

# Quality info

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## **Building the Story of Quality Integration, harmonization, and risk-based thinking**

Quality management systems (QMS) have become strategic components that touch more and more of the business today. With new versions of QMS standards, and the enrollment of all people in the quality management effort, the need for cohesion from one system to the next is becoming critical.

Let's consider the "story of quality"—the chain of quality's effect on various areas of the business, and how those operational areas rely on quality-based information to gain visibility and control, affect operations with a quality eye, and create a hub of quality throughout design, production, supply chain, and post-market.

There are three elements here that are necessary to this story of quality—integration, harmonization, and risk-based thinking.

### **Integration**

In today's business environment, it is nearly impossible to effectively manage operations, quality, and the product life cycle without implementing business software systems. Applications such as supply chain management (SCM), enterprise resource planning (ERP), manufacturing execution systems (MES), and similar tools have become a necessary part of enterprise technology.

As a company grows, so does the need to implement more of these types of systems. In the past, business systems have served a single purpose for a single set of users within the company (e.g., product design, operations, shop floor), without any need or forethought to integrating these systems into a larger environment. This results in information silos, whereby data across all systems are disconnected or redundant, and communication is hampered between departments. Problems begin to arise when critical information must be passed from one system to another: There is no seamless way to extract the data, and visibility into other systems is foggy at best. This hinders overall performance within the organization and limits the efficiency of operations.

QMS are not excluded from this information silo scenario. In many cases, the quality system is a completely separate function of the business, and the connection between the quality system and other business systems is usually achieved through offline forms, periodic reports, and verbal communication. Although QMS play an important role in the assurance of product quality and process compliance, the business systems that control the products and run the process are "blind" to the status of the quality system. This often results in critical errors in the production environments being overlooked, which leads to defective products and noncompliant processes, all of which can pose potential danger to the consumer and affect the bottom line.

Decisions within the QMS affect decisions within production systems. Production systems rely on the QMS before they can release a product. Instead of tracking quality assurance status manually, processes within the quality system can automatically trigger decisions in the production system.

For example, change management events within the QMS affect processes related to product. Through integration, once an engineering change request is completed within the QMS, the production system is notified of the change and can respond accordingly. Similarly, applications such as document control can also affect production environments. When a new procedure, work instruction, specification, or test script is completed within the QMS, the production system is automatically notified and is able to make changes to production based on the completed event.

The bottom line is that your quality system can be integrated into other business systems to provide visibility into quality issues that pertain to that system. As these systems communicate with the QMS, they reduce the likelihood of poor quality across the enterprise.

The true benefit in integrating systems, specifically integrating your QMS, lies within creating a window into quality for the rest of the enterprise, whether corporate, production, customers, suppliers, or others. Quality issues affect the entire organization, and by streamlining your operations and improving quality, you can provide a single, closed-loop process that spans the enterprise and has a legitimate effect on the bottom line.

## Harmonization

A business enterprise entails various sites within an organization that are all working toward the same common goal, but often with their own unique processes. These processes should not have to change, so the question becomes, “How can we keep everyone on the same platform without sacrificing individual sites’ processes?”

Harmonization is the answer for doing this effectively. Harmonization makes it possible for corporate to have a single source of the truth (SSOT), while maintaining each site’s individual processes. It allows an organization’s various sites to be synced up as to how their corporate culture approaches quality. Different sites will be able to “speak the same language,” and a single system will handle multiple facilities while keeping sites unique, yet with a common framework.

Harmonization relies on all elements being in sync with each other. To do this, an organization needs the help of people, processes, technology, and governance:

- **People.** One of the most important elements of harmonization is getting a champion, or champions, to drive the initiative. Without a group to collaborate and organize the standardized processes, harmonization can be difficult to achieve. An organization needs team members to manage the new process, make any necessary changes, and encourage multisite cooperation throughout the enterprise.
- **Processes.** Getting a process in place that satisfies corporate reporting and assimilates site-level practices is a challenge in and of itself. The key areas to ensuring a standardized process involve putting in place the resources, the people,

and the technology to foster success. Harmonization relies on having a process that is repeatable, adaptable, has one standard operating procedure (SOP), and is auditable.

- **Technology.** Another element in successfully incorporating a harmonization initiative is to select the right tools for the job. Often, people and processes alone cannot successfully maintain a harmonization effort. Software tools must be implemented that not only foster the management of standard quality management processes, but also provide the functionality needed to assimilate site-level processes to the enterprise.
- **Governance.** Success relies on the “buy-in” of executives to sponsor the harmonization project, team leaders to influence fellow employees and create an action plan, and team members to push the need for action and provide their expertise in the process for improvement. Governance ensures that all standardized processes are effective by tracking the progress of harmonization initiatives, resolving any issues that occur, and avoiding the need to start over if surprised by any issues once the process is in place.

To truly harmonize your organization, you need to automate your business processes. Doing so allows you to host all sites from a single location, resulting in consistency across all sites and leading to commonality in business processes, lower cost of resources, and visibility that is enabled from site to site. The result is that your organization will be truly connected from site to site, and able to provide the highest quality product for your organization.

### **Risk-based thinking**

The release of ISO 9001:2015 introduced the concept of risk-based thinking around quality management. Risk-based thinking requires companies to evaluate risk when establishing processes, controls, and improvements in a QMS.

ISO 9001:2015 offers a companywide approach, and the leadership needs to be enrolled in the concept of quality. However, not all leadership is thinking in terms of quality. They don't always “speak the language” of quality, and that can be a disconnect when you are trying to promote a culture of quality.

Risk management acts as a “universal translator” of sorts to quality events. Although leaders may not speak quality, they will be able to speak risk. That is why the standard encourages the concept of risk-based thinking. This refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect their ability to achieve objectives. Risk-based thinking replaces what the old standard used to call preventive action.

Risk-based thinking requires companies to evaluate risk when establishing processes, controls, and improvements in a QMS. However, risk isn't limited to just negative possibilities. Companies can also use risk-based thinking to pinpoint opportunities, which represent the positive side of risk.

One of the most important parts of applying risk-based thinking to quality management is to make it part of the process rather than a silo activity. This means having risk tools

built into the QMS rather than using a separate point solution or time-consuming manual processes.

The key capabilities of a risk-enabled quality management solution are:

- **An integrated risk register.** An organization needs a centralized place to record and monitor individual hazards and risk items. Although this is not formally part of ISO standards, consistently using a risk register will help satisfy several requirements.
- **Flexible risk tools.** Organizations should be able to activate risk assessment tools such as a risk matrix or decision tree within any QMS application, from audits to deviations to regulatory compliance tracking.
- **Risk-based effectiveness checks.** Adding a final risk-based verification step for processes like corrective action helps satisfy performance evaluation and improvement requirements.

One of the most important ways companies use technology to reduce risk is through automation. Creating automated risk-management processes ensures nothing falls through the cracks and provides a documented history to look back on.

## Conclusion

The three elements discussed here each play their part in ensuring a high level of quality. Integration provides visibility into all processes across the enterprise and beyond, to third parties. Harmonization is the answer to unifying an organization on a corporate level while maintaining each site's unique method of doing business. Risk-based thinking acts as a “universal translator” of quality—because, although leaders may not speak quality, they do speak risk.

Together, these capabilities contribute to this story of quality, helping to ensure that quality becomes a consistent, companywide event.

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