Decoding Quality Management Systems

Quality defines the character of any product or process. To better manage and extend brand reputation, organizations need a holistic, long-term view of enterprise quality management systems to tamp down costs and drive profitable growth by keeping customers loyal and satisfied.

Executive Summary

Whether building a new product or improving processes or services, quality is the bedrock of an organization’s long-term success. In fact, quality increasingly defines the brand. Consider that of the estimated 250,000-plus new products launched annually, between 85% and 95% fail; clearly, to build a successful brand, companies must make the most of the 5% to 15% of products that gain market acceptance – tough odds, indeed, for building a winning business.

Although multiple factors can cause product failure, quality is considered by most experts to be among the leading contributors. And if or when products fail, companies need to understand the role that quality played and calculate the resulting cost to their reputation and brand image. Building in quality from the get-go is critical to market success and is typically attained by deploying quality management system (QMS) applications that help to continually improve process efficiency and effectiveness to drive high performance.

This white paper offers insights into the QMS landscape, highlights challenges of selecting the right solution and partner, details leadership dilemmas, and provides sound advice on how to make quality job one across the enterprise.

A QMS Primer

Several factors – including an ever-evolving product manufacturing landscape, internal organizational challenges and a dynamic global business climate – are driving organizations across industries to transform product and process quality, as well as keep closer tabs on supplier quality (see Figure 1, next page). Market pressures remain intense, both in heavily regulated industries, such as life sciences, medical devices and food and beverage, as well as in industries such as automotive and industrial manufacturing.

These pressures are driving organizations to strive for the highest level of quality in all aspects of their operations. However, they must overcome many challenges along the way to achieving that goal, as well as strong cost competitiveness and rapid speed of delivery.
In the manufacturing world, QMS applications provide the foundation for enforcing quality policy and processes across the extended enterprise. Organizations often approach QMS as a means to not only meet regulatory and compliance requirements but also better manage and achieve operational goals, such as enhanced product quality, continuous business efficiency and accelerated time-to-market. QMS maturity plays a significant role in enhancing shopfloor manufacturing operations, product and process quality performance, and overall organizational performance.

Figure 2 illustrates the role of QMS across the value chain, revealing how these systems touch every functional area, from product planning and definition to customer engagement. It also highlights how QMS addresses key quality areas, including advanced product quality planning (APQP), statistical process control (SPC), audit, corrective action and preventive action (CAPA), non-conformance (NC), customer complaints and regulatory compliance.

### Role of QMS across the Value Chain

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<th>QMS Touchpoints</th>
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<td>Good laboratory practice</td>
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<td>AQL checks/ in-process checks</td>
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<td>Manufacturing scale-up</td>
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Figure 2
Quality Process and Application Challenges

At many organizations, quality is looked upon as a separate department rather than as a shared responsibility; as a result, it is often addressed in a reactive and inefficient manner. In these cases, quality remains a “just fix the issue” concern rather than an investment in sustaining competitiveness. However, winning organizations have demonstrated that continued outperformance requires a collective effort, in which every individual who is part of the quality process shares responsibility for meeting customer requirements.

Most manufacturers lack an integrated view on quality or a consensus on which functions to centralize, source, localize or share across the enterprise. Most also lack enterprise-wide governance; instead, each business unit has its own mandate for budgeting and prioritizing quality. To coordinate quality across the enterprise, senior management must tap an executive with direct responsibility for quality improvements within all functional areas of the organization.

Quality processes — whose values are interconnected and correlated — must be integrated to fully leverage the data capabilities of applications that manage quality. An integrated view establishes a culture of collaboration across functional groups; for example, a production part approval process (PPAP) requires close collaboration not only between the purchasing and quality functions but also with the external supplier.

Organizations have built a complex set of disparate applications over the years to manage enterprise-wide quality processes. These siloed applications — including homegrown applications, spreadsheets, point solutions and applications based on outdated technology — are often not integrated with one another and lack broader functional capabilities to support the business.

