The Quality and Compliance Management Handbook — Supporting a Quality Culture Across Your Business

An investment in quality management will deliver an immediate return, while enhancing your organization's long-term prospects

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Foreword

A commitment to quality sits at the heart of every successful organization. Industry-leading enterprises in every marketplace have access to detailed data about their performance, and use those granular key performance indicators to constantly strive for improvement in every area of business.

In an era of increasing regulation in most, if not all, industries, detailed attention to quality and compliance is crucial if organizations are to meet their statutory obligations, withstand the rigors of inspections and avoid reputational and financial damage. But even in less tightly-regulated sectors, there is an increasing recognition of the value of quality management.

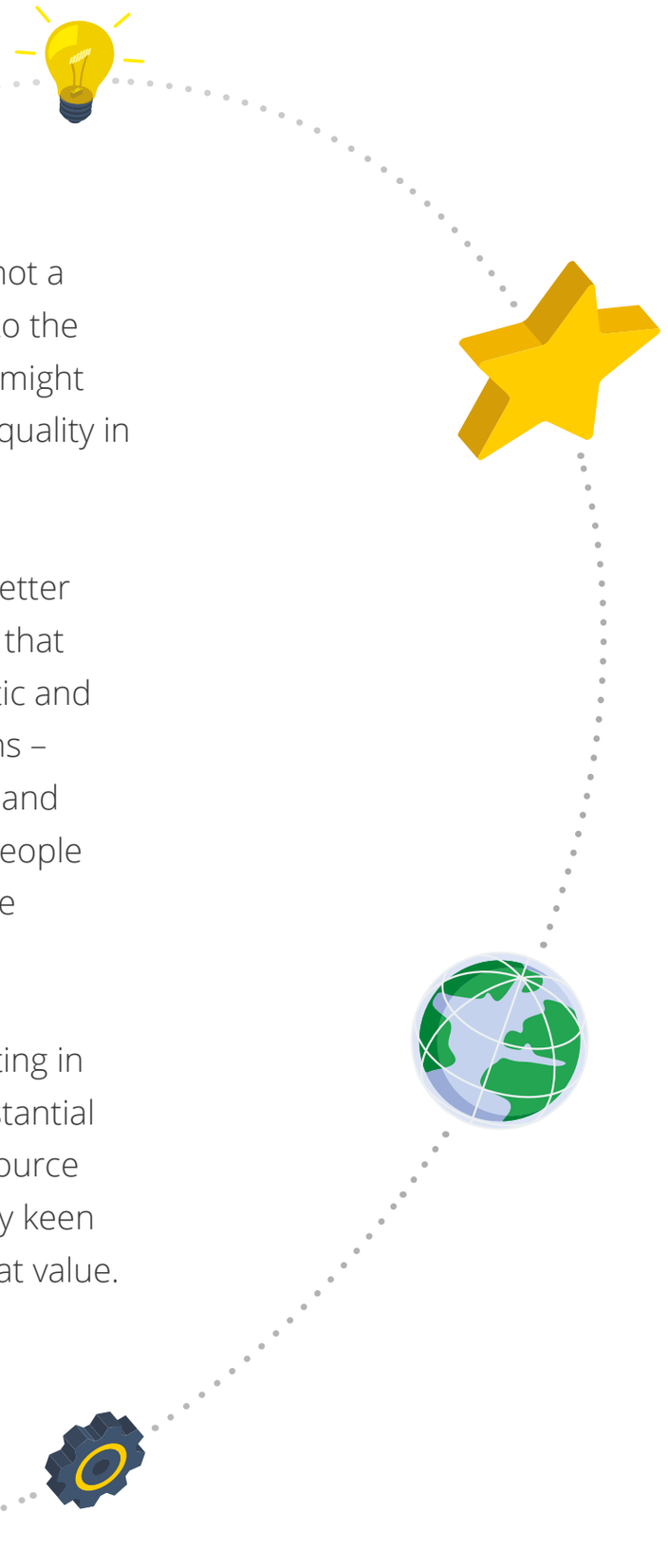
Indeed, look at the dynamic of quality management today, and the way in which regulations and and standards are changing, and you see a shift in mindset. Exemplified by changes in the ISO family of standards, major companies have begun to ensure that quality becomes a culture, that it involves every stakeholder in the organization – not just people involved in the quality function, but everyone.

The latest quality standards promote "risk-based thinking." Really, that means applying the concepts of risk to the processes that you already do. In fact, risk is common to many organizations – they may not speak in terms of quality in every area of the organization, but they speak risk. They've been able to normalize the metrics of how they meet their risk goals.

