AssurX

WHITEPAPER

How to Safeguard Your CAPA Process from Stakeholder Failures

Table of Contents

Introduction

While the corrective and preventive action (CAPA) process is a critical component of any company's quality management system (QMS), quality managers often struggle with lack of stakeholder engagement and accountability.

Even if a quality manager has developed a solid CAPA program that checks all the compliance boxes, it is at risk for failure if those individuals involved lack understanding and commitment to carrying a CAPA through to resolution.

Ultimately, it is the quality manager who will face scrutiny if an audit reveals CAPA compliance failures. Process breakdowns and gaps due to human error or indifference – from inadequate root cause analysis to a flawed effectiveness check - will raise red flags among auditors who may then question the integrity of the company's overall QMS.

Companies that fail to correct a quality issue or prevent one from happening initially or repeatedly, risk poor product quality, complaints, lack of customer confidence, damaged brand reputation and loss of market share.

So how can a quality manager secure stakeholder engagement and hold individuals accountable for the quality of their work throughout the CAPA cycle?

After reading this paper you will understand:

- The importance of engaging stakeholders at the start of the CAPA process
- Common pitfalls at each stage of that diminish stakeholder accountability
- 3 key strategies to keep stakeholders engaged and collaboratively working toward efficient and effective issue resolution

CAPA Stakeholders: Don't get stuck in a quality silo

With the burden of quality and compliance on their shoulders, it can be tempting for a quality manager to gather information from the necessary stakeholders then move forward with each stage of the CAPA process on their own.

But the strategy of CAPA in a silo typically backfires as stakeholders see the quality manager as solely responsible for addressing or preventing an issue. More effective is a collaborative approach where stakeholders understand quality is an enterprise-wide responsibility; therefore, they must play active roles in the process.

Stakeholders that have "skin in the game" so to speak, working together with the quality manager to provide input on the CAPA process and help carry it through to completion, are more likely to have a sense of ownership.

Fostering ownership is one thing, holding individuals accountable is another. That's why, when it comes to stakeholder engagement, securing C-suite support is critical to CAPA success.

But the strategy of CAPA in a silo typically backfires as stakeholders see the quality manager as solely responsible for addressing or preventing an issue. More effective is a collaborative approach where stakeholders understand quality is an enterprise-wide responsibility; therefore, they must play active roles in the process.

Stakeholders that have "skin in the game" so to speak, working together with the quality manager to provide input on the CAPA process and help carry it through to completion, are more likely to have a sense of ownership.

