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Quality Management

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Create a culture of quality

Improve efficiency and customer satisfaction

Empower teams with a digital QMS

Plex, by Rockwell Automation Special Edition

Anthony Murphy
Brian Martensen

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Plex, by Rockwell Automation, is a leader in cloud-delivered smart manufacturing solutions, empowering the world's manufacturers to make awesome products. Our platform gives manufacturers the ability to connect, automate, track, and analyze every aspect of their business to drive transformation. The Plex Smart Manufacturing Platform includes solutions for manufacturing execution (MES), ERP, quality, supply chain planning and management, asset performance management, production monitoring, process automation and analytics to connect people, systems, machines and supply chains, enabling them to lead with precision, efficiency and agility. To learn more, visit www.plex.com.

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Introduction

In today's fiercely competitive business landscape, the pursuit of excellence is not just a lofty goal — it's an imperative for success. Businesses like yours understand the critical role that quality plays in building customer loyalty, optimizing operational efficiency, and staying ahead of the competition. That's why we invite you to embark on a transformative journey through the pages of this book.

Within these chapters, you will uncover the untapped potential of digital quality management as a catalyst for driving your organization towards unparalleled success. We dive deep into the world of QMS, shedding light on the essential principles, strategies, and tools that can elevate your quality efforts to new heights. Whether you're a seasoned quality professional or new to the realm of quality management, this book serves as a starting place, providing actionable insights and practical solutions to fuel your quality initiatives.

Discover how to unlock operational efficiencies, streamline processes, and enhance customer satisfaction by harnessing the power of QMS. From building a culture of quality throughout your organization to implementing robust measurement systems and continuous improvement practices, this book equips you with the knowledge and tools needed to thrive in today's demanding business environment. Written in the simple-to-follow *For Dummies* style, you will be able to get started on the path toward quality excellence.

About This Book

This book is an introduction to using quality management systems and how they are used to manage a culture of quality within your enterprise. Learn about how using a digital quality management strategy can help avoid some of the pitfalls of unhappy customers or product recalls. See how integrating a QMS with your factory floor can impact your bottom line, improve quality, and manage the supply chain effectively. Discover how using a QMS for reporting brings new insights that will impact your ability to

compete in a rapidly growing marketplace while giving company managers an overview about what's now possible with the Plex QMS product from Rockwell Automation.

Icons Used in This Book

Like most *For Dummies* books, you find icons in the margins that help you spot important information highlighted in this book.


TIP

The Tip icon points out helpful information.


REMEMBER

Find information marked with the Remember icon next to things you might want to file away for later use or remind you of important details.


WARNING

The Warning icon alerts you to information that will save you from making decisions that might be harmful.


EXAMPLE

This icon highlights how companies used Plex QMS from Rockwell Automation to improve their business processes.

Beyond the Book

Entire volumes could be written about the topics covered briefly in this small book. You may want to check out this additional resources for more information:

- https://www.plex.com/blog/quality-journey-part-1-digitized-quality-processes
- https://corporatefinanceinstitute.com/resources/management/quality-management/

IN THIS CHAPTER

- Understanding quality as a dynamic pursuit of excellence
- Creating a culture of quality
- Successfully developing a quality management strategy
- Automating quality management
- Adopting continuous learning

Chapter 1
Building Culture and Driving Process with a Quality Management System

It seems silly to say that a quality management program starts with developing quality as a mindset, but it's absolutely true. You must start thinking about quality when you're starting to implement the management system — it's not something you can just plug in at the end. This chapter discusses how quality permeates the entire manufacturing process, how you can drive quality into your organization's culture, supported by a digital quality management system, and gives you an overview of the benefits of implementing a digital quality management system.

REMEMBER

Throughout the book, we use the word continuous rather frequently. It is intentional. Continuous means an unbroken whole — it speaks not only to a spirit of never-ending improvement, of a drive for excellence, but of a culture and team that acts as one. Quality is not a department's job; it's everyone's job. It's only in

the building of a culture of quality that permeates the organization, in the spirit of never-ending improvement and the unbroken whole that manufacturers can truly thrive.

Getting into the Quality Mindset

Quality is the degree to which a product or service consistently meets or exceeds customer expectations. It encompasses various dimensions such as reliability, durability, performance, functionality, aesthetics, and customer satisfaction. It's about people, product, and process. It's about the quality of engagement with customers, communities, and others. Quality isn't a static concept but rather a dynamic pursuit of excellence that demands continuous improvement and adaptation to evolving customer needs.

TIP

Creating a culture of quality is about the development of both mindset and engrained processes.

Here are some key elements that form the foundation of a culture of quality:

- **Leadership commitment:** Quality begins at the top. Leaders must champion quality initiatives, establish clear quality objectives, and allocate necessary resources to ensure they are met.
- **Employee empowerment:** But simultaneously, building a culture of quality requires engaging and empowering employees throughout the organization. The culture of quality is an environment where employees not only follow quality guidelines, but they also see and hear others around them doing the same thing.
- **Ongoing learning and improvement:** A culture of quality thrives on a commitment to ongoing learning and innovation. Enterprises should foster an environment where employees are encouraged to explore new ideas, experiment, and learn from failures. Embracing a growth mindset and promoting knowledge sharing enables organizations to adapt to change, drive innovation, and maintain a competitive edge.

REMEMBER

While quality starts at the top, it is equally important that the quality culture permeates the entire organization. Then, quality extends beyond products and services and extends to everyone involved. It is both intentional and visible.

- **Process excellence:** Robust processes are the backbone of quality. Enterprises should employ process improvement methodologies, such as Lean or Six Sigma, to eliminate waste, reduce defects, and enhance efficiency. By continuously refining processes, organizations can enhance the quality of their products and services while optimizing resource utilization.
- **Focus on needs and preferences:** Leading manufacturers define quality metrics to include customers, the community, the environment, and products. By understanding and anticipating customer needs and preferences, organizations can align their efforts to deliver products and services that consistently exceed expectations.

REMEMBER

Building a successful culture of quality begins when you combine commitment from leadership with employee engagement.

Cultivating Modern Quality

Developing a quality mindset in a modern world will necessitate using modern quality tools. If you're still using an analog system to manage quality, it's time to make the switch to digital. Managing quality with pen and paper, outdated software, or even a spreadsheet can be time-consuming, error-prone, and inefficient.

TIP

By transitioning to a digital system, you can streamline your processes, reduce errors, and improve overall quality while improving the top and bottom line.

Quality management is an essential aspect of any organization, ensuring that products and services are consistent and of a desired level of quality. Meeting customer demand, regulatory requirements, and competing in an ever-changing global market all depend on maintaining a true culture of quality. You can take specific steps for implementing quality management and a strong quality management system:

- Digitize quality processes to introduce an elevated level of control, automation, tracking, and analysis that aligns with industry standards, without adding headcount or overhead.

- Make quality management inherent to workflows and processes to foster team engagement and help reduce quality loss and the risk of warranty issues or recalls.
- Focus on validating quality to compliance and error-proof production operations, with cross-functional reviews.
- Enable continuous learning and improvement through cross-functional continual improvement cycles with integrated quality standards and processes in a digital system of record.
- Increase visibility by centralizing quality information and documents, putting the right information in the right hands at the right time. Proper quality management connects information with people at every point in the organization and allows fast decisions and agile reactions to opportunities and obstacles.
- Improve data management by organizing and managing recorded data in real time, ensuring records are always in sync and obsolete documents are removed from circulation.

A modern quality management system (QMS) is a closed-loop digital system that drives an organization to ensure that its products and services consistently meet and exceed customer requirements and expectations. This living system is designed to proactively support, manage, and control all aspects of an organization's operations that impact product quality, including: design, development, production, governance, reporting, delivery, customer feedback, and support.