The big challenge now is how to implement risk, and many organizations have some trepidation about starting that journey. But the good news is that they're already doing it, and it is not a big readjustment to start applying that to the way they operate – to think about what might happen and how, and how to prioritize quality in the face of potential risks.

With more qualitative work producing better data, many companies have discovered that it is possible to be much more systematic and objective about how they make decisions – and to translate the concepts of quality and compliance to a much larger group of people across the organization so that everyone is involved.

The results speak for themselves. Investing in quality and compliance can deliver substantial savings – cost savings, time savings, resource savings – and organizations are naturally keen to minimize the time taken to secure that value.



> And as for return on investment, we've seen companies achieve first-year returns of up to

3,000%

Tim Lozier, Director of Product Strategy, EtQ

At EtQ, we're designed around delivering that visibility and control, while decreasing the time to value. We've had customers who have been able to save 600 man hours a year, just by automation. Companies that once required three people to do a job now find they can do that job with one person, freeing up time for more value-added activities. And as for return on investment, we've seen companies achieve first-year returns of up to 3,000%.

The broader measures of success are part of the big picture too. Organizations prioritizing quality management may be looking for many different things – a combination of automation, integration and collaboration, say – but the core drivers are visibility and control. Organizations want control of their processes and they want the visibility to make better decisions. Investment in quality management can deliver exactly that.

Tim Lozier, Director of Product Strategy, EtQ

EtQ's Tim Lozier discusses current capabilities and future trends in Enterprise Quality Management Systems

Watch now

Supporting a **Quality Culture** Across Your Business

Why should your organization commit to investing in a quality culture? Well, the aim of any systematic approach to ensuring and improving quality is to ensure the organization's products and services are always of the highest possible standard. That should produce substantial dividends in terms of customer satisfaction and therefore long-term sales revenues.

> A real and meaningful danger facing quality leaders is lip service to quality without a hard and fast commitment to quality at the executive level.
>
> **Dan Judge,** LNS Research

20%

Of annual revenues could be saved with QMS systems

American Society for Quality

However, if that benefit feels a little intangible, it's important to understand there are real and measurable returns on investment in quality. These returns comfortably outstrip the cost of investment. Indeed, the American Society for Quality estimates that the savings available to an organization that is able to use quality management to eradicate internal and external failures could be as high as 20% of annual revenues. Those savings come from avoiding costs ranging from wasted materials to dealing with customer complaints, and easily outstrip the expense of investment in quality management programs, software, training and testing.

Importantly, however, it won't be possible to secure those returns without the strongest possible commitment to quality from senior leaders in your organization. As the management specialist Dan Judge puts it: "A real and meaningful danger facing quality leaders is lip service to quality without a hard and fast commitment to quality at the executive level."

To confront that danger, the C-suite of the organization must work hard to promote a culture of quality, in which those responsible for day-to-day quality management are given the power and support required to drive operational excellence. That may require some tough decisions – a willingness to delay a product launch, say, or to incur higher production costs – but there will be long-term benefits.

Only in organizations that back quality leaders as they make those decisions will these benefits be secured.

What, then, does a commitment to a quality culture across your organization look like? To begin to put such a commitment in place, consider the following elements of a quality strategy:

Audit

Unless you understand what level of quality your organization is achieving – and how it is doing so – it will be impossible to design a strategy for improvement. For this reason, a continuous audit process is crucial to any organization that is serious about quality.

In practice, auditing is a way to check that your internal processes are working in the way they should – organizations should continually audit themselves throughout the year to ensure that this is the case. The outputs you'll monitor and the nature of the audits you'll conduct will naturally vary according to the individual characteristics of your business, but the aim should be to establish measurable and actionable key performance indicators that reflect performance across your organization's activities.

Some organizations fall into the trap of auditing on an ad hoc basis, or of failing to "join up the dots" so that they can assess performance in the round, rather than on very specific points. A quality management system with internal auditing tools can be an effective way to avoid this danger, providing configurable functionality and then delivering feedback that is simple to manage and track.

Your quality management system should also enable you to set out audit plans for the year ahead and to pull results into a single and comprehensive audit report that looks at quality across the whole business.

