

Quality Management Systems Trends

TREND REPORT

Start Your Transition To Next-Generation Quality Management

Summary

Quality management systems (QMS) traditionally focus on incident response and remediation or postproduction audit and analysis. Even methodologies like total quality management (TQM) focus on detecting and reducing errors in manufacturing and supply chain, to improve customer experience. But today, products have much shorter product lifecycles, many more variants, and more-complex elements, such as sensors and embedded software. To be sure, regulators continue to expect more-detailed compliance reporting, but the real quality imperative is from customers. Mandatory enterprise capabilities to both comply with escalating regulatory requirements and boost value to customers depend on an enterprise's target markets, industry ecosystem, and value proposition characteristics. Use the QMS framework to evolve your quality management from retrospection to intelligent intervention and then to predictive preclusion.

Deploy Modern QMS To Improve Product Lines, Inspire Trust, And Attract New Customers

For years, manufacturers struggled to assemble, manage, and document process control and product traceability data strewn across legacy systems such as enterprise resource planning (ERP), quality management systems (QMS), product lifecycle management (PLM), and manufacturing execution systems (MES). But manufacturing enterprise CIOs now must take a fresh look at the QMS landscape to:

- **Boost quality process completeness and consistency.** Manufacturers aim to deliver products with consistent conformance to specifications, regardless of variations (for example, variations in potency between raw material batches). But to conform with regulations and to meet customer requirements, manufacturers need formal quality processes that consistently anticipate quality risks. They need systems that match digital quality certificates to consignment notes and advanced shipping notices before suppliers can dispatch components or intermediate products to receiving bays. They must deploy standardized failure modes and effects analysis to design for continuous quality improvement. They must implement consistent event monitoring, escalation, and recall processes. Modern QMS help enterprises comply with standards that the International Organization for Standardization (ISO) publishes.
- **Resolve data challenges.** Most existing quality systems depend on paper documentation and signatures. Modern QMS can standardize workflows and permissions, automatically escalating quality issues for resolution by email or text. They can ensure that appropriately qualified colleagues with current certifications undertake quality-sensitive tasks and inspections. Best of all, digitization, date timestamping, and even geolocation certification deliver the chain of custody and responsibility that helps guarantee quality products and processes. Finally, digital QMS records offer the potential for search and statistical analysis to determine and, if necessary, correct adverse quality trends.
- **Master modern QMS practices.** Automotive manufacturers pioneered methodologies like Advanced Product Quality Planning (APQP) and closely related Design for Six Sigma processes, which many other industries adopted. They deploy

Modern QMS to scrutinize design for potential product quality risks. They use QMS to document and automate tasks shared between coworkers, customers, and suppliers to standardize process instructions and measurements for each stage of conversion, from raw material to finished products. Usually, they incorporate simulation data from PLM to anticipate and forestall production or field deployment quality incidents. MES data from manufacturing plants or embedded sensors, together with customer feedback or, in the worst case, product recall or rectification, complete the quality feedback loop to continually improve design and production.

- **Choose the most suitable QMS platform.** CIOs should apply the QMS capability framework to their specific industry and ecosystem or market structure. In general, more-regulated industries demand a wider scope of QMS capabilities, and services industries focus more on training and certification and naturally, except for retail, focus less on supplier and materials quality. Given the greater variability of both raw materials and production processes, process industries and life sciences focus on incident management and recall. Discrete manufacturers benefit from embedded simulation in PLM to evaluate multiple deployment scenarios anticipating and “designing out” multiple potential quality issues. Process and life sciences industries, where regulators give permission, can also anticipate and preclude quality problems by conducting comprehensive in silico simulations, to complement their sample in vitro and in vivo trials (see Figure 1).

Figure 1

QMS Capability Diagnostic

Capability	Document control	Training certification	Incident management	Risk register	Supplier and material quality inspection	Corrective action or recall
Industry vertical						
Discrete manufacturing	● ●	● ●	● ●	● ●	● ● ●	● ● ●
Process manufacturing	● ●	● ● ●	● ● ●	● ●	● ● ●	● ●
Highly regulated service, e.g., retail financial services	● ● ●	● ● ●	●	● ● ●	●	● ●
Minimally regulated service, e.g., retail	●	●	● ●	●	● ● ●	● ● ●

Supplemental Material

Companies We Interviewed For This Report

We would like to thank the individuals from the following companies who generously gave their time during the research for this report.

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