The QMS provides a framework for monitoring and improving quality across all areas of the organization, from supply chain management to customer service. This enables a holistic approach to quality while enabling efficiency, building a culture of quality in a circular, closed-looped, and intentional fashion.

REMEMBER

Build a culture of quality by engaging your team where they identify, develop, and implement meaningful quality goals that are appropriate throughout the organization and develop relevant processes throughout the enterprise. You manage this process through your digital QMS, making it easier to do the right thing the first time using real-time data.

Overall, a QMS is critical to a successful quality management strategy, improving business operations and helping organizations

meet the requirements of customers and quality management standards. By maximizing the capabilities of a strong QMS, organizations can move beyond simple compliance and create excellence and an elite supplier status.

A QMS can be tailored to meet the specific needs of an organization, but it generally includes the following elements:

- **Quality policy and objectives:** Defines the organization's commitment to quality and the goals it aims to achieve. Historically, this required a quality manual that encapsulates policies and procedures, but with digital systems, it's paperless.
- **Document control:** Ensures that all documentation related to quality management is updated, controlled, and stored appropriately, preferably digitally.
- **Training and competency:** Ensures that employees have the necessary knowledge, skills, and training to perform their job functions effectively and are continuously engaged to grow skill sets.
- **Process control:** Monitors and controls all processes that impact quality. This can include design and development to product and service delivery. It's these processes developed with a culture of quality consciousness that lead to excellence.
- **Risk management:** Identifies potential risks to product quality and implements measures to mitigate them.
- **Measurement and analysis:** Collects and analyzes data on product quality to identify trends and areas for improvement.
- **Continuous improvement:** Implements processes to continuously improve the QMS and ensure that it remains effective over time.

Automating Quality Management

One of the most significant advantages of a digital QMS is the ability to automate the processes and employee engagement that are essential to quality management.

Saving time and gaining accuracy

Automation can save time, reduce errors, and eliminate the need for manual data entry. With a digital QMS, you can automate tasks such as scheduling inspections, collecting measurements, creating reports, and implementing these metrics as a living part of your quality plan by making them shareable throughout the organization. This automation can help ensure that your quality processes are consistently applied, and that the recorded data is accurate. This drives efficiency within the workforce.

Gaining more insight

Going beyond the eight elements of a QMS, one of the most important features of a good QMS is that it takes your digitized data and drives data analysis, providing valuable company insights and fosters employee engagement. Automating your quality data collection means fewer errors from manual data entry and provides real-time results. Real-time control requires real-time access to data. No more waiting for the time-consuming manual processes to be completed. Without automation, it's not possible to fix problems in real-time. The speed at which businesses now operate requires real-time quality management and decision making.


TIP

Connect, automate, track, and analyze operations with real-time and actionable information for repeatable and consistent quality that permeates the workforce.

Abolishing the data silo

Data silos are a common problem in many organizations. They occur when data is stored in separate systems or departments and is not easily accessible by other parts of the organization. This leads to duplication of effort, inconsistencies, security issues, and errors. A digital QMS helps reduce the problem of data silos by providing a single and trusted source for all quality-related data. Having a single source of truth allows for the creation of trusted quality goals that are clear and actionable by everyone within the culture of quality. This unified approach is only possible using a modern digital QMS solution, particularly one hosted in the cloud for centralized data storage and retrieval.


TIP

Cloud-based solutions overcome the challenges of data siloes by engaging more people into both the process and culture of quality, from the plant floor through to customer support.

With quality key performance indicators (KPIs) in place, developed to foster a quality culture, a digital QMS supports quality growth through reporting on the successes and failures to meet these goals. This creates the circular path of continuous improvement.

Increasing visibility

A digital QMS helps increase visibility into quality processes. A functional QMS has real-time data dashboards, where you can easily:

- Engage team members
- Track metrics
- Identify trends
- Monitor performance
- Enforce compliance
- Take action

The increased visibility assists you in identifying areas that need improvement and allows you to make data-driven decisions to improve quality.

Validating quality

Validation is a critical step in ensuring that your quality processes are effective. Quality should not be subjective. There should be objective, attainable, and measurable goals that can be checked rather than guessed at. Validation reduces guessing. With a digital QMS, you can simply validate your quality processes by tracking and analyzing data.

Like visibility, validation can help you identify areas where processes are not meeting expectations or may be reporting inaccurate data. Once your data has been validated, you can then go about making necessary changes to improve quality.

Adopting Continuous Learning

Continuous learning is essential for any organization that wants to stay competitive. A QMS helps organizations achieve this goal by providing a framework for ongoing improvement and learning.

Continuously learning to improve quality that meets customer needs involves improving organizational performance by identifying, monitoring, and controlling processes, products, and services.

One of the important benefits of adopting continuous learning through a QMS is that it can help organizations to identify areas for improvement and take corrective actions to address them using the visibility and validation previously mentioned.

REMEMBER

Continuous learning develops employee skills that improve the bottom line by increasing efficiency, reducing costs, and most importantly, enhancing customer satisfaction.

Another important benefit of continuous learning through a QMS is that it can help organizations stay current with the latest industry trends and best practices. In today's fast-paced business environment, it's important to stay ahead of the competition by continually improving processes and products. A QMS program can help organizations do this by providing a framework for ongoing learning and improvement while assisting them in embracing a culture of ongoing improvement and learning.

IN THIS CHAPTER

- Understanding the Plan, Do, Check, Act Methodology
- Checking the results of your plan implementation
- Preparing for the next cycle of improvement
- Building effective cross-functional teams

Chapter 2
Executing the Plan, Do, Check, Act Methodology

The Plan, Do, Check, Act (PDCA) method is a proven approach to quality management that enables organizations to achieve continuous improvement. Originally developed by the father of modern quality, W. Edwards Deming, the PDCA method has gone through many changes over the years.

This chapter covers the continuous cycle of a PDCA method: Plan (identify a problem or opportunity for improvement and develop a plan to address it), Do (implement the plan and carry out the necessary actions), Check (evaluate the results of actions taken), and Act (take corrective actions).

Plan: Planning to Succeed

The *Plan* stage of the Plan, Do, Check, Act (PDCA) methodology is the first step in achieving continual improvement. This involves setting clear objectives and developing strategies to improve quality. It provides a roadmap for managers to align their resources, focus their efforts, and work toward achieving quality goals.

Identifying the problem or opportunity

The first step in the Plan stage is to identify the problem or opportunity for improvement. This could be a problem with a process, a product, or a service that the organization provides. Or, this could be an opportunity to improve a process, product, or service to better meet the needs of customers or to increase efficiency. The result of this stage is a clearly worded statement of the measurable goals of the plan that is easily understood by all.

TIP

Gather data and feedback from customers, employees, and other key stakeholders. This data could be in the form of surveys, customer complaints, suggestions, and feedback from employees who work with the process or product.

Developing an action plan

Once the problem or opportunity has been identified, the enterprise should develop a plan to address it. The plan includes specific actions that will be taken to improve the process, product, or service. The plan should also include timelines, resources needed, the responsible person, and the roles needed to accomplish the task, along with how the results of the action plan will be measured (metrics).

WARNING

Developing a plan without input from stakeholders, involved employees, customers, and management is doomed to fail.

During the Plan stage, it's important to develop a measurement/validation plan to establish a consistent and valid method of collecting and verifying data. This plan includes defining the metrics or key performance indicators (KPIs) that will be used to measure progress and evaluate the effectiveness of quality improvement initiatives. We talk about KPIs in Chapter 5.

