RIGHT ON TIME

Why Businesses Need Quality Management System Software

environmental LEADER

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QUALITY & QUANTITY

Benchmark QMS

Establish enterprise-wide quality expectations
Identify risks, report concerns, & assign corrective actions
Manage employee training
Conduct audits
Maintain documentation

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INTRODUCTION

Ensuring top quality products and services requires businesses to invest time, money, and energy in improvements such as establishing new production processes, training employees, and audits. Although that outlay may be significant, the cost of poor quality products and services can be much higher. When quality suffers, organizations waste money on discarded materials, reworked products, handling product returns or recalls — and that's not even counting the loss of customers and PR fallout.

To prevent these kinds of losses, leading companies are turning to sophisticated quality management system (QMS) software. This type of technology allows organizations to meet their quality program expectations as well as conform to certification systems and high customer standards.

EHS, MEET QMS.

Those tasked with managing a company's environmental and sustainability efforts know they cannot operate in a vacuum: while they must, on the one hand, ensure that the company adheres to strict environmental, health and safety (EHS) expectations, they also understand that the quality of the company's products and services must remain high. Many are also coming to understand that, just as EHS software systems can simplify a company's overall sustainability management, so can quality management systems (QMS) software help a company meet its quality program expectations.

The two types of software dovetail nicely because QMS and EHS functions overlap in so many areas. For example, both quality programs and EHS programs must take into consideration elements such as audits and compliance, risk assessments, document control, employee training, etc. Additionally, the goals of each program are often aligned: improving a production process, for example, can lead to a be tter product while also reducing waste. And achieving certifications such as ISO 9001, ISO 14001, and OHSAS 18001 can benefit both quality and EHS programs.

Fortunately for the environmental manager, EHS and QMS software can be used together to manage and improve both environmental and quality programs in a way that supports and enhances each other, further streamlining overall sustainability management. And the IT needs for the two are

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Streamlining and digitizing the quality management process also provides a chance to finally leave behind inefficient paper-based systems and timeconsuming manual data entry.

Selecting and implementing QMS software can save an organization time, especially when recording nonconformities and preparing for key industry certifications.

QMS platforms centralize access, enable data analytics, enhance communication, and help foster confidence that quality issues are getting addressed quickly and properly rather than getting unintentionally delayed. QMS software provides document control, tracks employee training, and can prevent enormous losses caused by poor quality products or services. In short, using a holistic QMS platform to manage quality minimizes a range of organizational risks.

MEET THE MODERN QUALITY MANAGEMENT SYSTEM

Quality management systems, generally defined as a formalized set of policies, processes, and procedures that help an organization meet its quality program expectations, have been around for decades. The years after World War II saw the emergence of total quality management (TQM), a method for quality management that incorporated statistics and approaches that embraced an entire organization, according to the American Society for Quality, a global community of quality professionals. Then, in the late 20th Century, TQM gave way to "quality management systems" that took into account the multitude of systems that can be applied, the American Society for Quality points out.

Quality tends to be industry specific. In healthcare, for example, quality is synonymous with patient safety. For manufacturing, it may mean making sure that all the products are the same whenever they leave the lot. At service organizations, quality could be addressing a customer issue within a single visit. While the service representative or technician is there, he or she fixes the problem so it won't happen again.

QMS goes right to an organization's core business. These policies, processes, and procedures don't appear out of thin air. Each organization establishes them as a way to ensure the effective delivery of high-quality products, services, or both to their customers — whoever they may be. A QMS also helps organizations meet

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regulatory requirements, depending on the industry. In addition, quality management systems help organizations measure compliance with industry standards such as ISO 9001, AS9100, GMP, and TS that are known to evolve over time.