Document Control

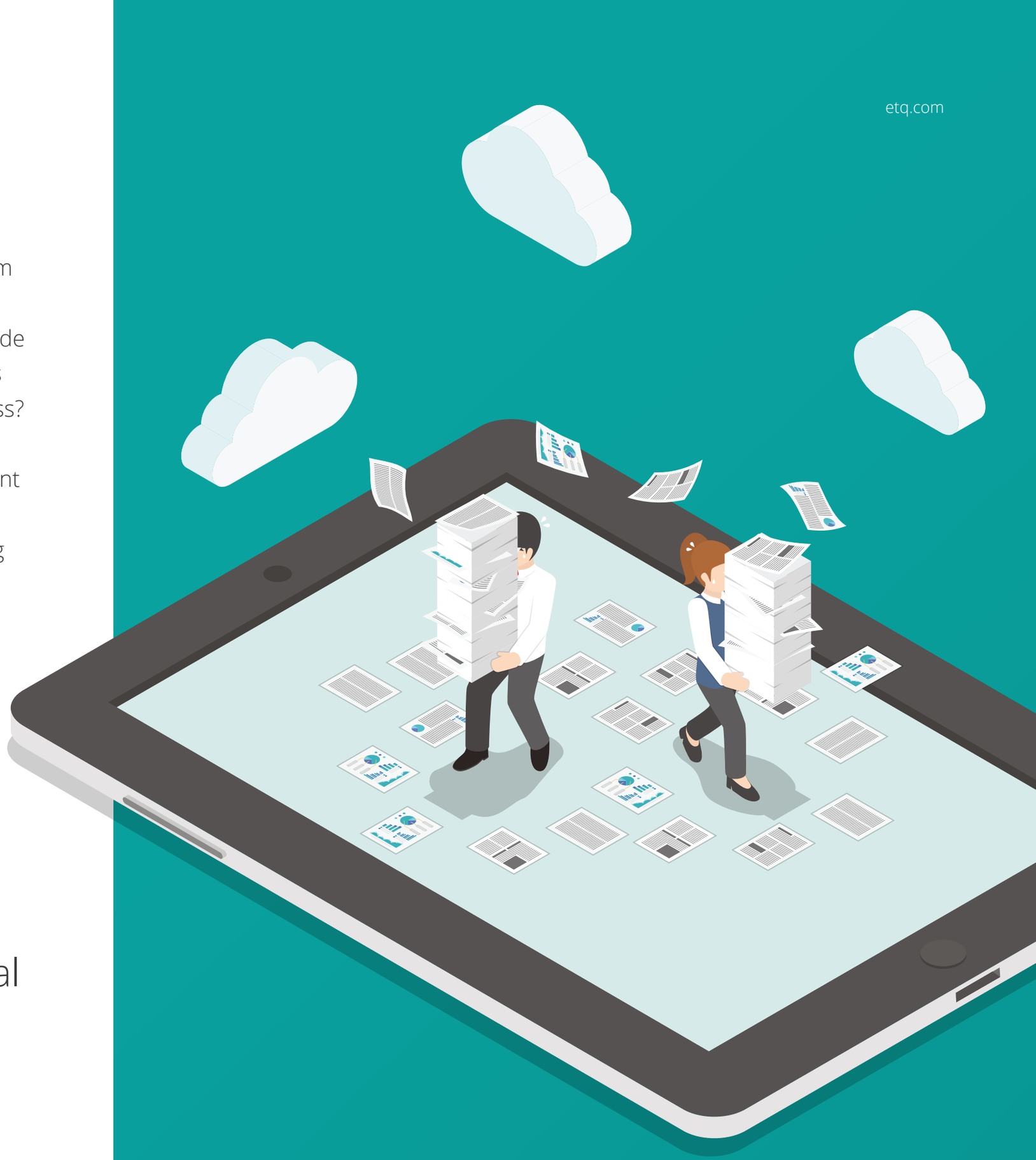
A good system for document control should be the foundation of your organization's approach to quality – it's where you'll manage and hold all of the crucial information around process and workflow, including policies, procedures and work instructions.

It makes sense to automate document control – manual interventions are time-consuming and can generate errors or lead to omissions. An automated document control system, by contrast, should make it simple for you to track documented processes, jobs, specifications and other mission-critical data and information. It will also help you to standardize processes and workflows to deliver greater consistency and reliability.

What you're aiming for is a system that will ensure documents are properly routed, reviewed and approved. You need to be sure that each document has been received and reviewed by all those employees to whom it is relevant, and approved for distribution in a timely manner.

Also think about how your document control system integrates with other elements of your quality management processes. For example, does it provide links to training, so that you can be sure employees are being properly trained on key aspects of process? Do updates made in one part of the organization automatically get included elsewhere for a consistent approach across the whole business? Are there standardized procedures for updating or amending key documents?

