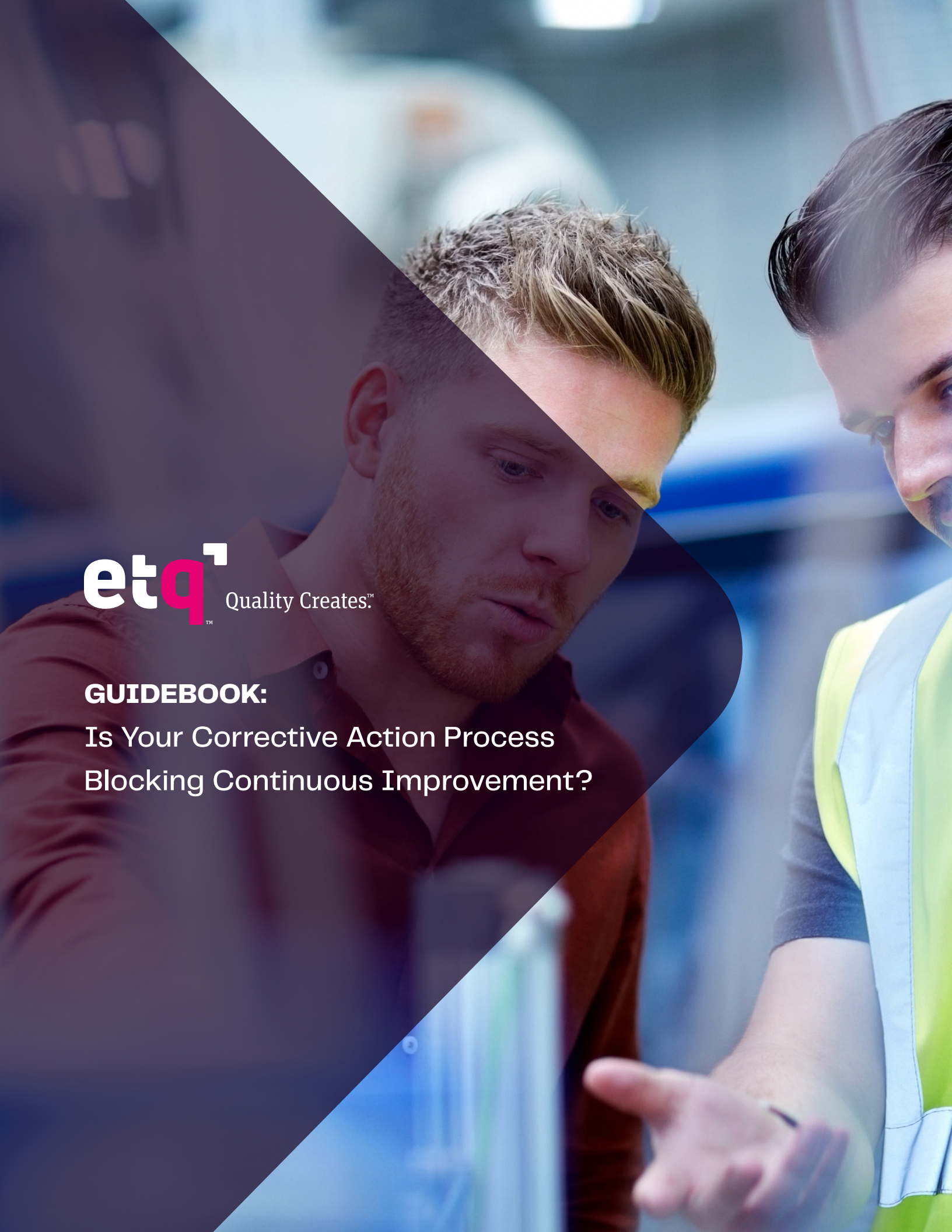

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GUIDEBOOK:

Is Your Corrective Action Process Blocking Continuous Improvement?

Corrective action can become a bottomless pile of paperwork and email overflowing from the quality manager's inbox, allowing high-risk issues to lurk hidden among less critical matters ...

