Leveraging Enterprise Systems for Efficient Quality Management and Regulatory Compliance

Abstract

Today’s marketplace demands higher quality products and many manufacturers have adopted a corporate quality culture to elevate the quality recognition of their brands. Today’s top tier manufacturers are also more dependent on their supplier networks and therefore more interested in standardizing quality management practices in the entire industry. These factors have led to a heightened awareness of the importance of quality management systems and to the enhanced development and enforcement of industry standards and regulations.

ISO 9001 establishes a standard for a Quality Management System (QMS) defining basic practices and procedures required for organizations to ensure that quality goals are systematically and consistently improved and sustained.

In the past, some organizations have established QMS procedures and forms separately from operations management efforts with a focus on passing audits and achieving required certifications. However, new ISO 9001:2008 QMS requirements continue to raise the bar. The new QMS standards require a higher level of demonstration of process control and risk management. Auditors must be able to navigate normal operations management processes and see evidence of policy enforcement mechanisms along the way.

This paper reviews the requirements of the ISO 9001 standards with a perspective on how modern software applications and information technology can be used to ensure compliance in different areas of the QMS standard. The QMS should be an integral part of the enterprise systems landscape architecture.

Instead of treating QMS compliance as a side initiative, organizations can take a new look at improving their business processes and enterprise systems to assure QMS compliance while optimizing the entire information flow in the organization. Filling gaps where necessary and integrating systems with risk management, process control and quality management in mind. The improved procedures and processes will not only satisfy compliance, but will also reduce cost, improve product quality, and ultimately improve customer satisfaction and the bottom line.
ISO 9001 and the Enterprise Systems Landscape

The ISO 9001 standards have been maturing over the last two decades and have become the standard by which Quality Management Systems (QMS) are evaluated and certified internationally across different organizations.

Many industries have contributed to the development of the ISO 9001 standard and several industry specific standards refer to ISO 9001 as their foundation. The following is a list of industry specific standards that expand on ISO 9001 requirements:

Examples of industry specific standards developed around ISO 9001:

- Aerospace - AS / EN / JIS 9100
- Automotive - ISO / TS 16949:2002
- Computer software - ISO / IEC 90003:2004
- Food and drink industry - ISO 15161 : 2001
- Medical Devices - ISO 13485:2003
- Telecommunications - TL9000 (-H for hardware, -S for software, -V for services)

Many manufacturing companies and regulatory agencies look to these international standards as part of the basics for their requirements. Certification to these quality management requirements have become competitive advantages and are common contractual requirements for suppliers to large manufacturers.
A QMS encompasses management processes for the following elements of the manufacturing process and the historical records required for analysis and audit of the system’s performance.

- Management Oversight
- Resource Management
- Product Realization
  - Requirements, Design, Plan, Product
- Measurement, Analysis, and Improvement

ISO 9001 describes “system” in Quality Management System (QMS) as the processes and procedures ensuring that the quality goals of an organization are systematically and consistently improved and sustained. The use of information systems is not part of the requirements in the standards; nevertheless information technology is often used in larger organizations to efficiently meet the enforcement and documentation required for compliance to QMS procedures. The next figure illustrates how different types of information systems overlap with the definition of the ISO QMS model.
The figure above relates functional areas in different information systems to the QMS model in ISO 9001. These functional areas can be used as a framework to review the use of information systems to support QMS and regulatory compliance.

- **Management Oversight**
  - Performance Goals
  - Audits, Corrective and Preventive Actions (CAPA)
  - Process Management, Communication and Workflow
- **Resource Management**
  - Program Management
  - Planning and Scheduling
- **Production Realization**
  - Product and Process Requirements Management
  - Product and Process Design Management
  - Supplier Management
  - Production Management
- **Measurement, Analysis, and Improvement**
  - Historical Archives
  - Dashboards and Alerts

There are two major flows of information in the QMS functional landscape diagram above: (1) the flow of information from Requirements through Product Realization to Aftermarket Services, and (2) the flow of information through a corporate continual improvement process for the product, manufacturing processes and the QMS itself. The underlying product realization processes are continuously feeding the process improvement loop—the two flows are interlinked.

