Qualityinfo

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Improve Risk Management and Quality Across the Value Chain by Increasing Visibility

Imagine building a brand over decades. Hundreds of millions of dollars invested in design and development. Sponsorships with celebrity athletes and professional and college teams. Leading-edge marketing making your company one of the top 20 brands in the world. It only takes one incident to unravel all this investment.

Nike found that out the hard way when Duke University superstar Zion Williamson ripped through the sole of his Nike sneaker 33 seconds into the grudge match with North Carolina. Williamson ended up leaving the game with a knee sprain, Duke went on to lose the game, and millions of viewers were left wondering if Nike's quality was up to par. The immediate reaction by investors the next day was a more than 1-percent drop in shares, equating to $1.1 billion in market value. Ouch... on so many levels. It's a reminder of how important product quality is to a company, the brand, and consumers.

Why quality management is critical

Quality is a foundation in the development and delivery of a safe and reliable product to consumers, which can be a key differentiator in the marketplace. It's important for organizations to create a formalized system of processes, procedures, and systems to manage quality policies on a continuous basis.

One of the key drivers elevating the importance of quality is the cost associated with poor quality. The cost of poor quality (COPQ) calculates more than rework and disposal costs. Organizations need to include planning delays, inventory shortages, retesting, employee overtime, complaint handling, customer returns, product recalls, and customers switching to competitive products.

According to iSixSigma, COPQ can reduce sales revenue by 15 to 40 percent. In a world where profitability is king, reducing the impact of poor quality is a top priority.

When organizations look at product quality, there tends to be tunnel vision in managing risks associated with producing a finished good. At first glance, the focus may be on preproduction planning, work in progress, and finished goods. However, quality is affected at every touch point in the product development process, from a supplier's parts or raw materials, internal manufacturing, or finished goods completed at co-manufacturer's or contract packaging facilities. Any issue at any one of these points can have a lasting impact on the product, brand, or the consumer.

Being proactive and identifying risks early in the process can help organizations manage product quality both internally and externally.

The importance of internal risk management

One of the biggest challenges organizations have is the dependence on manual and paper-based processes in an Industry 4.0 world. How are organizations supposed to leverage new technologies when they still manage quality, environmental, health, and safety (EHS), and other shop-floor processes with paper documents and siloed spreadsheet records? The risk of outdated procedures, missing nonconformance reports, and delayed corrective and preventive actions (CAPAs) leaves the company open for product failures, increased product recalls, and regulatory compliance issues and fines.

We have seen the benefits firsthand with many of our clints. We recently worked with a chemical company to update its paper-based data collection process so our system could directly interface with mobile and other shop-floor devices to collect data. It eliminated manual entry, which greatly reduced the time, effort, and data-entry errors common with the company's manual process. According to the project lead at the company, the biggest benefits have included a reduction in human error; improved security of data; and recognized savings in expenses, fees, and fines. Regulators have given kudos to the process and data improvements.

According to an Industry Digital Readiness Index study, 46 percent of employees waste significant time on paper-intensive processes, and 81 percent expect that digitization will streamline processes and improve document workflow. Now is the time for organizations to join the 65 percent of businesses beginning to digitize paper-based processes and automate workflows in a quality management system (QMS) to eliminate data silos and provide greater visibility into each step of the process. This also ensures that all handoffs and approvals are monitored and recorded to track accountability at each touch point.

Organizations also must integrate systems for greater transparency across the enterprise. That connectivity provides visibility into trends and issues that may need further investigation and corrective actions. When data are shared across enterprise systems, they provide greater insights into risks and disparate processes that can have a negative impact on product quality.

For example, food manufacturers must comply with a plethora of regulations to ensure safety and compliance. One of those requirements falls under FDA 21 CFR 110.10, which addresses personnel and disease control. There are similarities to the FDA Food Code 2001 as it relates to food employees, both current full-time and conditional job applicants; both regulations list the big four food risks: hepatitis A virus, *Salmonella typhi, Shigella,* and the Shiga toxin that produce*s E. coli*. Any employee who, by medical examination or supervisory observation, appears to have an illness or infection must be excluded from food operations until the condition is corrected.

Say, for example, a production-line employee at a food manufacturer tests positive for an infectious illness. The operations director can trigger alerts to production and quality managers to review the employee's shift schedule, identify production lots produced during that person's shift, and schedule sanitization of production areas. Assignments can be issued to specific employees and tracked within the system, and product can be quarantined in the enterprise resource planning system to prevent contaminated product from leaving the warehouse. This type of integrated data sharing enables users to proactively monitor risks and address issues earlier in the process to limit the exposure of the issue.

Organizations also need to create a risk management team with cross-functional members to develop product plans and standard operating procedures to identify high-risk areas that should be monitored and managed proactively. This ties into failure mode and effects analysis (FMEA) and hazard analysis and critical control point (HACCP) plans to prevent failures in the design or manufacturing process that could impact product quality. Automating these plans in a QMS enables audit reminders, plan analysis, and reporting to monitor and manage policies and procedures effectively.

External risk management

The next step is to enhance visibility outside the four walls of a facility to include value chain partners made up of suppliers, contract manufacturers, and packagers. Organizations need to have a greater focus across the quality spectrum—all internal and external touch points that affect product quality—to reduce the risk in the final product.

Organizations often have hundreds (or thousands) of suppliers and contract vendors, which makes it very difficult to monitor and track quality procedures outside the facility. In order to protect customers and a brand's reputation, manufacturers need to extend risk management and quality management to these vendors to verify that standards and requirements are being maintained.

Look for an automated QMS that provides supplier management functionality so users can store supplier and vendor information, such as contact information, certifications, and necessary documentation (e.g., safety data sheets, ISO 9001 certifications). This allows cross-functional users to easily locate information without having to rely on purchasing as their point of contact.

A vendor scorecard should be developed to record risk, performance levels, and audit ratings to determine the vendor's overall performance and reliability. Identify key performance indicators that are important for achieving on-time quality product, such as purchase order and delivery data, nonconformances, rework issues, and transportation delays. Monitor and share data with the vendor to build a collaborative partnership and resolve issues quickly.

Manufacturers can enhance visibility across the partner network by managing supplier quality in the same QMS they use for internal quality issues. Administrative users assign access permissions to vendor contacts to send nonconformance data and task assignments for follow up. This provides an audit trail across the value chain into issues and resolutions to support continuous improvement efforts by both parties. This type of collaboration reduces costs associated with COPQ and supports innovation, speed to market, and competitive differentiation in the long run.

A strong reporting tool will allow management to review overall results across the shop floor and value chain, and drill down into specific issues or trends to determine if further investigation is needed to manage a situation proactively.

When it comes to quality and risk management in a global marketplace where competition is strong and consumer expectations are high, perhaps the best advice is: *Just do it.*

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