The way organizations actually design and implement their quality management systems may differ dramatically. Some rely on physical paperwork filed to cabinets. Others use spreadsheets and emails for documentation. In recent years, however, businesses large and small have turned to quality management software to digitize and streamline the process. Software features and industry focus vary by vendor, but the software generally includes the ability to establish quality program expectations, an approach for reaching specific goals, and a way to measure facilities. A system within the software defines corrective and preventative actions, sets closure targets, and ensures that actions get addressed in a timely manner. The system works in real time or near real time so that the organization's leadership has visibility to any issues as soon as they arise.

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The total cost of a new QMS platform depends on factors that include the organization's size, industry, and requirements for software functionality. Some systems come with hefty price tags, but it's important to consider how the investment will compare to potential savings. The right system should provide a remarkably advantageous return on investment, freeing organizations' IT departments from having to create and manage a new platform.

HOW QMS SOFTWARE IMPROVES PROGRAMS AND PROCESSES

Several years ago, a top mobility systems manufacturing and service company was still relying on a tedious manual system for recording quality issues. This diversified business with a global facility and customer footprint captured nonconformities using a combination of emails, spreadsheets, and even a finance system.

Previously, a service technician who had completed a repair like replacing a broken circuit board would send an email or enter details about the part failure into a spreadsheet. This process usually took about 10 minutes per visit, and the capture happened after the repair was completed or cumulatively at the end of the day. There was no guarantee that anyone on the company's manufacturing side

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would see these logs, much less respond right away.

The company's IT department started to work on creating an internal quality management system, but that effort stalled out. Instead, the leadership team began looking for new quality management system software. Before selecting the software, the mobility system company's leaders polled employees to find out which ones had the most interest in using new tools for capturing defects and resolving issues. The poll also asked the workers what they wanted to see in such a system. The software had to be easy to use because it would be deployed across the enterprise and utilized by thousands of employees. In addition, the software needed to have mobile capabilities that allowed for its use in the facilities where the company managed quality.

After the company's team selected a new QMS software from a vendor, the company piloted it in 2016. Feedback from that testing period allowed the software to be reconfigured to better meet the organization's needs. The final QMS was released a month after, and more than 1,000 employees were trained on the new system.

With the new software, quality employees could log issues and initiate corrective actions easily. Instead of taking 10 minutes, the process became as short as one minute using the software's mobile interface, according to one user. Plus, issues no longer got lost in an inbox or stuck in a spreadsheet. Not long after the company had implemented the new system, one of their service

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QUALITY 4.0

The fourth industrial revolution is here, spurred by smart manufacturing, robotics, and the Internet of Things. Generally acknowledged as Industry 4.0, this shift has also brought about advancements on the quality side. Welcome to Quality 4.0.

In a recent study, LNS Research found that innovation leaders are expanding into quality and driving advantage by:

- Utilizing connected devices
- Applying machine learning
- Adopting collaboration technologies
- Automating compliance
- Using apps that connect people and machine data

"Quality can and does play an important role in innovation," according to LNS Research. "Its core processes contribute to the successful launch of new innovations, and capture the seeds for future innovation."

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The Ultimate Quality Management System

A dependable QMS system manages the many high-risk activities involved with production. Our tools, developed by Environmental, Health & Safety and Quality experts with two decades of experience, help companies manage quality throughout the entire production & distribution lifecycle.

– It's the only tool you need for QMS –

technicians went to a training session having logged an issue the day before. During the training session, a member of the engineering manufacturing group actually called him up to say they had received his request, were fixing the part, and shipping a new one to him the next day.

That level of responsiveness enabled by QMS software, which didn't exist before, started to provide enormous value to the company's employees. They feel more confident that there's a network of people behind them that supports the quality program. It helps them perform their work better, delivering better service to customers. That service technician who got a call within 24 hours will no doubt head out to another repair job, but he's now going there with the knowledge that he won't have to install the same problematic part in the future.

Workers also had full visibility to quality issues across all the company's sites. Digitizing quality management meant that the company could perform data analytics on the issues logged. In the year and a half since the company implemented the software, they have collected more than 8,000 records from service technicians. By coding them, the company can now figure out which parts fail most frequently and address them by issuing what they call engineering change orders (ECOs). In other words, the problems identified through data analytic get engineered out. So far, they have been able to issue over 30 ECOs. Taking into consideration time and parts, the ECOs have saved the mobility systems company $16 million annually.