Software solutions applicable to these functional areas include: Product Lifecycle Management (PLM), Enterprise Resource Planning (ERP), Manufacturing Execution System (MES), Manufacturing Operations Management (MOM), Quality Control System (QCS), and Supplier Quality Management System (SQMS).

Some niche software vendors specialize in certain industries, specific users and specific functional areas; others cover broad functionality footprints across multiple industries. Each company must decide on the best information systems combination to meet their goals and requirements. As illustrated by the QMS model above, in order to optimize the information flow for a complete quality management system, business processes spanning across engineering, operations and business information systems should be as integrated as possible.

Each functional area overlaid on the QMS model above is further described below along with how enterprise systems can support compliance with the respective QMS requirements.

**Management Oversight, Performance Goals, Audits, Corrective and Preventive Actions (CAPA)**

The management team is responsible for setting goals for the organization including goals for sales, new product introductions, and continual process improvement. The management team depends on good business intelligence and production data as the basis for decision making and goal setting.

The management team has the responsibility to establish and staff the QMS. Management must communicate the importance of quality management and regulatory compliance to the entire organization, periodically review
performance and audit reports to ensure that the QMS is performing adequately, and prioritize and approve corrective actions.

Corrective and Preventive Action (CAPA) could stem from audit findings or from follow-up on discrepancies found during receiving inspection or manufacturing. CAPA focuses on finding the root-cause of the discrepancy in order to prevent recurrence. Preventive actions are taken by extrapolating from one experience and applying lessons learned to other similar areas.

Management should review key performance indicators (KPIs) and customer feedback at planned intervals looking for opportunities for improvement. The organization should also conduct periodic internal audits and reviews of the QMS itself and act on audit findings with corrective actions to continuously improve the QMS. Management actions and projects should be documented and cross-referenced to the issue or correction action that each is addressing. Integrated information systems can provide an effective way to provide the KPI metrics required by management along with the tracking of process improvement projects and their effects on the related KPIs. The recognition of the link between improvement projects and better KPI numbers is essential to keeping the team motivated and engaged in the continual improvement process.

**Business Process Management, Communication and Workflow Control**

Information systems can be used to enforce procedural workflow for documentation, revision and approval activities. Activities can be automatically routed to responsible personnel based on pre-established workflow rules. Workflow for business process control can be automated within each ERP, MES and QC application and can also be enforced across applications and integrations with Business Process Management platforms.

Alerts mechanisms can automatically trigger communications to appropriate personnel when product configuration or production processes changes impact work-in-process or when specific warning conditions or thresholds are reached. Information systems can also route change and issue notifications to suppliers, approval requests to customers, and receive digital customer issues and warranty claims.

Data exchange standards from organizations including ISO, ISA, OAGi, and OpenO&M should be considered when architecting communications across applications and across the supplier network. Many software vendors have some level of support for these communication standards built into their commercial applications. If required, standards have extension mechanisms, and standards organizations are always looking for contributors to continue evolving the standards.

**Program Management, Resource Management, Planning and Training**

Based on goals set by management and demand for products, the organization plans facilities, resources and production. Many regulations have introduced the concept of risk management at several levels. Regulations like Sarbanes-Oxley focus on identifying potential risks to shareholders, and regulations like ISO9001 focus on identifying and mitigating potential risks throughout the supply chain and product realization processes that would lead to missing customer deliveries or product quality. Program management, capacity planning and scheduling practices must address and mitigate these risks. Integrated information systems can support the QMS and provide the required visibility of production status and resources to keep schedules optimized.
The organization needs to plan and manage product realization in a structured and controlled way to meet requirements at acceptable risk levels and within resource and schedule constraints. Activities to meet contractual requirements including delivery and post-delivery activities like warranty provisions, maintenance services, recycling, or final disposal services must be managed. A Customer Relations Management (CRM), PDM or ERP system provides a platform for managing contract requirements, and a SQMS can provide a cross-reference between requirements and verification procedures planned into inspections and audit processes for supplier management.

