions with respect to integrating a proposed QMS solution with other business systems, soliciting input from both internal stakeholders and vendors as necessary:

• Which business systems will be integrated with the QMS?

• In what ways will potential QMS solutions complement other systems and vice versa?

• What specific benefits can you expect when implementing a QMS solution into the existing architecture?

• In what ways will integrating a QMS solution within the existing architecture increase the overall level of quality, decrease the cost of quality, reduce the risk of product recalls and ensure ongoing compliance?
Position your supply chain organization for success. Explore these additional complimentary resources and tools related to quality management:

**Research**
Creating a Culture of Quality
Learn the four highest-impact drivers on creating quality culture.

**Report**
Cost of Quality Do’s and Don’ts
Learn three simple steps to reduce cost of quality.

**Webinar**
The 8 Quality Management Trends You Need to Prepare for 2025
Understand how the value, scope, governance and implementation of quality management will change by 2025.

**Customer Success Story**
Building a Cost of Quality Model
Read how Gartner helped a leading packaging company optimize costs by reducing cost of quality.

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