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KEY QMS FEATURES AND CONSIDERATIONS

Specific QMS software features may differ by vendor, but these platforms do offer similar core functionality. Let's take a closer look at the important aspects of features to consider before choosing a QMS platform.

Document Management
Most QMS platforms will have some way to create, approve, store, and distribute qualityrelated documents in a variety of file formats. The ability to host and collaborate on documents is key, especially the control aspect. Using QMS software, quality professionals can manage document versioning. Employees then know that the materials they're reading, whether training guides or specific procedures, have been fully vetted and are the most up-to-date. QMS software may include features such as the ability to manage permissions and access, create approval workflows, and assign specific tasks for each document.

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Centralized Access

The beauty of a digital system is that all the data becomes easily accessible globally. It's no longer tucked away in someone's inbox or a spreadsheet that could get lost by mistake. Data related to quality goes into a centralized place where quality leaders, floor managers, frontline supervisors, service technicians — anyone with the right access — can get to it and perform analytics. Some platforms are cloud-based, meaning that the vendor provides secure hosting for the software. This option may be attractive for organizations that want to avoid having to invest in new infrastructure and IT staff.

Speed

QMS software doesn't just connect quality professionals to tools. It also provides realtime or near real-time data to employees at other sites and to management so they can have a comprehensive view of the organization's performance. From the quality lead to the service technician to the manufacturing floor employee, the software gives everyone a way to report nonconformities right away. Then the employees in that department get notified immediately with a message so the issue can be addressed quickly. Easy-to-use dashboards and intuitive interfaces across devices shave time off the reporting process as well.

Employee Training

Organizations will have mechanisms in place so that workers get properly trained in the quality program and understand exactly what they need to do. If there's an expectation that a worker needs to be able to cut in a straight line, for example, quality suffers when that person can't do that. It's imperative to have a way to track employee training. QMS software assists with that through capabilities such as recording training histories for each employee and capturing details such as education level, job descriptions, and professional certification records. A QMS platform allows quality professionals to manage training initiatives as well as quickly identify and assess any gaps in training.

Automation

In this Internet of Things age, some QMS platforms can integrate with manufacturing equipment, adding smarts to the whole system. For example, a machine produces parts that are supposed to have 1 mm of size tolerance. Then, for some reason, the machine suddenly begins to send out parts that have 2 mm instead. In the past, it could take a long time to catch the off-spec products. However, as the machine produces parts in a manufacturing environment, it can perform checks on attributes such as size and shape, and feed that data to a QMS platform. Any time the machine sends out bad product, the system sends out an alert. Everything connects: Machine A talks to System B, which can notify a quality professional about off-spec products. That information could also be sent into the warehouse feed, allowing the team to do data mining later and improve production for the future.

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Offline Capabilities

Connectivity is an important factor in QMS software, not just to the internet for cloudbased platforms but among the machines and mobile devices that are part of the system. For years, businesses requested that QMS software have mobile capabilities, including apps for workers to record issues on the go from their smart devices. Over the past three years, however, there has been increased demand from organizations in certain industries for offline capabilities. Despite the internet's ubiquity, there are locations where a service technician may not have a cell signal. Natural gas pipelines, for example, can be in the middle of nowhere, beyond cell service. Similarly, repair workers might need to go down a hole or into a shelter that doesn't have any Wi-Fi. If the ability to capture quality data offline is a consideration, look for a QMS platform that has this feature.

QMS AND ISO 9001: 2015 CERTIFICATION

The International Organization for Standardization's 9000 family of standards addresses various aspects of quality management, and ISO 9001 is their flagship quality management systems standard. ISO 9001 was established to help businesses and organizations improve their products, services, customer satisfaction as well as meet environmental and organizational objectives, and comply with applicable regulations.