With such a system in place, your organization will have much greater control over every aspect of documentation, from the creation of key documents to change management, approval and training.



Corrective and Preventive Action

Corrective Action (CAPA) is how your organization will identify and eradicate adverse events – and seek to minimize the chances of such events recurring.

Such events might be anything from a customer complaint to a supply chain failure, but it's important to have an approach to Corrective Action that ensures your organization is making systematic and proportionate response.

The key to good Corrective Action (CAPA) systems is integration with effective risk management. The reality of day-to-day life for any organization is a series of issues and problems, but many of these can be dealt with immediately without triggering full-scale corrective action. If every event is treated with the same level of seriousness, the system will be overwhelmed and the organization will fail to identify the most pressing challenges.

Corrective Action solutions therefore need to include a risk assessment tool that is capable of prioritizing events and identifying those with the potential to have the greatest impact on the organization. These will be the events where corrective action is most crucial.

At this stage, the system should seek such action plans kick in automatically, with the right people identified to deal with the problem, and given specific deliverable actions in order for the corrective action to be successful.

Systems incorporating workflows and intelligent business rules can help streamline this process, ensuring the immediate problem is solved as quickly as possible and that a recurrence is made much less likely.

Make sure too that your approach to Corrective Action (CAPA) includes monitoring of effectiveness – checks that problems have been resolved as expected. If not, the system will need to be refined.

Change Management

The extent to which your quality management processes and systems are adaptable and scalable as the organization itself changes will be crucial.

Delivering quality is a continuous process, but no organization stands still – flexibility and adaptability are therefore crucial components of any quality management strategy.

Look to build processes and use systems that can be tailored to the unique characteristics of your particular organization – and re-engineered over time if necessary. The idea is to build a quality management structure that fits around the organization, rather than the other way round – and one that grows as your organization grows.

This will be particularly important if the organization itself goes through a period of considerable change – perhaps with new launches of products or services, ventures in new markets, or through an acquisition. Your quality processes should be able to support the organization through this change, rather than representing another challenge to be addressed.

Indeed, business change can often be a factor in the deterioration of the quality of an organization's output

– because it takes its eye off the ball while it is adjusting – so quality management through periods of transition is especially important. Reporting functions that provide quality leaders with ongoing and accurate feedback on performance will force the organization to keep its focus, even while dealing with distractions. These functions will also need to continue offering organization-wide reporting once the change is complete.

Employee Training

It's neither fair nor realistic to make demands on your employees if you've not made it clear what you expect of them – and kept them up to date on how those expectations are changing.

Effective employee training should be a key element of every organization's approach to quality – it's your opportunity to drive higher standards throughout the business.

In practice, this requires a systematic approach to training, through processes that are able to assess what training is required by each employee, to ensure the right training is delivered and then to evaluate its effectiveness. An automated training management tool can therefore be a crucial element of a quality management system.

This tool will need to be integrated with your organization's human resources database, so it has access to key data on employees, and so that training can be organized by department, facility or in any other way deemed necessary. It should also link to other elements of quality management, with training requirements identified and programs created according to the organization's ongoing needs and circumstances, and training delivery documented.

Testing, meanwhile, will enable your organization to assess whether employees are getting the right level of training delivered in the most appropriate way. Training systems therefore need to include a means for assessing what employees have learned – even with pass/fail tests – and identifying omissions, whether individually or across the organization.

Get this right and every employee has the opportunity to play their part in your commitment to quality, which really should be a mission for the whole organization.

Standard in **Focus** ⟶⟶

The ISO 9001 standard sets out criteria for best practice for the operation of quality management processes and systems, and is a valuable way for an organization to assess its ability to meet customer and regulatory requirements. The first iteration of the standard came into force in 1987, though there have been a series of updates including, most recently, the ISO 9001: 2015 revision.

For those organizations already certified to ISO 9001, there is now a three-year transition period – until September 2018 – to get certified to ISO 9001:2015. Those that fail to do so – or those looking for certification for the first time – will have to go through an entirely new audit and registration process.