By outlining this plan, you ensure that the data collected during the current state analysis is comparable to the data that will be gathered in the future state. It helps in maintaining consistency and reliability in the measurements, enabling a meaningful comparison between the two states.

The measurement/validation plan should specify the methodologies, tools, and procedures that will be employed to gather data accurately. It should also address potential sources of bias or variation, ensuring that the data collected is representative and valid.

PDCA IN THE AUTOMOTIVE, DISCRETE, AND PROCESS INDUSTRIES

EXAMPLE

Companies across multiple industries have successfully used the PDCA methodology as part of the continuous improvement process for a variety of processes in their organizations. For instance, manufacturing process improvements use PDCA to make incremental gains and control the pace of process change.

One automotive manufacturer used PDCA methodologies to determine the root cause of splitting material as a manufacturing process defect. Steel tubes were CNC turned for a diameter reduction and tears were occurring in the base metal at the tube's end during the turning process. Combined with metallurgical analysis, different process parameters were tried and analyzed for defects and the material structure was analyzed to ensure the process formed the part to specifications. Once the optimal tooling paths were confirmed, the CNC program was changed to the new parameters and scrap from material tearing was significantly reduced.

Food and beverage companies also utilize PDCA to improve their processes. One instance includes a final pack line, where the operator used the PDCA methodology to make significant ergonomic improvements to address worker fatigue that was causing quality issues. The operator experimented daily with different presentation heights for the material being presented for the final pack operations and recorded the results. After multiple iterations the optimal presentation height was determined and the process was permanently modified to help alleviate operator fatigue and increased throughput.

The PDCA process is a universal improvement methodology that is used for office and support processes, resulting in improved delivery, order realization, and customer satisfaction.

Validating the data ensures that any improvements observed in the future state can be confidently attributed to the implemented changes rather than external factors. It helps in assessing the impact of the quality improvement efforts accurately and drawing reliable conclusions.

Do: Doing What You Planned

The *Do* stage is the action stage of the Plan-Do-Check-Act (PDCA) methodology. The Do stage is a critical step in the PDCA methodology because it brings the plan to life and puts the organization on the path to continuous improvement.

TIP

To ensure your actions achieve your intentions, it's smart to begin with the future state so you know what you're trying to accomplish and then start small with manageable plans.

The Do stage is where you implement the planned changes. This could involve carefully changing a process, modifying a product, or improving a service. Importantly, make sure you document the process to ensure traceability and consistent change application.

The Do stage also involves training and development. Employees who are involved in the process or who will be affected by the changes should be trained in the new procedures or products. This ensures that everyone understands how to implement the changes effectively and efficiently and also creates a more engaged and informed team member.

REMEMBER

Training and development help ensure that employees are engaged in the process and feel valued, leading to increased motivation and productivity. Making the plan clear and then documenting the processes taken to accomplish the goals develops a culture of quality.

The final step in the Do stage is to monitor progress. Track the results of the changes as they are being implemented and compare them to the goal set in the Plan stage. Data should be collected and analyzed to determine whether the changes are effective. This is a little different from the Check stage, which tends to look at results after the fact. Monitoring the results tells you whether you are achieving the desired results and identifies any further improvements you may need.

TIP

It's helpful to document the current state before making changes (photograph and layouts, for example) so there is a record of change and that changes are easily identified by everyone involved.

Check: Validating Changes Along the Way

The *Check* stage is the third stage of the methodology and is where the results of the plan are evaluated. This stage involves measuring the effectiveness of the changes that were implemented and comparing the results to the original problem or opportunity identified in the Plan stage to determine whether any further improvements are needed.

TIP

In the Check stage, a robust QMS provides you with the data to validate the change results.

The first step in the Check stage is to refer to the validation plan identified in the Plan stage, which includes important details on what to measure, how to measure it, and the tools needed to measure the change. Then, measure the performance of the changes that were implemented in the Do stage. The QMS collects data and helps analyze the results. The data should be compared to the original problem or opportunity identified in the Plan stage to determine whether the changes have been effective.

TIP

A digital QMS creates a single source of truth — reliable and accurate data that ensures that the results are trustworthy. Validate your measurement system to ensure it's measuring data accurately before and after the change.

Once the data has been collected and analyzed, the results should be evaluated. This involves determining whether the plan was followed and that the changes have been effective. If the changes have been effective, the organization can move on to the Act stage. However, if the changes have not been effective, the organization may need to go back to the Plan stage and develop a new plan. This is what leads to continuous improvement.

REMEMBER

The goal of identifying further improvements is to ensure that the organization continues to improve and achieve long-term success.

The final step in the Check stage is to communicate the results to all stakeholders. This includes employees, customers, and management. By communicating the results, everyone involved in the process can understand the effectiveness of the changes that were implemented and any further improvements that are needed. Communicating the results also helps to ensure that everyone is

engaged in the process and feels valued, which builds culture by showing that the organization is dedicated to quality, the spirit of continual improvement, and building the culture of quality. That in turn can lead to increased motivation and productivity.

Act: Taking Action to Improve

The *Act* stage is the final and transitional stage of the Plan-Do-Check-Act (PDCA) methodology. The Act stage of the PDCA cycle is about taking action and making improvements based on what you've learned from the previous steps.

In this stage, you reflect on what worked well and what didn't. You analyze the data and feedback gathered during the previous steps and use that information to make decisions about whether adjustments or improvements are needed. Then, make a plan to try a different approach or modify your processes.

REMEMBER

The PDCA cycle is all about continous improvement. The Act stage helps refine and optimize the methods to achieve better outcomes.

Employing Cross-Functional Teams

Engaging cross-functional teams in the quality management process is crucial for achieving comprehensive and effective outcomes. By involving representatives from different departments or areas of expertise, organizations can tap into diverse perspectives and harness collective knowledge to drive quality improvements throughout the entire operation.

REMEMBER

Teams that bring together individuals who have different skills removes experience silos and leads to more robust problem-solving and decision-making, fostering a shared understanding and commitment to quality throughout the organization.

IN THIS CHAPTER

- Proactively meeting requirements using an effective QMS
- Complying with regulatory and industry oversight
- Introducing IATF 16949 for the automotive industry
- Achieving quality and alignment with food and beverage industry standards, such as SQF, BRC, and FSMA

Chapter 3
Keeping Up with Changing Quality Requirements

As quality regulations are more rapidly changing, it's essential for organizations to stay informed and implement effective strategies to ensure compliance. Organizations can thrive in an environment of rapidly increasing quality regulations by understanding the impacts of recalls, overseeing quality, applying ISO 9001, driving quality requirements with industry standards such as IATF 16949, as well as engagement in industry associations and technical groups to stay current with industry requirements and trends.

HACCP (Hazard Analysis and Critical Control Points) and FSMA (Food Safety Modernization Act) are two important sets of tools related to food and beverage quality and safety. HACCP seeks to identify, evaluate, and control hazards that may pose a risk to food safety and FSMA is food safety legislation that aims to shift the focus from responding to food safety problems to preventing them.

Adapting to Changing Requirements

Thriving in an environment of increasingly changing quality requirements requires organizations to be proactive in identifying and addressing potential issues before they become problems. This involves implementing effective quality management systems and processes, as well as regularly monitoring and reviewing performance metrics to identify areas for improvement. By taking a proactive approach to quality management, organizations can stay ahead of the curve and maintain compliance with the relevant quality regulation standards.

Some trends in quality management include risk-based auditing, which is a performance-based reduction of the number of audit days required during IATF audits, and the integration of quality management with other systems such as environmental management (ISO 14001), occupational health and safety (ISO 45001), and information security (ISO 27001). This integration promotes a holistic approach to organizational management and improves efficiency.