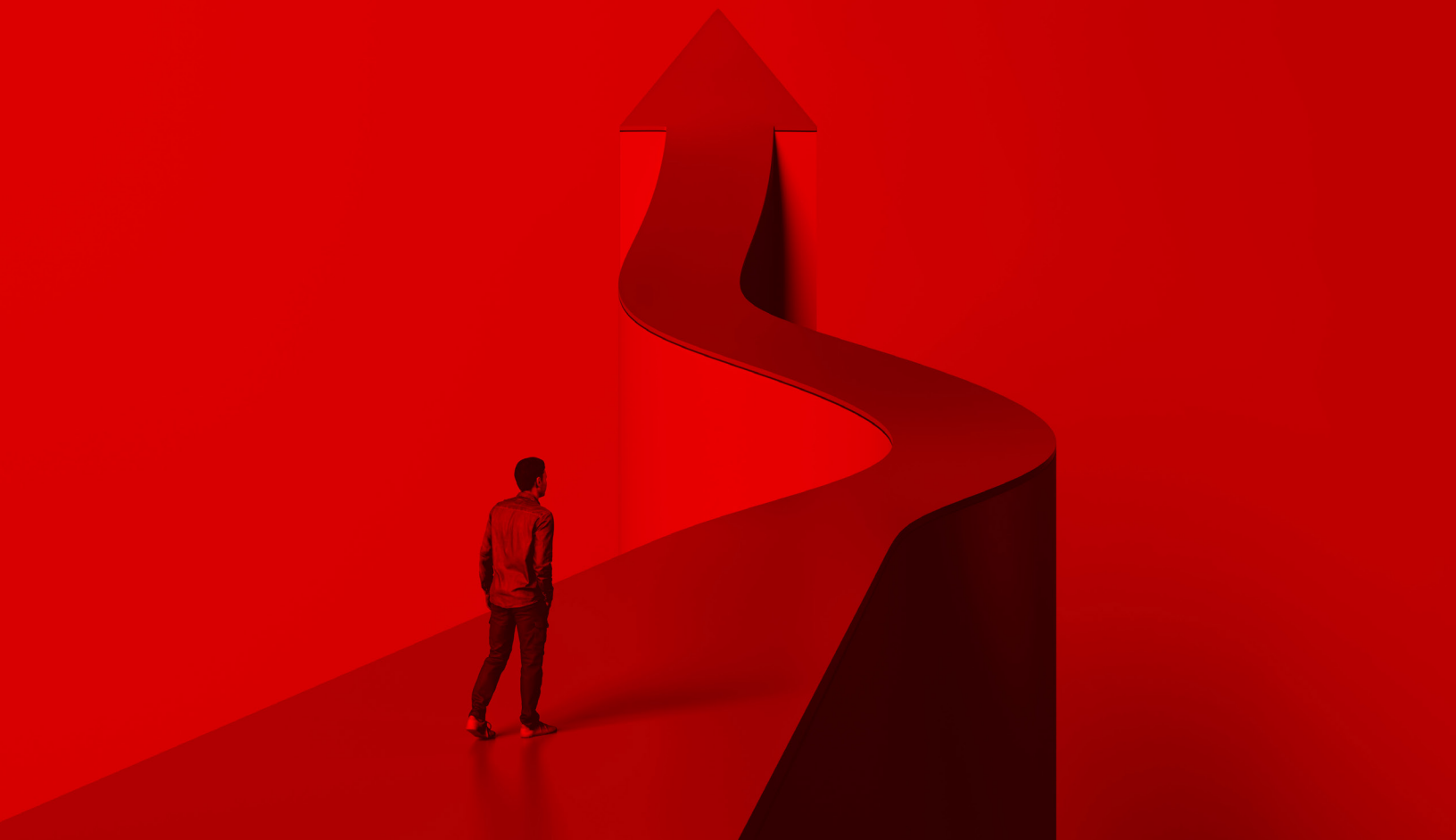
Fostering ownership is one thing, holding individuals accountable is another. That's why, when it comes to stakeholder engagement, securing C-suite support is critical to CAPA success.

When quality managers take the time to communicate to their company's executives the importance of the CAPA program and the risks of compliance failures, leadership is more likely to intervene and help managers hold stakeholders accountable for their actions.

For example, the production manager has once again missed a deadline for an assigned task related to a CAPA despite the fact the quality manager has been consistently reminding them. The quality manager, having secured leadership support of the CAPA program, could leverage this relationship to hold the production manager accountable for current and future deadlines (more on accountability strategies later in this paper).

“Quality is moving up in the chain, and making people responsible for their own quality is more and more important.”[2]

- Gartner



CAPA Process Pitfalls: Avoid these traps

Establishing relationships and engaging stakeholders in a collaborative CAPA process is just the beginning. At each stage, there are risks for individuals to miss deadlines, perform poorly or skip critical steps. Here are some of the common pitfalls of which quality managers should be aware so they can manage effectively through them.

Documentation of the details

The initial work to determine exactly what went wrong from a quality perspective - who was involved, and when and where it happened - can be an uphill battle namely because no one wants to be blamed for making a mistake. While an effective CAPA relies heavily on the quality manager understanding the details, responsible parties might withhold information in fear of being reproached or reprimanded.

Investigation and root cause analysis

In most cases, identifying the root cause of a quality issue isn't a straightforward A-Z path. Rather, it requires stakeholder dedication and a level of detective work and digging below the surface to uncover the source.

While managing the day-to-day responsibilities of their roles, stakeholders might find it challenging to dedicate time and resources to investigation. After conducting an initial review of the situation, an individual might surface a problem related to the nonconformance and name it as the root cause while the underlying issue remains.

Failure to ask enough questions and perform a deep dive to get to the heart of a quality issue can have far-reaching implications. For example, while a CAPA is focused on addressing a contributing factor, the core upstream nonconformance continues, posing risks for even more issues downstream.

Corrective action plan development

A quality manager, armed with the details of a thorough investigation and root cause analysis, has the information they need to develop an effective plan. No matter how targeted the steps, if the manager assigns tasks to teams and not to dedicated individuals, there is a good chance completion of those tasks will fall through the cracks.

It can become a "kicking it down the line" game where missed deadlines result in team members pointing fingers at each other assigning blame and not taking responsibility.

Another pitfall in the planning process comes with the proposed timeline. Quality managers must strike a balance between assigning unrealistic deadlines that set stakeholders up for failure and setting due dates far into the future where individuals push off their assigned tasks and forget the critical details when attempting to complete them months after the fact.