Each stage of the design and development process should have tasks defined with resources, responsibilities, inputs and outputs. Scheduling software helps plan the design and production tasks considering resources in order to meet target product delivery schedule.

Project risks related to new technology, new suppliers, or lack of experience or skill in certain areas must be identified and managed throughout product realization. A SQMS and a MES help mitigate certain risks and reduce variability in output from suppliers and manufacturing processes.

Personnel performing work affecting conformity to product requirements must be certified competent on the basis of appropriate education, training, skills and experience. Processes must be documented and standardized to facilitate training. The risks of learning curves can be mitigated for new product introductions and new processes by carefully planning training programs for new employees and tracking employees’ certifications for new processes in a Human Resources system. An MES or MOM system can link to this data to verify that the certification requirements specified on the job are met by the mechanic signing on to perform the job. In addition, the MES can maintain certification, on-the-job training, and proficiency records in relation to personnel history performing specific jobs and processes.

The work environment required to achieve product conformity needs to be managed including facilities, equipment, material handling, and communication and information systems. A Maintenance Management System (CMMS) helps keep track of assets and their preventive maintenance schedules.

**Product and Process Requirements Management**

The organization must determine product design requirements including criteria related to safety, reliability, availability, producibility, inspectability, maintainability, suitability of parts and materials, and disposal of the product at the end of its life. The requirements must consider customer needs and applicable contractual and regulatory requirements. Modern engineering Computer Aided Design (CAD) and PDM systems do not just manage the 3D design geometry of the product; they also maintain relationships to customer and engineering requirements. Requirements flow down to product specifications including key characteristics and tolerances that must be verified during production and inspection.

In addition to product requirements from customers, an organization also has contractual and regulatory requirements. An SQMS can ensure compliance by cross-referencing requirements to oversight procedures for audit of suppliers and verification and inspection of supplier parts.
Product and Process Design Management

Product design output must be validated against product requirements, and must be in a form suitable to enable verification of product against design during production and inspection. Design output must include product acceptance criteria including specifications for key characteristics of the product that are essential for its safe and proper use. 3D CAD models can embed this data as engineering requirements in the product structure. Native 3D CAD modeling applications are usually not practical for use by mechanics on the shop floor, however graphical work instructions tools can be used to create illustrations based on 3D geometry that are easy to navigate for manufacturing personnel and display the engineering requirements as annotations. 3D models and PDM systems can also be mined for product key characteristics that must be verified through inspection instructions in QCS or MES systems. Integration of these systems facilitates change information flow from engineering requirements to key characteristics to inspection plans.

Design activities must document risk assessment and mitigation through formal processes like failure modes and effects analysis (FMEA) and should strive for error-proofing processes. When error-proofing is not possible, early error-detection procedures should be part of the process instructions by calling out automated or manual inspection methods that verify required tolerance levels.

Design output must specify the data required to identify, manufacture, inspect, use and maintain the product including: drawings, 3D models, part lists, tool lists, and inspection criteria to ensure conformity of the product to design.

Design changes must be verified, validated and approved before implementation. The use of 3D simulation software allows early validation of the producibility of designs. The organization must also have product configuration management and change control practices. Design and development changes must be identified, executed and recorded according to the configuration management process. The use of a PDM system to control CAD models and product configurations satisfies the requirement for the product design, but change management practices must extend to manufacturing processes. The integration of PDM and MES software can ensure that engineering changes are incorporated into work-in-process as indicated by the effectivity of the configuration changes.

The integration of engineering and production systems also mitigates risks of production mistakes related to new product introductions and major product upgrades. It is important to clearly communicate changes to production personnel and make sure that work instructions for production processes reflect the latest product changes to avoid costly scrap or rework.