Corrective action is at the heart of the quality management process, attracting scrutiny from regulators and certification bodies worldwide. In fact, U.S. Food and Drug Administration (FDA) data shows that corrective and preventive action (CAPA) problems are consistently a top driver of FDA Form 483 observations and agency-issued warning letters1. For companies struggling to keep up with constantly evolving regulations and standards, corrective action has become a roadblock on the quality journey that stands in the way of continuous improvement.

When companies generate corrective action requests for every event from minor audit findings to high-risk incidents, problems of prioritization occurs. No matter the scope or severity, the corrective action process acts as the ultimate catchall.

The result of which can be a backlog of hundreds or more corrective actions, all with varying degrees of severity and assigned in chronological order. To put it into simple terms, corrective action becomes a bottomless pile of paperwork and email overflowing from the quality manager's inbox, allowing high-risk issues to lurk hidden among less critical matters ... until these previously identified problems spiral out of control.

Stop Making Everything a Corrective Action

This paper discusses how to address these problems, using an integrated quality management system (QMS) to reduce risk in the corrective action process from start to finish.

The question that companies must address is simple: does every event require a corrective action? Recognizing that the answer is no is the first step to reducing the overall volume of corrective action requests.

Many low-risk events can be corrected on the spot, such as one-off cosmetic defects and minor complaints or audit findings. When documented in the QMS according to internal and external standards, these immediate corrections:

- Provide data for analysis of repeat or systemic issues
- Reduce the backlog of corrective action requests
- Free up resources to focus on critical, high-risk events

Within a workflow-based QMS, organizations can easily create a shortcut that bypasses the corrective action process, allowing teams to quickly record a minor issue and mark it as closed. The end result is that when an event finally enters the corrective action process, it is simply a critical event that impacts quality or the company as a whole.

...survey data shows that only six percent of companies think their companies are effective at managing risk.

Assess Risk of Remaining Corrective Actions

Risk plays a central role in many standards and regulatory frameworks, including ISO 9001 for quality management, ISO 45001 for health and safety and ISO 13485 for medical device quality. ISO has already dropped the “preventive action” from corrective and preventive action (CAPA), with risk-based thinking requirements woven throughout its standards to replace the concept of preventive action.

And while most organizations know they should incorporate risk-based thinking into their quality processes, McKinsey survey data shows that only six percent of companies think their companies are effective at managing risk[2].

Part of the problem lies in how companies actually define risk. Ask a front-line worker, plant manager and a member of the C-Suite what high-risk means and you're likely to get three completely different answers. Too often, organizations rely on individual interpretations of risk rather than using real-life data from previous events to define it.

For instance, widely used tools like a risk matrix can help eliminate subjectivity and create a common definition of unacceptable risk. On a basic level, risk is defined as likelihood or frequency multiplied by severity[3]. A risk matrix plots these two variables, allowing companies to calculate risk. The resulting number will fall into one of three areas on the risk matrix:

- Generally acceptable (green)
- Generally unacceptable (red)
- Moderate risk that may or may not be acceptable (yellow)

In other words, teams can proactively prioritize corrective actions according to risk, rather than just reacting to the most overdue items.

The caveat to this approach is that it only works when companies go through the process of comparing their risk matrix against historical data to test whether it correctly identifies acceptable versus unacceptable risks. Making the right decision also depends on defining what level of risk is unacceptable, and this is something that manufacturers must carefully evaluate when they create their risk matrix.

Incorporate Risk into the Corrective Action Process Itself

The good news is that corrective action follows a similar process across all industries and can be applied to both quality and safety elements. The key is to incorporate risk throughout the corrective action process.

Taking that into account, the basic steps of a risk-based corrective action process include:

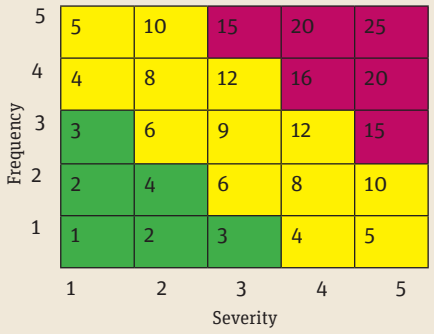
Identifying the problem: Companies may do extensive pre-planning for issues with strategic impact on the business, ensuring the right department is involved in the process. Risk-based filtering helps identify the most critical items that should be addressed first.