ISO quality management standards, including 9001, are based on seven principles:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

As ISO points out, the relative importance of each principle varies from organization to organization and is likely to change over time. Each principle has associated benefits such as increased revenue and enhanced collaboration. When applied, the principles typically improve an organization's performance.

There are nearly 2,000 individual ISO standards, and all of them get reviewed every five years to make sure they are staying relevant to the marketplace. In 2015, ISO revised the 9001 standard to focus more on managing processes using a plan-docheck-act approach rather than on prescriptive documentation of procedures and records. The changes stemmed from the rise of service-based economies and increasingly complex supply chains. ISO's revision emphasizes risk-based thinking, as not all processes have the same impact on the ability to deliver conforming products and services. Certified organizations have until September 2018 to transition to the revised ISO 9001 standard.

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The same ISO 9001 standard applies to all organizations that are certified to it, regardless of their size, or the products or services they offer. Although ISO doesn't carry out accreditations itself, certification by an independent external body can provide numerous benefits that may include higher demand for products and services. More than 1.1 million companies and organizations in over 178 countries have ISO 9001 certification, and they report being paid 7% more than those that lack certification. This particular certification is akin to a stamp of approval. For many potential customers, it's a selling point that demonstrates quality materials and services. One QMS software vendor points out that government agencies in particular use ISO 9001 as a filter for their contracts. Having certification can get a company over the early hurdles and that much closer to discussing details about timing and finances.

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In order for an organization to receive ISO 9001 certification, it must have an audit performed by an official, licensed certification body. ISO 9001 comprises several sections, each one concentrated on the requirements involved in different aspects of a quality management system. The use of QMS software doesn't guarantee that an organization will receive ISO 9001 certification, but having this type of platform will go a long way toward helping achieve and maintain certification.

QMS software vendors tend to match their applications and product features to the specific aspects of the ISO standard that the software can help facilitate. Having a control aspect enables an organization to manage document versioning so that everyone knows the training materials or procedures they're reading have already been vetted. Software tools that allow users to track nonconformities and perform data analytics help enforce the reporting and continuous improvement based on ISO standards. In terms of employee training, the software can certainly track that, ensuring that workers are meeting specific criteria to perform their roles well. That kind of feature also shows which professional certifications employees have in order to do their jobs.

One vendor's client recently used QMS software as part of a larger system to gain ISO 9001:2015 certification. This company was tracking findings and auditing nonconformities through the platform, which helped them prepare for the certification process. Without a digital system, providing evidence to an official certification body may take an

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extremely long time. Consider having to track down all that manually logged information. Access to data is inherent in a digital system, whereas with paper-based systems, spreadsheets, and email it's possible to overlook data. Because all the information gets digitized, whether that means training records or nonconformities, quality professionals can go into the system quickly, pull the data they need, and produce it for a certifying body. The vendor's client discovered that having QMS software made her job much less stressful than it otherwise would have been with a manual system.

CONCLUSIONS

Organizations that don't invest in modernizing their quality programs assume enormous risk. The true costs of low quality products and services — returns, recalls, warranties, waste, reworking, loss of customers, and the hit to the brand — can easily dwarf the cost of an investment in QMS software.

As we've seen, advanced QMS software provides organizations with a helpful way to establish quality program expectations as well as an approach to achieving goals that measures actual performance against those program expectations. QMS software allows businesses to maintain and manage important documents with centralized access to them. Organizations can use the software to manage corrective action plans as well as assign responsibilities, notifications, and escalations. Business leaders can also track training and qualification status for employees.

QMS software enables members of the team to report concerns and defects quickly as well as escalate key issues. In addition, the software helps companies perform data analysis for continuous improvement, which ultimately saves time and money. And finally, QMS software eases the process of pursuing or maintaining certifications such as ISO 9001 by putting nonconformity and tracking information at quality professionals' fingertips. The future of QMS looks more streamlined and connected than ever.

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