Most of these applications are also heavily customized and are non-intuitive; moreover, the same application is often used differently across various business units and geographies, and different applications are sometimes used for the same process to address internal and external quality. There is no single dominant application, and little or no integration among applications. This fragmentation, incompleteness and lack of consistency have resulted in operational inefficiencies, increased cost and end-user dissatisfaction.

Further complicating matters, multiple applications are often required to manage closely linked areas such as audit management, non-conformance (NC) handling and corrective action and preventive action (CAPA). This forces users to manually manage the linkage between an audit finding and its respective CAPA.

With the emergence of millennial workers, tech-savvy, mobile-centric, socially-networked employees who will dominate the workforce by the end of this decade — the relevance and effectiveness of addressing quality issues now requires organizations to meet a fast-rising and accelerating benchmark for minimum digital competency. This includes adopting an enterprise QMS, made possible by the new digital-centric world.

Organizations wrestling with the complexity of duplicate quality functionality and processes across legacy systems usually attempt to simplify and consolidate applications into standardized platforms that help eliminate unnecessary costs, as well as position enterprise QMS as a strategic business capability for the future.

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Selecting a QMS: An Executive Determination

With minimal data or experience, business leaders need to evaluate if or how a QMS they are considering delivers the following capabilities:

- Greater visibility and escalation of operational quality issues.
- The ability to address potentially risky operational trends.
- Adaptation to regulatory changes and corresponding business initiatives.
- The ability to impact quality procedures across business units or operating sites.
- Coordination of quality control across suppliers and extended partners.

A QMS investment requires a systematized program approach to scoping, implementation and management across system lifecycles. The following factors should also be considered:

- The ability to bridge process gaps.
- Simplification of the existing technology landscape and adoption of newer technology.
- Effort vs. benefits.
- Sunk investments.
- Growth strategy and business objectives.

Based on these factors, business leaders should identify quality improvement opportunities by assessing current process and application gaps. The decision to grasp these opportunities and commit to a future course must be viewed in light of practical constraints, current and future needs, business continuity and the ability of the organization to handle change.

The future course of action can be determined by evaluating several possible hypotheses (see Figure 3).

Key Factors Impacting QMS Hypotheses

The selected hypotheses will directly impact the key considerations outlined above. In Figure 3, Hypothesis 4 will have maximum impact on these key factors and will offer the greatest level of benefits with respect to the effort required. Meanwhile, Hypothesis 1 and 2 will involve sunk costs for customization or future upgrades to maintain the systems or applications. While Hypothesis 1 offers fewer long-term benefits, Hypothesis 3 helps close the process gap through out-of-the-box (OOTB) functionality; it does not, however, deliver greater...
benefits than Hypothesis 4, and it provides little long-term flexibility. The results of all four hypotheses are summarized in Figure 4.

Evaluating QMS Applications
Because enterprise QMS centralizes various functions (i.e., audit management, NC handling, etc.), it can help improve quality management across geographies and divisions through process standardization and automation. It creates a single platform for cross-functional communications and collaboration that synchronizes and ingrains quality across the value chain.

Organizations are revisiting their quality strategies and are in the early stages of centralizing the quality function. QMS providers are beginning to adopt elements of social networking, real-time analytics and mobility, and are also working on their next generation of products, as a result of:

- Cloud-based technology, which has the potential to drastically reduce costs.
- Modular platforms that can accelerate return on investment (ROI) before the full implementation is completed.
- Digital transformation.

Multiple niche and stand-alone players offer QMS, as well as enterprise system vendors that are incorporating QMS into enterprise resource planning (ERP), product lifecycle management (PLM) and manufacturing execution system (MES) applications suites.

Where QMS Fits in the Manufacturing Value Chain and Technology Landscape
To choose the right approach, organizations need to understand the QMS landscape and their own specific needs.