Supplier Management

Today's global manufacturers require information systems to manage the network of global facilities, partners and suppliers. Information systems used to manage supplier network transactions and collaboration may include PDM, Contracts Management, ERP, Warehouse Management System, Supply Chain Management (SCM), SQMS and MES solutions. When implementing and integrating these systems the following QMS requirements should be kept in mind.

The organization must evaluate, qualify and select suppliers based on their ability to supply product in accordance with the organization's requirements. Organization must periodically review supplier performance,
approval status and maintain records of the results of evaluations. Process certification bodies may be used to evaluate and validate the supplier’s quality management system.

The organization should establish and implement the inspection and oversight activities necessary for ensuring that purchased product meets specified purchase requirements. Verification activities may include inspection and audit at supplier premises, and records from suppliers including certificate of conformity, test reports, statistical records, and process control documents. Some verification may be delegated to the supplier based on prior performance, but suppliers must still be audited periodically because ultimate responsibility for meeting customer requirements falls on the top tier OEM.

A supplier portal on the web facilitates formal communications with suppliers. Purchasing information should include the following:

- description of the product with engineering specifications
- list of applicable revision of specifications, drawing, process requirements
- requirements for approval of product, procedures, processes and equipment
- requirements for personnel qualification
- quality management system requirements
- inspection/verification and test instructions including key characteristics
- record retention requirements

Supplier communication requirements also include the following:

- notification of nonconforming product
- defect containment alerts and shipping holds
- approval of nonconforming product disposition
- notification of changes in product/process definition
- changes of sub-suppliers
- change of manufacturing facility location
- corrective action requests and completion

An SQMS can provide a supplier communication portal and automate processes for oversight of suppliers including inspection of products received from the supply chain, documentation of discrepancies, defect containment procedures, and dispatch of corrective action and audits for suppliers.

**Production Management**

Design for manufacturability aims at creating products with simpler error-proof manufacturing processes, yet many manufacturing processes remain complex and subject to variability. Production management practices strive to deliver quality products on-time by reducing variability through standardization of repeatable processes and early in-process verification of critical product features. MES and QCS software help automate and institutionalize many of these practices ensuring compliance for many of the following requirements supporting QMS processes for (a) guidance, (b) verification, and (c) correction of issues.

**Guidance**

The organization must determine the need for manufacturing process documentation including work instructions, and required validation, monitoring, measurement, inspection and test activities for product
acceptance. Requirements for production documentation range depending on the product and industry requirements.

The organization should plan and execute production processes under controlled conditions including:
- availability of information that describes the characteristics of the product including drawings, 3D illustrations, parts lists, materials and product specifications
- availability of work instructions where necessary which may include task sequence, process flow charts, and inspection documents
- the use of suitable equipment including jigs, fixtures, moulds, and software programs
- availability and use of measurement and monitoring equipment

Common work practices should be documented as process standards. Standard practices and work instruction changes should be under revision control including changes to equipment, tools or software programs.

An MES and QCS maintain accountability for production quantity, split orders, and nonconforming product, and evidence that all production and inspection/verification operations have been completed.

Where traceability is a requirement, the organization shall maintain unique identification of the product throughout its lifecycle; for materials, the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch; for assemblies, the ability to trace components to each assembly and to the next higher level assembly.

The planned configuration of the product must be clearly described during production. At the end of production, differences between actual and planned configuration must be verified.

**Verification**

The characteristics of the product must be monitored and measured to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process and in accordance with the planned inspection instructions.

Inspections criteria would include
- criteria for acceptance and/or rejection
- inspection instructions specifying sequence within manufacturing process
- specific measurement instruments required and instructions associated with their use
- sampling plans
- method of recording measurement results

Authority identifications including stamps, electronic signatures, and passwords should be controlled.