Investigating the cause: Root cause analysis should involve people with intimate knowledge of the overall process, as opposed to just the quality department. In an enterprise QMS, the corrective action system serves as a knowledge repository for learning how other facilities have addressed similar risks.

Risk assessment is defined as the probability of an event multiplied by its impact. Levels of probability and impact can be broken up into verbal and numerical scales like so:

Severity		
Verbal	**Numeric**	**Description**
Catastrophic	5	Likely to result in death
Critical	4	Potential for severe injury
Moderate	3	Potential for moderate injury
Minor	2	Potential for minor injury
Negligible	1	No significant risk of injury

Frequency		
Verbal	**Numeric**	**Description**
Frequent	5	Hazard likely to occur
Probable	4	Hazard will be experienced
Occasional	3	Some manifestations of the hazard are likely to occur
Remote	2	Manifestations of the hazard are possible, but unlikely
Improbable	1	Manifestation of the hazard are very unlikely



Implementing an action plan: The action plan breaks down individual tasks in the corrective action, allocating due dates and responsible parties. To reduce risk at this stage, companies should leverage the QMS to closely track due dates and notify supervisors of overdue tasks via escalation rules.

Verifying effectiveness: Measuring residual risk that remains after the corrective action is complete provides a less subjective measure of effectiveness. If the residual risk falls in the unacceptable range on the risk matrix, the issue should be fed back into the beginning of the process.

Conducting ongoing monitoring: Best practices dictate that organizations check in periodically to ensure the corrective action is still in place, typically by adding new questions to internal audits. If not, the issue goes again to the beginning of the process.

Connect Corrective Actions to the Entire Quality Process

Corrective actions can have far-reaching implications across the quality process. Fully implementing changes may involve: document control, change management, employee training or other affected areas of the quality process.

An automated QMS seamlessly integrates these processes, allowing organizations to add new training requirements, initiate revisions of documents affected by corrective actions and more.

The QMS should also be integrated with other IT-based infrastructure like enterprise resource planning (ERP), manufacturing execution system (MES) or laboratory information management system (LIMS) software. This integration means the QMS can pull key data from these systems into corrective action requests and also enable companies to push data from corrective actions to other affected systems. Ultimately, this level of visibility and control is necessary to fully close the loop on corrective actions.

In many industries, QMS automation has become a driving force in making corrective action a risk-based process and allows companies to:

- Record immediate corrections and leverage data for trend analysis
- Quickly identify critical events and prioritize them according to risk
- Ensure timeliness, visibility and accountability of action items
- Link corrective actions to other QMS processes and external systems

Ultimately, a flexible QMS that adapts to your processes and business requirements—one built around industry best practices—provides a platform for transforming the corrective

The Supplier Connection

Suppliers have a make-or-break impact on quality, revenue and brand reputation. According to LNS Research, nearly 70 percent of innovation leaders have real-time visibility into supplier performance.[4]

Integrating your suppliers into the corrective action process via permission-based QMS access allows companies to:

- Centralize tracking of supplier corrective action requests (SCARs)
- Partner with suppliers in solving problems
- Hold suppliers accountable for commitments and compliance with supplier quality agreements

of innovation leaders have real-time visibility into supplier performance

action process. By correcting minor issues immediately and using real data to inform risk management efforts, companies can ensure high-risk issues receive the attention they deserve. The end result is a process that's more focused, more impactful and more efficient overall.

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[1] FDA. FY2017 Annual FDA Medical Device Quality System Data. [Accessed 19 September 2019.] https://www.fda.gov/media/111345/download

[2] McKinsey & Company. Value and resilience through better risk management. [Accessed 11 October 2019.] https://www.mckinsey.com/business-functions/risk/our-insights/value-and-resilience-through-better-risk-management

[3] American Chemical Society. Risk Rating & Assessment. [Accessed 11 October 2019.] https://www.acs.org/content/acs/en/chemical-safety/hazard-assessment/fundamentals/risk-assessment.html

[4] LNS Research, 7 Reasons to Insist on Accurate, Real-Time Quality Data [Accessed 19 September 2019.] https://blog.lnsresearch.com/7-reasons-to-insist-on-accurate-real-time-quality-data