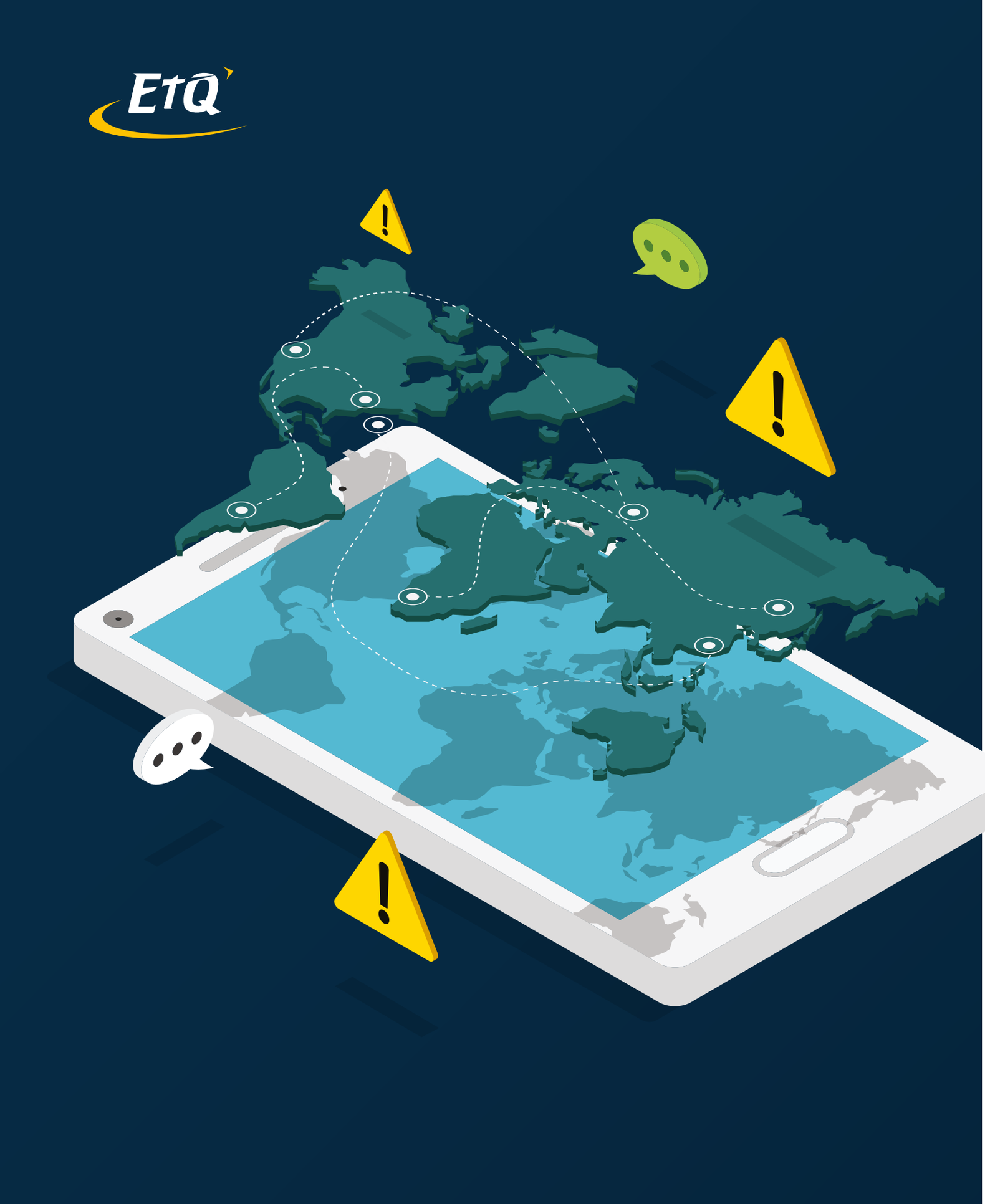
The standard offers organizations across all industries and sectors an opportunity to improve output quality, enhance efficiency and lower operating costs – and ultimately to secure better levels of customer satisfaction. It also offers positive benefits to leadership, management and supplier relationships.

“Another significant difference is that the latest version of the standard has moved from a focus on **“management leadership”** to **“leadership.”**

The 2015 update followed increasing recognition that customers now expect much more of the organizations with which they have dealings. But also, at a time when supply chains have become increasingly complex, new technologies are emerging, and issues such as sustainability and reputation management are to the fore, quality management systems must do more.

This has led to several key changes. For example, the 2015 standard now explicitly sets out a requirement for organizations to approach quality management through a clear process – the so-called PDCA (plan, do check, act) protocol. It also requires organizations to establish a systematic approach to consider risk, rather than adopting prevision as a separate component of a quality management system.

Another significant difference is that the latest version of the standard has moved from a focus on “management leadership” to “leadership.” The organization’s leadership must be accountable for the effectiveness of the quality system, ensure objectives are compatible with strategy, promote use of process approach and risk-based thinking and support relevant management roles.