Quality standards are particularly important in all industries. It is no longer enough to simply comply with quality standards — what is compliant today may not be compliant tomorrow. This is why this book stresses that a culture of quality with a top-down and bottom-up approach allows a company to thrive and quickly adapt to changing industry and customer requirements. Building such a system can lead to:

- Customer safety, which runs across every industry such as food and beverage, medical devices, and automotive. Quality failure can lead to serious injury and death.
- Customer satisfaction, particularly in the automotive industry where a vehicle purchase is one of the largest expenditures people make and where quality issues are often communicated publicly. Continual quality issues cause the customer to either return products or spend significant time and effort in having their product repaired. Either option can be the first step in losing your customer base.
- Customer loyalty is driven by continually improving quality. Brands that suffer from poor quality lose their customer base and risk significant business losses.

REMEMBER

Thriving within an industry of increasing regulatory demand requires that you use a digital QMS and build a culture of quality.

Here are some tips for dealing with ongoing, rapid changes to quality regulations and requirements:

- **Understand the requirements.** Have a solid understanding of the requirements and regulations that apply to your industry and avoid penalties or fines.
- **Stay organized.** Keep your documentation and records up to date and well-organized to optimize your QMS performance and demonstrate compliance with the regulations and respond to any audit or inspection requests. This is the advantage of using a digital QMS.
- **Communicate effectively.** Use a cloud-based digital QMS to communicate outside the four walls of your organization and include suppliers, customers, and other key stakeholders, because transparency equals trust — even with auditors, transparency equals trust.
- **Train your employees.** Ensure that your employees are trained in applicable requirements and understand the benefits of meeting and exceeding these requirements, which include delivering high quality products and services to your customer.
- **Continuously improve.** Look for opportunities to improve your QMS. This ensures you are meeting or exceeding the requirements and your customers' needs.
- **Use the right tools.** A digital solution, like Plex QMS by Rockwell Automation, provides document management, issue tracking, corrective and preventive action management, a supplier and customer portal, and audit management. It also includes analytics and reporting features to help organizations monitor quality performance.

Understanding the Impact of Recalls

Recalls have significant impacts on organizations, including risks to consumer safety, financial losses, damage to reputation, delays in product delivery, and legal penalties. As such, it's essential for

organizations to have effective recall management processes in place to minimize the risk of recalls occurring and to respond quickly and effectively in the event of a recall. While the QMS should strive to prevent recalls and other quality interruptions, an organization is wise to implement effective quality control measures that include having clear communication channels and contingency plans that maintain product flow.

TIP

Recall management within Plex QMS by Rockwell Automation helps organizations reduce product recalls, handle targeted recall management, increase the speed of recalls preventing brand damage and financial loss, and ultimately leads to improved consumer safety.

Recalls in the automotive industry

In the automotive industry, recalls can have serious safety implications. A faulty component or system in a vehicle can lead to accidents, injuries, or even fatalities. Recalls not only affect the reputation and brand image of automotive manufacturers but also result in substantial financial costs and production and delivery delays. Companies may face legal liabilities, repair expenses, and compensation claims from affected customers.

REMEMBER

Consumer trust is the hardest thing to rebuild after a recall. Rebuilding consumer trust is challenging, as consumers may become wary of purchasing products from the affected brand.

Impacts of recalls on the food and beverage industry

In the food and beverage industry, recalls are primarily related to food safety concerns such as contamination, allergen mislabeling, or product nonconformity. The impacts of food recalls can be severe, posing health risks to consumers. Contaminated or unsafe food products can cause illnesses, foodborne diseases, or allergic reactions, resulting in harm to individuals and potential legal actions against the food manufacturer. As with other industries, recalls lead to financial losses due to wasted inventory, production stoppages, reputational damage, and lost business.

Requirements of a recall

In any industry, the impacts of recalls extend beyond immediate financial costs. Companies must promptly notify consumers about

the recall and provide instructions for returning or disposing of the affected products. Recall management also involves assessing the *root causes* of the issue, one of the important reasons to use a digital QMS. With a digital QMS, the root cause analysis process becomes streamlined and standardized. The system enables the systematic documentation of problem details, including symptoms, potential causes, and associated data. It facilitates the collection and analysis of relevant information, such as customer complaints, process data, inspection results, and corrective action history.

Applying ISO 9001

ISO 9001 is a quality management standard that sets the requirements for a quality management system. You can think of it as the foundation of other quality management standards. By implementing ISO 9001, organizations can improve their customer satisfaction, efficiency, and overall performance through implementing a quality management system based on the Plan-Do-Check-Act (PDCA) cycle (covered in Chapter 2).

Quality standards based on ISO 9001

ISO 9001 forms the basis of several other industry-specific standards:

- **IATF 16949:** IATF 16949 is tailored to the automotive industry, including requirements beyond those in ISO 9001.
- **ISO 9004:** Unlike ISO 9001, which is a standard for quality management systems, ISO 9004 focuses on providing guidance for organizational excellence. Its focus is on the satisfaction of interested parties and the organization's performance, but like ISO 9001 it focuses on continual improvement.
- **AS9100:** The guiding standard for the aerospace industry, AS9100 adds industry-specific criteria related to safety, reliability, and regulatory compliance.
- **ISO 13485:** The quality management standard for the medical devices industry, ISO 13485 has at its focus the design, development, production, installation, and servicing of medical devices. It also incorporates the principles of ISO 9001.

TIP

Additional regulations to be aware of are BRC, FSSC-22000, and SQF that focus on food safety, legality, and quality in the food industry.

Going beyond quality standards

While not directly related to product quality, ISO/IEC 27001 is a standard for information security management systems. It provides a framework for organizations to establish and maintain information security controls. ISO/IEC 27001 is also based on the structure and principles of ISO 9001, enabling integration with quality management systems.

TIP

When developing quality management standards and regulations it's best to begin with the fundamentals of ISO 9001.

Driving Quality Requirements with IATF 16949

IATF 16949 is an international standard that specifies the requirements for a QMS specifically designed for the automotive industry. It is based on the ISO 9001 standard but includes additional requirements that are specific to automotive suppliers. The IATF (International Automotive Task Force) developed this standard in collaboration with major automotive manufacturers and regional industry quality associations to promote consistent quality throughout the supply chain.

IATF 16949 covers a wide range of areas, including the basic organizational quality structure, risk management, product realization, measurement, analysis, and improvement.

REMEMBER

IATF 16949 places a strong emphasis on defect prevention, continual improvement, and effective control of processes.

A specific requirement of IATF 16949 that has a significant impact on automotive suppliers is the use of Failure Mode and Effects Analysis (FMEA). FMEA is a method for identifying potential failure modes in a product or process, assessing their potential effects, and providing prevention and detection methods. This analysis helps suppliers proactively identify and mitigate risks, ensuring that potential failures are addressed before they occur.

REMEMBER

FMEA emphasizes comprehensive risk assessment, detection controls, and detailed documentation.

Suppliers are expected to use the FMEA methodology and tools to:

- Confirm the structure and function of the product/process.
- Identify potential failure modes.
- Assign severity rating to failure mode.
- Analyze risk and determine occurrence, and detection rantings.
- Optimize the FMEA based on severity, occurrence and detection ratings.

PFMEA (Process Failure Mode and Effects Analysis) is a structured risk assessment tool used to identify potential failure modes in a process, evaluate their potential effects, and implement preventive measures to mitigate or eliminate them. The complexity of PFMEA requires that a digital solution be in place to provide the structure and data to proactively identify and prioritize potential failure modes. Integrated team collaboration built into a digital QMS is essential to success with PFMEA.