- **PLM-based QMS** is advantageous when PLM investments have already been made. Generally, PLM-based QMS is best for organizations that engineer complex products with a focus on time-to-market. PLM helps integrate the functions of quality from design through manufacturing by employing a lifecycle approach; this approach ensures that feedback from sources such as non-compliance and corrective actions is routed to engineering to help address quality issues. PLM couples model-based development and simulations, helping organizations to better leverage visualization and variation analyses that greatly impact quality, as well as reduce cost of quality (compared with physical prototypes). In this scenario, a separate QMS must be tightly integrated to leverage these benefits.

- **ERP-based QMS** makes sense if the organization is in the middle of an ERP deployment. Among the primary benefits of ERP-based QMS is the use of a single platform, which reduces the need for multiple systems and costly integration. For large organizations, an ERP-based QMS is usually included as part of the broader ERP deployment.

- **MES-based QMS** is best suited for an organization that is highly focused on manufacturing, has already established operational excellence, has a continuous improvement group seeking to enhance quality processes and manufacturing performance, and has harmonized quality processes. Many MES vendors include complementary QMS functionalities within their solution sets.

- **Best-of-breed QMS** applications provided by niche players typically represent the unique quality needs of a manufacturing organization. Their solutions generally offer reduced time-to-value, lower costs and high flexibility compared with dedicated PLM and ERP systems.

Business executives need to evaluate the advantages and disadvantages associated with the various solution types from a long-term strategic standpoint to make a business case and forecast the impact of the QMS build-vs.-buy decision. Application types can be classified as point and enterprise applications.

Point applications are typically offered as customized off-the-shelf (COTS) or OOTB and are implemented to address a particular need, such as production part approval process (PPAP) or audit management; they address an immediate problem within a functional area of the organization. Enterprise applications, on the other hand, address the needs of the organization across departments and functions, and include more than one solution. They are scalable, configurable and flexible enough to address future QMS needs.

**Selecting a Best-Fit Enterprise QMS**

Common challenges that organizations face when deciding on a QMS include:

- Making the fundamental design choices required to get the entire QMS challenge right.
- Keeping QMS lean, simple and agile so that the right information gets to the right employees at the right time.
- Ensuring the QMS fully meets regulatory requirements and reduces compliance concerns.

When selecting an application, organizations need to begin with a long-term vision of their QMS strategy. In the short term, a point application often seems to be the most viable, cost-effective option; however, organizations with a long-term quality vision need to ensure that the solution will evolve to meet their needs as they grow.

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Over time, organizations typically invest in multiple point applications; however, the associated costs (maintenance and support, training, licensing, etc.) are often greater than expected due to needed customizations. Eventually, organizations move to an enterprise-wide application, under-
mining the time, effort and investment in the point solution. When making their application selection, organizations should weigh the following parameters:

- Functionality.
- Industry fit.
- Ability to integrate with the organization’s internal systems, as well as those of its customers, partners and suppliers.
- Scalability and flexibility.
- Software pricing/licensing model.
- Vendor’s ability to provide service and support across geographies.
- Ease of use.

Moving Forward

In today’s digital world, it is increasingly important for business leaders to assess and understand the potential for a QMS initiative to enhance sustainable competitive advantage and profitable growth. Effective QMS programs build and support quality policies and processes across organizational functions to not only fulfill the company’s quality vision but also enable the enterprise to be future-ready.

The success of the quality initiative to adopt and implement an enterprise QMS requires the unwavering commitment and dedicated support of executive leadership. Evaluation conclusions need to be supported by evidence and assessed against criteria or standards agreed upon by business executives. Justifying a decision involves the following steps:

- Analysis of an evaluation’s findings and synthesis of various sources of information to reach a deeper understanding.
- Interpretation of the findings to convey evidence in relevant ways that leadership can truly appreciate.
- A comparison of investigative findings and interpretations with agreed-upon criteria and standards.

Figure 6

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Footnotes


References

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