Monitoring and measuring equipment should be maintained with a register and processes for their calibration/verification should be defined including details of equipment type, identification, location, frequency of checks, check method and acceptance criteria.
Correction

It is necessary to ensure that nonconforming product is clearly identified, and that a procedure exists to review and disposition nonconforming product. The organization deals with nonconforming product by one of the following ways:

- taking action to eliminate the detected nonconformity
- authorize the use, release or acceptance under concession by a relevant authority or customer
- take action to scrap or preclude its original intended use or application

In addition it might be necessary to take action to:

- communicate nonconformity to internal organizations, customers, suppliers, distributors or regulatory authorities
- mitigate the potential effects of the nonconformity when it is detected after delivery or first use
- contain the effect of the nonconformance on other activities or products.

Corrective actions must be taken to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions should be appropriate to the effects of the nonconformities encountered and can be prioritized by risk assessment based on severity and probability of recurrence. Corrective action procedures shall include:

- reviewing nonconformities including customer complaints
- determining the root-causes of nonconformities
- evaluating the need for action to ensure nonrecurrence
- approved plan of corrective actions to be taken
- records of the results of action taken
- if applicable, flow down of corrective action to suppliers
- identification of preventive measures that would avoid similar situation in other areas or product lines

Document and Records Control, Historical Archives

Quality policy, objectives and procedures must be documented, revision controlled, and readily available at points of use, and under revision control procedures. Procedures must prevent unintended use of obsolete documents. An MES can ensure that the latest work instructions and the latest engineering specifications are displayed to the mechanic.

Records of the execution of the QMS procedures including production and inspection records must be kept vaulted, archived and available for audits. History records must include nonconformity disposition, audits and corrective actions taken by the organization. Database of history records must prevent data loss, data tampering and provide redundancy mechanisms.

ISO standards also define guidelines for archiving electronic data to meet the integrity requirements of the old paper-based archival standards. Standards for archiving electronic documents include PDF/A for document archiving (ISO 19005-1:2005) and PDF/E for Engineering documents, and the newest ISO 32000-1.
**Measurement, Analysis, Dashboards, Alerts and Process Improvement**

QMS performance metrics should be designed to promote the ultimate goal of meeting customer requirements and satisfaction. Management dashboards and reports should include audit results, customer feedback, process performance, product non-conformity records, escapes found at customer inspection, and status of corrective actions.

A QMS database facilitates search and access of historical records and also provides data to measure the performance and effectiveness of the QMS. History records must include nonconformity disposition, audits and corrective actions taken by the organization. The recorded data is used to create QMS performance dashboards and reports in order to:

- demonstrate conformity of product to customer, regulatory and design requirements
- ensure compliance of the QMS to regulatory requirements
- continually improve the effectiveness of the QMS

The organization must monitor information relating to customer perception as to whether the organization has met customer requirements. Customer satisfaction information recorded and reported should include product deficiencies, on-time delivery, customer complaints, warranty claims, corrective action requests, and perhaps customer satisfaction surveys.

The organization must conduct internal audits and reviews of dashboards and reports at planned intervals to determine whether the quality management system is effective and conforms to the requirements of the ISO standard and the QMS requirements established by the organization. Corrective action must be taken and documented to correct deficiencies found during audits.

This completes the feedback loop back to the management team which takes action to continue improving the product and processes and thus the company’s ability to maintain satisfied customers and earn new ones.

**Summary**

In the past, some organizations established QMS procedures and forms separately or on top of regular operations management procedures in order to pass audits and get a required certification. Many older QMS processes focused on generating the paper trail necessary for evidence in a checklist-based certification process. However, the new ISO 9001:2008 QMS standards require more. The new standards are process-based versus checklist-based and require that a company walk auditors through normal every day processes demonstrating mechanisms that enforce disciplines dictated by the QMS requirements—disciplines that identify, manage and control any risk of missing quality goals throughout the entire product realization process.

Instead of treating a QMS as a side initiative required for compliance, organizations can take a new look at their existing business processes and enterprise systems to optimize not just QMS compliance, but optimize the entire performance of business operations. Perhaps filling gaps where necessary and integrating systems with risk management, process control and quality management in mind. The improved procedures and processes will not only provide compliance, but will also reduce cost, improve product quality, and ultimately improve customer satisfaction and the bottom line.
References

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