Overseeing Quality

Regulatory oversight plays a crucial role in ensuring the safety, quality, and compliance of products and services across various industries. Compliance using a QMS is a key aspect of regulatory oversight, as it focuses on maintaining consistent standards and process alignment throughout supply chains.

REMEMBER

Quality management is an ongoing journey, not a one-time task. Similarly, quality oversight is a dynamic process. To stay effective, it demands constant improvement and adaptability.

Changes in automotive quality oversight

The automotive industry is undergoing rapid transformation with the integration of complex technologies like autonomous driving, electrification, and connectivity. This shift necessitates stringent compliance with safety and quality standards to ensure the

dependable performance of vehicles. Consequently, regulatory certification and oversight bodies are proactively adapting and strengthening their measures to address the evolving technologies and associated risks.

Additionally, the globalization of the automotive industry has led to the establishment of harmonized regulatory frameworks across different regions. Organizations operating in the automotive sector must comply with various international standards such as ISO 9001 (quality management systems) and IATF 16949 (automotive QMS certification scheme).


REMEMBER

Adherence to regulatory standards through a digital QMS provides a common foundation for QMS compliance, enabling organizations to benefit from industry recognized best practices, streamline their businesses, maintain efficient cost controls, and demonstrate their commitment to quality. These are best made possible using a digital QMS.

Sustainability and environmental impact

The automotive industry is also under pressure to reduce its carbon footprint, improve fuel efficiency, and transition to alternatively powered vehicles. This shift requires organizations to implement effective environmental management systems (EMS) and comply with relevant environmental regulations. QMS compliance, therefore, encompasses not only quality and safety but also environmental considerations.

Food and Beverage Quality and Safety

Food and beverage safety requires organizations to implement effective quality management systems and processes and adhering to relevant food safety regulations and standards. This involves implementing effective quality control measures and regularly reviewing and updating quality management processes to ensure ongoing compliance with the relevant quality regulation standards.


REMEMBER

Keeping up with increasing quality regulation requires a proactive and continuous improvement approach. The only way you can identify, adapt, and stay ahead of regulatory oversight is by having a culture of quality.

Here are some of the food and beverage industry oversight regulations and standards:

- **Food Safety Modernization Act (FSMA):** Focuses on preventing foodborne illnesses by implementing preventive controls throughout the food supply chain.
- **Hazard Analysis and Critical Control Points (HACCP):** HACCP is an international system that identifies, evaluates, and controls food safety hazards.
- **International Organization for Standardization (ISO) 22000:** Provides a framework to establish and maintain effective control over food safety hazards.
- **Good Manufacturing Practices (GMP):** GMP regulations provide guidelines for maintaining sanitary conditions and quality control during food processing, handling, and storage.
- **Food and Drug Administration (FDA) Regulations:** Regulations and standards related to food safety, labeling, packaging, and handling practices.

Regulations establish guidelines and requirements for food handling, processing, and storage to prevent contamination. They outline standards for hygiene practices, facility sanitation, equipment maintenance, and proper handling of ingredients, reducing the risk of introducing harmful pathogens or contaminants into the food supply chain.

Regulations such as ISO-22000 emphasize the identification and analysis of potential hazards throughout the food production process. This approach enables you to proactively assess risks, implement preventive controls, and establish monitoring systems to minimize or eliminate hazards that could compromise food safety.

REMEMBER

The importance of traceability and recall management can't be understated. Food producers and distributors must maintain records to trace products throughout the supply chain and quickly identify and remove potentially unsafe products from the market in the event of a contamination or safety issue. This is most effectively done using a digital solution.

Lastly, inspections, audits, and enforcement actions are carried out to ensure compliance with food safety regulations. Non-compliance carries severe consequences that act as a strong deterrent and encourages businesses to adhere to food safety standards. This process is made efficient and cost-effective using a digital QMS.

IN THIS CHAPTER

- Infusing quality into enterprise culture
- Building teams for quality management

Chapter 4
Developing a Culture of Quality

Developing a culture of quality is important to the ultimate success of quality efforts in an enterprise. It's more than simple buzzwords. Building a strong culture of quality is both possible and rewarding; it improves quality and includes the workforce, stakeholders, and consumers in the quality process of continuous improvement, resulting in a positive impact on the bottom line.

Creating a culture of quality in a manufacturing company means fostering an environment where every member of the organization is committed to delivering high-quality products or services. As you might imagine, the idea of building such a culture is part of nearly every quality management system. It involves instilling a mindset of continuous improvement; one where everyone is encouraged to identify areas for improvement, take ownership of the quality of their work, and hold their peers accountable to produce higher quality.

In this chapter, we examine how organizations can develop a culture of quality that leads to success. We discuss involving everyone, creating cross-functional teams to define and implement

processes and KPIs, promote consistent communication, building continuous improvement, employee training, and rewarding success.

Involving Everyone

One of the key factors in developing a culture of quality is involving everyone in the organization. Quality is not just the responsibility of the quality department; it's the responsibility of every department. Employee development should stress the importance of quality, how their role contributes to the overall quality of the product or service, and how their work and the product contributes to the success of the company and even the broader community. This development includes courses on quality control measures, good manufacturing practices, quality assurance procedures, and training validation to confirm training and highlight any areas still needing development.


TIP

Begin your culture-building with communication. This communication includes collaboration and setting clear expectations for the quality you are attempting to achieve, along with the initiatives you're undertaking and how you'll measure progress.

Every employee should be encouraged to take ownership of quality within their role. This means they should be empowered to identify quality issues, report them, and take corrective action. This includes a bit of peer pressure by encouraging other workers to perform to the highest standards. After all, this is the very definition of a team effort. By involving everyone in the quality management process, organizations can create a culture of quality that is engrained in the organization's culture.

Sharing Responsibilities

So often, departments are silos when it comes to managing specific responsibilities. For example, problem-solving seems to always fall to the quality department to fix. But, for an organization to flourish, problem-solving needs to be cross-functional. A digital QMS allows all departments to collaborate and share in responsibilities.

REMEMBER

A digital QMS manages important tasks related to the quality process. Assigning roles, managing tasks, and collecting data on results are just a few of the many key features that streamline quality management.

Building Continuous Improvement

Continuous improvement is a critical component of quality management. This involves using performance metrics to drive improvements, FMEA optimization, lean initiatives, benchmarking to best practices, and embracing and implementing technology.

Continuous improvement should be engrained in the organization's culture. All employees should be encouraged to identify potential areas for improvement and contribute to the improvement process. This creates a culture of continuous improvement that leads to long-term successes such as:

- Building a culture of quality and fostering employee involvement.
- Setting clear quality objectives.
- Successful audits and assessments validating the effectiveness of the digital QMS.
- Implementing a framework such as PDCA.

EXAMPLE

SPECIAL PRODUCTS MANUFACTURING

Special Products Manufacturing (SPM) is a contract manufacturer specializing in metal fabrication, machining, electromechanical assembly, welding, and power coating. Prior to implementing Plex, SPM relied on an operationally focused quality management system that lacked robust reporting and metrics. This resulted in time-consuming processes, such as manual data entry and retrieval from various sources, leading to increased labor requirements and potential data entry errors.

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By transitioning to Plex QMS by Rockwell Automation, SPM automated previously manual tasks, significantly reducing time and labor needed to support various functionalities and operations. The integration capabilities of Plex allowed for seamless data flow across departments, resulting in enhanced data accuracy and eliminating errors caused by manual entry. This automation not only improved operational efficiency but also enabled SPM to determine automation opportunities throughout the organization, resulting in leaner operations, lower prices for customers, timely product completion, and the maintenance of high-quality standards.