The 2015 update has also introduced the concept of the **“context of the organization.”**

The idea is to encourage leaders and quality managers to think more strategically about the environment in which they operate, and the internal and external factors that may have an impact on the organization. The precise strategic imperatives will vary according to the nature of the organization, but it will be important to be able to show that quality management is fundamentally embedded in every part of the organization.

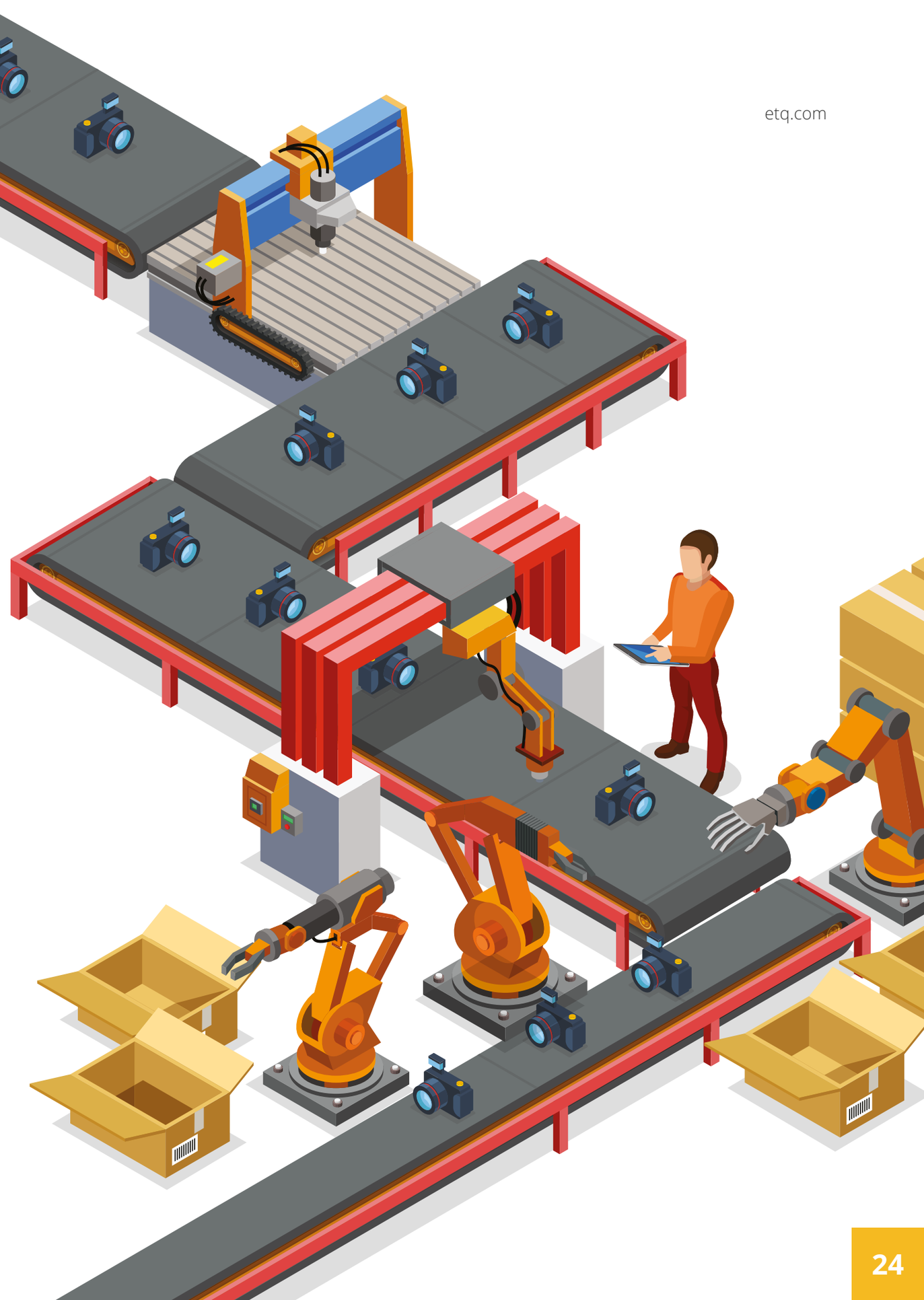
Case Study

Managing Quality and Compliance at FUJIFILM

Located on a 500-acre complex in rural South Carolina, FUJIFILM Manufacturing U.S.A., Inc. boasts five state-of-the-art manufacturing facilities for producing conventional and digital printing plates, one-time-use recyclable cameras, color photographic paper, medical imaging products and projection screen products.