Plex enabled SPM to adopt a just-in-time manufacturing approach, reducing lead times for customer parts during the manufacturing process. By utilizing Plex's forecasting features, SPM could accurately predict component lead times, enabling proactive purchasing based on forecasts and receiving materials precisely when they were needed. This capability optimized inventory management, reduced costs associated with inventory holding, and ensured timely completion of customer orders.

Using Plex's reporting functionalities, SPM gained valuable insights into rework, remake, and various other quality metrics both internally and externally. With this information, SPM effectively identified areas for improvement and communicated these insights throughout the organization. This organizational focus on quality, supported by data-driven metrics, resulted in a significant reduction in costs, achieving a remarkable 35 percent decrease over the past year. These cost reductions not only improved SPM's bottom line but also provided them with a distinct competitive advantage in the marketplace.

Implementing Plex QMS enabled the development of a culture of quality where plant floor workers collaborated with management to develop quality solutions. This improved culture has led to an improved Cost of Quality program with better on-time delivery and customer satisfaction.

IN THIS CHAPTER

- Managing the financial impact of quality
- Utilizing quality key performance indicators
- Reporting on quality through manual and automated inspection
- Tracking the quality of your supply chain

Chapter 5
Reporting Progress

Mastering quality goals requires more than just setting them; it involves showcasing your progress. By presenting reports on predetermined quality metrics and the metrics tied to nurturing a quality-driven culture, you can arm yourself with valuable insights and engage others, reinforcing the culture of quality. Elevate your efforts by leveraging your company's key performance indicators (KPIs) as a foundation for establishing quality goals. Harness the power of a robust QMS to meticulously measure your advancement, validate your achievements, easily share progress with the broader company, and pinpoint areas demanding extra attention for improvement.

Strengthening the Bottom Line with Knowledge

Quality impacts the bottom line. A QMS provides valuable insights into an organization's operations at every level, even those outside your organization by measuring supplier quality. Some of the financial metrics used to measure impact on the bottom line include:

- Cost of quality (CoQ) measures the cost incurred by an organization to achieve and maintain quality. It includes

training and quality planning costs, appraisal costs, failure costs such as rework, and warranty claims.

- Return on quality (ROQ) evaluates the financial return of investments made in quality improvement initiatives. It measures the impact of quality on profitability, customer satisfaction, and market share.
- Cost of poor quality (COPQ) focuses on the impact of poor quality due to rework, scrap, customer returns, warranty claims, and lost sales opportunities.
- Return on investment (ROI) measures the financial return gained from investing in quality improvement initiatives.
- Cost avoidance refers to the financial savings achieved by preventing quality issues and associated costs.
- Customer lifetime value (CLV) measures the total value a customer brings to the organization over the entire relationship.

REMEMBER

Data collected in your digital QMS can be analyzed by modern AI/machine learning systems for further insights. Knowledge-based AI systems can also recommend ways to improve outcomes.

Streamlining your operations through continuous improvement can save your company considerable money. Managing the quality process using data-driven insights can help you balance quality efforts against cost. For example, cutting quality at first may seem like it's saving the company money when in fact it may have greater impact on the bottom line.

Using Quality KPIs as a Knowledge Base

Quality KPIs provide a means to track and monitor the performance of various aspects related to quality management systems. By regularly reviewing and analyzing these KPIs, businesses can identify trends, patterns, and areas of concern and make informed data-driven decisions.

TIP

When creating quality KPIs, consider what you are trying to measure and what measures are important to your company. KPIs should be reviewed regularly as part of continuous improvement and management review.

Monitoring real-time manufacturing process data in a digital QMS alerts you to quality issues before they occur. Using leading indicators such as the customer satisfaction index and supplier performance allows you to predict and prevent quality issues. When quality issues or deviations from the expected outcome begin to occur, quality KPIs serve as a starting point for investigating the root causes of in-process quality indicators, such as high defect rates, cycle time, and first-time quality (FTQ), as well as lagging indicators such as customer complaints, cost of quality (CoQ), and warranty claims. A digital QMS also helps you track company and product growth through the monitoring of your KPIs. For instance, you can measure your issue resolution time and use that data to drive and confirm the improvement in your corrective action process.

Quality KPIs can be used for benchmarking against industry standards or best practices. By comparing KPI performance with peers or industry benchmarks, businesses can identify areas where they lag or excel.

WARNING

Be judicious when choosing companies to serve as benchmarks for your organization, as other businesses operate in diverse environments with varying quality goals and customer requirements. Only relying on benchmarking can lead to a narrow focus on surpassing competitor performance rather than striving for overall excellence.

Quality KPIs are a foundation for continuous improvement efforts. By setting targets and monitoring KPIs, businesses measure the effectiveness of improvement initiatives and assess their impact on quality performance. This knowledge guides the selection of improvement projects and helps evaluate their success.

Inspection Results

Inspection results provide key insights into the quality of the product or service being produced and help organizations identify areas for improvement.

Inspection reports document the findings, measurements, observations, and test results, allowing for verification of conformity to specifications, root cause analyses, and regulatory requirements.

Additionally, inspection reports validate process and product performance to specifications, serving as a tool to identify and predict non-conformances before they occur. This data feeds into many of your organization's KPIs.

Being attentive to the intricate details is extremely important. Inspection results in a digital QMS are essential for effectively managing non-conformances by taking the right actions to fix the identified issues and preventing these issues from reoccurring.

REMEMBER

Inspection reports provide a traceable record allowing for visibility, accountability, and continuous improvement.

Measuring Progress through Verification and Validation

Verification ensures that the product or service can meet the specified customer and regulatory requirements. It involves thoroughly examining and testing the components, processes, and outputs to confirm their compliance with established standards. On the other hand, validation focuses on ensuring that the product or service can be produced repeatably and reliably.

A digital QMS allows you to effectively track progress and ensure consistent adherence to quality standards and provides a centralized platform where all verification and validation activities can be recorded, tracked, and managed, allowing for the efficient storage and retrieval of documentation, test results, and customer feedback.

By using a digital QMS, organizations can monitor the progress of verification and validation activities in real time and share the results with the team enabling timely identification of any non-conformances or gaps in meeting the requirements. The digital system facilitates collaboration and communication among team members involved in the verification and validation process, ensuring seamless coordination and prompt resolution of issues.

Defect Tracking by Category and Analysis

Tracking and analyzing defects by category is a powerful tool for improvement. By categorizing defects and diving into the data, organizations gain valuable insights into problem areas. Using a Pareto chart, they pinpoint the crucial root causes that demand attention. With laser-like focus, efforts are directed towards tackling the vital few factors that wield the greatest impact on quality. This targeted approach drives meaningful change and propels continuous improvement.

Expanding Your Culture of Quality

Clear reporting and in-line quality are critical to the quality management process. An efficient QMS supports supplier management, allowing you to select suppliers with quality cultures that match your own culture.

TIP

Customer feedback is critical when managing quality data. A good QMS captures and allows analysis of customer feedback and satisfaction metrics as well as quality KPIs.

A digital QMS helps measure and manage employee engagement by capturing employee feedback, training records, and performance metrics, which also helps assess the effectiveness of employee development initiatives. Enhance employee engagement and create a culture of quality where employees are empowered and motivated to contribute to quality outcomes.

Plex QMS from Rockwell Automation provides capabilities to capture and analyze financial data related to quality. Some of the metrics, such as cost of quality (CoQ), quantify the total costs associated with managing quality, including defect prevention costs and failure costs. The return on quality (ROQ) metric assesses the return on investment in quality initiatives, comparing the benefits achieved from quality improvements to the costs incurred in implementing those improvements.

When measuring first-time yield (FTY), you learn the percentage of products or services that meet all quality requirements without requiring rework or correction. On the other hand, the cost of non-quality (CoNQ) captures the financial impact of poor

quality, including the costs of rework, scrap, customer complaints, warranty claims, and product recalls.

The defect rate calculates the percentage of defective units or services produced within a given period. Tracking defect rates helps organizations monitor quality performance, identify root causes, and implement corrective actions to reduce defects and associated costs. Gathering metrics on customer complaints and returns provides insight into the impacts on the bottom line.

Lastly, cost avoidance measures the savings achieved by preventing quality-related problems or failures. This metric assesses the financial benefit of proactive quality management and preventive measures.

EXAMPLE

SHANK'S EXTRACTS

Shank's Extracts manufactures extracts, flavors, and colors in addition to providing packaging solutions to commercial and food and beverage markets. Before implementing the Plex solution, Shank's Extracts struggled with capturing real-time production data, hindering its ability to make informed decisions. With Plex QMS, the company gained visibility into production activities, enabling accurate inventory control and management. Detailed information on raw materials, inventory, and production locations became readily available, allowing the company to monitor material usage, identify issues, and take immediate corrective action.

Plex provided Shank's Extracts with a comprehensive system to track customer information, production details, product data, and packaging. With real-time data accessible by lot number, production day, and more, the company could make better-informed business decisions. Employees with access to the system gained a critical role in the organization, understanding the importance of their tasks in achieving overall business objectives and supported a culture of quality.

IN THIS CHAPTER

- Making quality management a holistic endeavor
- Utilizing features of a QMS on the plant floor
- Introducing Plex QMS, by Rockwell Automation

Chapter 6
Putting QMS into Action

A QMS is crucial for customer satisfaction and continuous improvement. Don't be intimidated by their implementation; they're an absolute must for success. A well-executed QMS creates a culture where quality permeates every aspect of your business and quality naturally improves. Moreover, it becomes an integral part of your plant or factory floor operations, driving excellence at every step.

Extending Quality Management Holistically

Quality management is an essential part of an organization's business operations and should extend beyond the quality control department and integrate into every aspect of the organization. This holistic approach to quality management ensures that quality is everyone's responsibility and is essential in the organization's culture.

REMEMBER

In manufacturing, success is only as good as the materials you use. A QMS can make the enormous task of managing quality throughout the supply chain easier, providing end-to-end visibility and control over the manufacturing supply chain.

With a digital QMS, you are not only measuring outputs but measuring and controlling process inputs, which allows the opportunity to control outputs and use measurements as product validation. Additionally, the digital QMS allows you to improve correlation between your inputs and your ability to predict the output of your process.

Integrating QMS with the Plant Floor

Integrating your QMS with your plant or factory floor operations guarantees consistent application of quality management processes across the development journey. This seamless connection fortifies your commitment to excellence.

REMEMBER

Quality management should not be an afterthought in the production process. Begin the process early.

When integrating a QMS with the plant floor it's important to:

- Define clear KPIs to determine whether you're meeting your quality objectives.
- Use real-time data that enables real-time decision making, immediate response to quality issues, and makes it possible to predict future issues before they occur.
- Engage stakeholders who may have hands-on responsibility for plant floor quality.
- Get your QMS speaking the language your employees understand. Customize report language to create understandable and actionable insights.
- Provide training that makes the most of your investment in a QMS and improve employee efficiency.
- Drive adoption by actively engaging team members, fostering excitement about the potential of a QMS to enhance their work efficiency and simplify their tasks.
- Build in security to protect company-sensitive information.

TIP

Measure and monitor objectives by creating quality key performance indicators (KPIs) that can be measured in real-time. This is covered in more detail in Chapter 5.

Ensure that people working in operations understand the benefits and objectives of the QMS implementation and actively participate in the planning and implementation phases. Help your team understand their importance to quality within the bigger picture.


REMEMBER

A good QMS allows you to configure the system to reflect your industry's unique terminology and processes. Using familiar terms creates engagement and supports the adoption of a digital QMS.

Offer training and development programs to ensure that employees understand how to use the QMS effectively. Include training on data entry, data analysis, document management, recording non-conformances, initiating corrective actions, and generating reports.

A digital QMS has cybersecurity best practices built in, allowing you to store proprietary product and process information, as well as other private information such as production levels, bills of material, employee names, and much more.


TIP

When setting up security, define user access levels and permissions, implement data backup and recovery strategies, and adhere to relevant data protection regulations.

Integrating a QMS into the plant floor is a continuous process, as it requires ongoing support, periodic reviews, and updates to ensure optimal utilization and alignment with the organization and industry's changing requirements.

Creating a Living QMS

Invest time and effort to support your QMS and maintain its relevance to your operations through the continual use of the QMS to ensure it supports your operations and that the data contained in your QMS is relevant and accurate. Support your QMS's function to keep it alive, vibrant, and at the cutting edge of quality management.


REMEMBER

Unleash the full potential of your digital QMS by adopting an approach that treats it as a living product — as if the QMS is a de facto member of your team. Recognize that the foundation of a thriving QMS lies in its daily utilization, content maintenance, and the pursuit of continuous improvement. With comprehensive

solutions and expert guidance, you can seamlessly integrate monitoring, measuring, and the PDCA cycle into your organization, fostering a culture of excellence and driving sustainable growth. Embrace the transformative power of a dynamic QMS and revolutionize your approach to quality and efficiency in your operations.

Improving Processes Procedurally

In the dynamic realm of quality management, embracing a PDCA approach is crucial for achieving excellence. PDCA is covered in greater detail in Chapter 2.

This proactive approach to process improvement is a catalyst for continuous growth and advancement and maintaining a competitive edge. This is crucial for your operations. Aligning quality management processes with production ensures that every step is optimized, resulting in consistent, high-quality outputs.

Staying current and continuously improving processes involves several key practices. Regular reviews are vital, as they enable businesses to actively monitor and evaluate the effectiveness of their quality management systems. By conducting periodic assessments, potential quality issues can be identified early on, leading to prompt corrective actions. Additionally, staying abreast of industry and technology trends helps organizations anticipate changes and adapt their processes accordingly. In-house experimentation fosters innovation and provides opportunities to test and implement new ideas. Lastly, data plays a crucial role in process improvement. By collecting and analyzing real-time data, businesses can gain insights into their operations, identify areas for enhancement, and make data-driven decisions to drive continual improvement.

Discovering the Root Cause of Quality Issues

Discovering the root cause of quality challenges involves identifying the underlying cause or causes of quality problems. A few tools that help are:

- A Fishbone Diagram (Ishikawa Diagram) helps identify potential causes by categorizing them into major categories such as people, process, materials, machines, and environment. Categorizing these defects according to type organizes the potential causes of a quality event to help brainstorm for root cause identification.
- The Whys technique involves repeatedly asking "why" to uncover deeper layers of causes and reach the root cause of a problem. When you think you reached the end of the Whys analysis, you can read back the results using Because instead of Why to ensure your Why analysis reached the logical root cause.
- A Pareto analysis prioritizes potential root causes by analyzing data and determining which factors contribute most significantly to the problem.
- Correlation charts, such as the scatter diagram, analyze the relationship between two variables to determine whether there is a correlation or pattern.
- The histogram is a graphical representation of data that displays the distribution and frequency of occurrences that reveals patterns or abnormalities that may point to potential root causes.
- Failure Mode and Effects Analysis (FMEA) examines potential failures, their causes, their effects, and identify actions to prevent and detect the failure effects. It helps identify risk by assessing the severity, likelihood, and detectability of failure modes and drives product and process design to "design out" the failure mode.
- Root Cause Analysis (RCA) investigates and identifies the underlying cause of a problem. It involves techniques such as brainstorming, data analysis, and evidence gathering to uncover the root cause. Real-time data is particularly useful in this tool as it provides rapid feedback for verifying root causes and validating corrective actions.