Managing quality and compliance across these facilities proved a challenge for FUJIFILM. Each facility used different systems for managing document control, Corrective Action (CAPA) and change management. As FUJIFILM began to establish site-wide quality and compliance guidelines, unifying and coordinating these disparate systems proved difficult.

The solution, following an audit of its needs and a wide-ranging procurement process, was to introduce EtQ Reliance™, a flexible, integrated software package that guides companies through quality and compliance management. EtQ Reliance™ allows users to configure workflows, forms, sections, and fields, including the use of intelligent business rules, and even the look and feel of the application, all without expensive and time-consuming programming.



The company is already reaping the benefits. Since implementing the web-based compliance management system, it has combined its external audits into an integrated continuous assessment, greatly reducing the cost to maintain registration to both ISO 9001 and ISO 14001.

Administration time lowered from **1,500** hours per year to an estimated

750

“What made EtQ Reliance™ stand out in the end, was its broad range of features and ability to be configured, which will enable us to change our system as our company grows and expands,”

Chuck Brinck, of FUJIFILM Manufacturing U.S.A., Inc.

As a result of systems consolidation, FUJIFILM reduced its number of servers from seven to three, and reduced the number of software products to accomplish document control, corrective action, and change management processes from five products to just one – EtQ Reliance™. Most notably, it lowered administration time from 1,500 hours per year to an estimated 750 hours and reduced overall yearly maintenance agreements by approximately $60,000.

Innovation Trend

The Internet of Things

> “The Internet of Things is reshaping or redefining industry practices.”
>
> **Dan Bigos,** of IBM

The Internet of Things, the rapidly-growing network of connected devices, is already having an impact on all our lives, but as well as consumer-facing applications, this technology has the potential to transform quality management. With sensors and monitoring devices installed in critical areas throughout the supply chain and production process, argues Dan Bigos of IBM, “the Internet of Things is reshaping or redefining industry practices.”

There are many possible applications that could make the lives of quality managers far simpler. For example, the Internet of Things offers an opportunity to detect at the earliest possible stage when sub-standard materials have been introduced into the supply chain, or when the attributes of a product have deviated from specific quality criteria. That enables organizations to intervene very rapidly, saving time and money costs that would have been incurred when the problem came to light later on.

Internet of Things technologies can also be used to monitor the production line – for example, to sound an alert if equipment is no longer functioning within a specific range, which might indicate a problem with the set-up or an impending breakdown. This enables quality managers to identify problems at source and to intervene before a costly outage occurs.

Another area now being explored by many organizations is robotics and artificial intelligence. By automating their operations, organizations often secure greater consistency and reliability, while AI offers the opportunity for smart production processes that deliver greater quality over time as the equipment “learns” from its work and the environment – Internet of Things technologies underpin this learning experience, providing the automated production line with constant feedback about the quality of its output. Risk management solutions such as complaint-handling can act as an important input source, to develop the business case that will identify what to monitor and where to make investments.

Beyond the production process too, the Internet of Things is beginning to have a substantial impact on quality management. With connected sensors built into increasing numbers of products – whether for consumers or business customers – it is possible to assess how the organization's products are performing, whether customers are using them in a particular way, and where problems are occurring. Using this feedback to improve future production, organizations can gain a competitive advantage over rivals that lack such data.

Overall, the Internet of Things now enables quality managers to take a much more proactive approach to their work, continually making improvements to the organization's processes and systems in order to deliver better performing and more reliable end products. This technology promises to be a valuable quality management tool.

Frequently Asked Questions

Why does quality culture matter?

The long-term dividend from investment in quality will be stronger relationships with customers, improved reputation and enhanced growth prospects. In the short term, however, quality failures, whether internal or external, create substantial costs.

What if my business isn't regulated?

In regulated industries, the focus on quality and compliance ensures businesses are able to meet their statutory responsibilities, but the broader benefits of quality management system include a rapid return on investment and an improved long-term outlook.

Do I need a quality management system?

The right quality management system for your organization will offer a modular approach that enables you to monitor performance and problems in each relevant area of your business, with automated processes and strong record-keeping.

Is this something even small organizations should consider?

Yes – put systems and processes in place that are appropriate to the size and nature of your business, but quality management should be a priority for all organizations. An adaptable and scalable approach will support your organization as it grows.

How can quality management systems help when social media users pick up a quality problem?

Social media now plays a huge role in disseminating product information. So quality problems can now be propagated rapidly, and that's a challenge for any size of organization. If it was then discovered that the organization did not have a quality system in place, the impact on customer confidence and business performance could be considerable.