REMEMBER

Environmental factors that affect your operation can play a part in quality. Temperature, humidity, dust or other contaminants and inadequate ventilation can all play a part in quality failures.

By discovering the root cause of quality issues, organizations develop more effective solutions to prevent the problem from recurring. Using a system that efficiently allows you to determine

root causes, such as environmental factors, can save the company money by limiting the time it takes to troubleshoot the issue and reduce the number of quality errors. As always, when the problem-solving process is completed, the QMS — including the corrective action, FMEA, and control plan — should be updated to capture the improvements and lessons learned.

Employing Plex QMS

Plex QMS by Rockwell Automation is cloud-based, providing a full-featured and centralized platform that is highly secure and fully digital. It includes:

- Built-in compliance and regulatory tools that support industry quality standards.
- Real-time data and statistical process control (SPC) for process monitoring, including tools to prompt the user to log trends and non-conformances for context when problem solving.
- Interconnected documentation, including linkage between PFMEA, control plan, and inspection checksheets, that allows the user to make one update that updates the relevant content in multiple locations.
- Tracks continuous improvement activities and houses all supporting documentation with the continuous improvement activity.
- Supports the Plan-Do-Check-Act (PDCA) cycle as identified in ISO 9001 and other standards.
- Other features such as:
  - Cybersecurity
  - Cloud-based/unlimited users
  - Real-time functionality updates (for example, compliance and regulatory updates)
  - Customer/supplier portals
  - Full QMS functions (for example, compliance, document authoring, in line quality, and continuous improvement)

IN THIS CHAPTER

- Using IoT in quality management
- Digitizing quality
- Following strategy tips for remote work
- Synchronizing quality and remote machine monitoring

Chapter 7
Eleven Trends and Tips for Integrating Your QMS

Increasingly, digital QMS sessions are aligning with other technologies such as advanced analytics, automation, artificial intelligence (AI), and Internet of Things (IoT) devices to enhance data-driven decision-making, process optimization, and real-time monitoring of quality parameters. By keeping up with industry trends your company can use the latest digital quality management systems to create visibility into processes at every level.

IoT in Quality Management

Integrating IoT into quality management processes can bring numerous benefits, such as enabling real-time monitoring, data-driven insights, and proactive quality control.

QMS & Remote Auditing

Auditors working remotely are faced with developing new procedures and methods to assess quality from a distance. Remote auditing offers several benefits, including the elimination of

geographical limitations, cost reduction, and increased flexibility. Remote auditors can collaborate seamlessly, enable prompt communication, and establish a centralized data source for audit evidence. Remote auditing of suppliers also allows your audit team to quickly review the supplier's organization and record features of the audit without incurring the travel expenses.

Quality Synchronization

Achieving synchronization between quality management processes and overall operations is key to success. By aligning your QMS with other business functions, such as supply chain management and production planning, you can optimize resources, minimize waste, and foster a cohesive quality-driven environment. This holistic approach ensures that quality considerations are integrated into every step of the value chain, resulting in enhanced performance and customer satisfaction.

Remote Equipment Monitoring

Advancements in technology have enabled remote equipment monitoring, providing real-time visibility into critical quality parameters. By using sensors, IoT, and cloud-based platforms, organizations can collect and analyze data from machinery anywhere and at any time. Predictive maintenance uses data analytics and machine learning to anticipate maintenance requirements. It can also reveal patterns that indicate potential equipment failures, which reduces unplanned downtime and prolongs the lifespan of your machines.

Foundation FMEA

Foundation Failure Mode and Effects Analysis (FMEA) is a powerful technique that identifies the baseline conditions for specific DFMEAs and PFMEAs. Foundation FMEA provides a head start by incorporating all the best practices identified by past products and processes into one document, which accelerates the development of new products and processes by ensuring these best

practices are incorporated into these new items. By incorporating FMEA into your QMS, you jump start your knowledge sharing for current and new processes, and you systematically analyze processes, products, and systems to identify potential quality risks at a macro, multi-disciplinary level. This enables you to take preventive actions, enhance product reliability, and optimize the overall performance of your organization.

Digital Connectivity

Integrating your QMS with machines and equipment through digital connectivity allows for real-time data exchange, process automation, and performance monitoring. This seamless flow of information empowers organizations to make data-driven decisions, optimize processes, and drive continuous improvement throughout the manufacturing cycle.

AI, Machine Learning, and Quality

AI and ML-driven quality management enhances process efficiency, optimizes resource allocation, and continuously elevates product quality. Modern machine-learning algorithms are a part of what makes this all possible.

Advanced technology, such as sensors, machine learning algorithms, and automated systems, identify quality issues early in the process. As soon as a deviation is detected, the system takes swift, automated steps to address it. For instance, if a nonconforming part is identified, it's promptly relegated to containment, preventing its integration into the production flow and ensuring quality standards are upheld.

Machinery also acts as a watchdog, continuously monitoring the production line for any signs of quality problems. If an anomaly or deviation is detected, the machine promptly alerts the operators, drawing their attention to the issue. This timely intervention enables operators to step in, resolve the problem, and rectify any potential disruptions to the production process before they escalate.

Quality & Cybersecurity

Protecting the integrity and confidentiality of quality-related data is essential to maintain trust with your company and your customers and prevent potential breaches that could impact product quality and proprietary information. Integrating cybersecurity measures into your QMS safeguards critical information, mitigates risks, and maintains the integrity of your quality management processes.

Asset Tracking

Asset tracking is the ability to track the location and condition of assets, which is essential for improving quality and reducing waste. Consider using automated tracking systems such as RFID tags.

Cloud-Based Tools

Organizations are recognizing the benefits of increased agility, collaboration, and data-driven decision-making that cloud-based quality management tools offer. Plex QMS from Rockwell Automation is a cloud-based software-as-a-service (SaaS) that brings with it the flexibility and efficiency of cloud availability. This availability supports the trend toward the building of an improved culture of quality.

Food Safety Modernization Act (FSMA)

If your organization works in food safety, you know about the Food Safety Modernization Act, which has a goal to prevent foodborne illness from happening. A digital QMS helps keep your organization on track with its nine rules that regulate the global supply chain.

ENSURE PREDICTABLE, REPEATABLE QUALITY

Rockwell Automation | PLEX

Meeting customer demands, maintaining regulatory requirements, and competing in a global market all hinge on one critical aspect of your manufacturing business – product quality. It can feel like you're swimming upstream when you're trying to sustain high quality levels while at the same time trying to reduce cost or find efficiencies. Luckily, it is possible to take control with the addition of an advanced quality management system in your toolkit.

- Meet industry compliance
- Adhere to customer regulations
- Drive business growth
- Improve customer satisfaction
- Reduce quality costs and risk
- Identify the root-cause of problems
- Enhance data management and visibility

Take the lead with a quality management system

With quality in the spotlight for manufacturers, many are turning to technology to help. A digital quality management system (QMS) is a catalyst for improvement that can elevate your quality effort to new heights. Whether you're a seasoned quality professional or new to the realm of quality management, this book serves as a starting place, providing actionable insights and practical solutions to fuel your quality initiatives.

Inside...

- Drive process improvements
- Execute the PDCA methodology
- Keep up with changing requirements
- Develop your culture of quality
- Enhance your reporting
- Put a QMS into action
- Leverage tips and trends

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