What if we don't have the right IT infrastructure to support such systems?

Cloud-based Software-as-a-Service solutions give every business access to sophisticated quality management systems that will support their organizations effectively.

Industry Tearaway – A Quality and Compliance Management Checklist for Your Industry

Quality management encompasses a broad range of functions and attributes.
Has your organization considered the following?

Complaint Handling

How are you managing the investigation and resolution of customer complaints, with record-keeping that ensures you comply with any regulatory responsibilities and learn lessons for the future?

Corrective Action

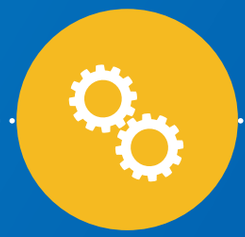
Do you have automated corrective action processes that will enable the organization to move more quickly to solve problems?

Supplier Management

Have you set up scorecards that contain both qualitative and quantitative elements for assessing supplier risk?

Audit

To what extent is the process of auditing and surveying risk and quality in the organization automated?



Change Management

Are processes in place to ensure change is well-managed, with rapid response to requests from a broad range of potential stakeholders?

Training

Do you have systems in place to map employee training to quality management processes, and to ensure all employees remain knowledgeable and informed?

Document Control

What systems are in place to manage the creation, approval, distribution and archiving of all controlled documents?

Enterprise Risk Management

Are users of quality management systems able to assess risk and group them into templates?

Reporting and Analytics

Do your quality management systems provide real-time business intelligence that enables you to respond to quality issues rapidly?

Data Management

Are you able to access the data required to make compliance submissions and monitor performance?

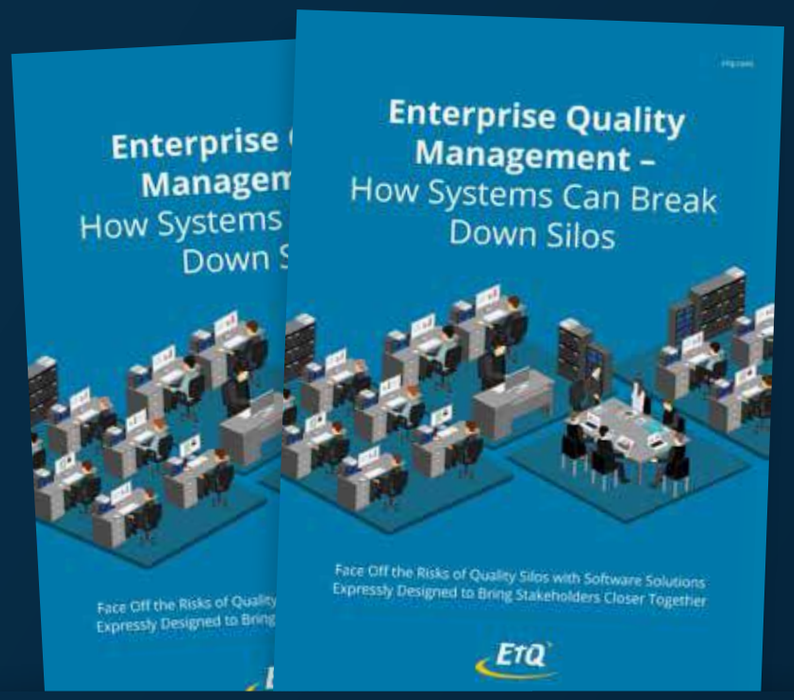
Takeaways

Quality management systems deliver an immediate return on investment.

Quality management systems can help your organization meet its regulatory and compliance responsibilities.

Quality management systems will help you embed a culture of quality throughout your organization.

Quality management requires a commitment to continuous improvement.



Find out how to break down the silos that stand in the way of enterprise-wide quality culture by downloading our free eGuide

Enterprise Quality Management – How Systems Can Break Down Silos

Download the eGuide now

About EtQ

EtQ is the leading Quality, EHS, Operational Risk and Compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. At the core of EtQ's framework is a compliance management platform that enables organizations to implement best-in-class compliance processes configured to meet their existing processes, create new compliance processes and automate and control their compliance ecosystem. EtQ's product lineup includes Traqpath™ for individual compliance users, Verse Solutions™ for small to medium sized businesses and Reliance™ for enterprise organizations. EtQ was founded in 1992 and has main offices located in the U.S. and Europe. To learn more about EtQ and its various product offerings, visit www.etq.com or blog.etq.com.