"Not only are our customers and consumers demanding higher quality, our regulators, our senior business leaders, are also demanding more, and that tolerance for quality errors has never been smaller."[3]

– Gartner

Plan implementation

A CAPA open 12 months or longer can signal failure of the quality manager to keep on top of stakeholders, continuously monitoring progress, reminding individuals of upcoming deadlines, and breaking down barriers and roadblocks.

A quality manager, faced with their own responsibilities, can find it challenging to keep a pulse on everyone else's tasks and timelines. Furthermore, many people shy away from what can be perceived as "pestering" team members, choosing instead to let things slide. But in the realm of quality management, delayed action commonly results in greater downstream consequences of the nonconformance at hand.

Effectiveness check

Even if a CAPA is carried out effectively and on schedule, and the deployed action appears to have corrected or prevented a quality issue, poor timing of the effectiveness check can derail the program.

The quality manager and other stakeholders, after spending considerable time and effort to carry out each stage of the CAPA, might be tempted to quickly check the boxes, close it out and move along to the next project. But in performing an effectiveness check too soon, they could miss issues that take time to develop and present themselves and run into the same quality problems again.

3 Key Strategies for Success

As McKinsey & Company analysts point out, "everyone owns quality."[4] The challenge of the quality manager is to convince stakeholders of their responsibilities and accountability in the CAPA process, provide them with solutions that help them succeed, and deploy methods to monitor and measure progress toward goals and quality issue resolution.

Here are three strategies quality management can employ to pave a successful path forward from the start.

Strategy 1: Lead with collaboration and accountability

While it is in the quality manager's hands to develop the CAPA program and write the standard operating procedures (SOP), other stakeholders will be required to follow the program and protocols when a quality issue arises.

To set the program up for success from the start, engage stakeholders in writing the SOPs so they know what will be expected of them during the CAPA process. Make it a collaborative activity where every person who could potentially be touched by the process can review the SOPs, provide their feedback, and sign off on the written procedures.

That way, if a someone questions or challenges anything during any stage of the CAPA process, for example, an assigned task or agreed upon deadline, the quality manager can point the stakeholder to their written approval of the SOPs to help keep things on track.

In taking a collaborative approach, the quality manager can also communicate to stakeholders the message "we are all in this together." Because fear of admitting a misstep or mistake is a major challenge to effective root cause analysis and investigation, it is important for the quality manager to foster an environment of collective issue resolution as opposed to finger pointing, blaming and shaming.

> "CQI requires celebrating success and failure without personalization, leading each team member to develop error-free attitudes."[5]

Take the opportunity from the beginning – during the development of the CAPA program and writing of the SOPs – to assure stakeholders of the understanding that humans are fallible. Rather than fearing retribution, stakeholders should feel confident in diving down into the details during documentation and investigation to identify the true root cause. That way, the team can act quickly based on relevant information to avoid issue escalation and safeguard the company, its products and its customers.

It is critical to note that while a collaborative approach to CAPA can help secure stakeholder engagement, accountability is key to keeping them committed. A quality manager should avoid assigning a task to a team, and assign to s specific individual instead. Holding individuals directly accountable for meeting deadlines and completing tasks contributes to CAPA process efficiency.

Strategy 2: Leverage tools and technology solutions

CAPAs can be very complex, with the quality manager orchestrating the actions of various stakeholders in alignment with SOPs where steps must be completed in accordance with a committed timeline. There are a variety of tools and technologies available to help stakeholders effectively and efficiently perform their tasks.

> "One of the most significant advantages of Quality 4.0 is its ability to foster collaboration by breaking down organizational silos and enabling a holistic approach to quality."[6]
>
> **– Clarkson Consulting**

For example, a root cause analysis facilitator can leverage The 5 Whys, Kepner-Tregoe Matrix, fishbone diagrams, pareto charts, and scatter diagrams. The facilitator should be well versed in multiple root cause analysis tools so they can switch from one to another to overcome roadblocks encountered during an investigation and truly dig down to the core of the quality issue.

On a broader scale, companies that have in place a cloud-based enterprise quality management system (EQMS) with integrated closed-loop CAPA management software can automate and standardize all processes to drive consistency, accuracy and efficiency from incident capture to closure. The move from manual processes and disjointed, legacy systems to automated, digital workflows and seamless system integration is a core component of Quality 4.0.

For example, when the quality manager needs to create a new SOP or launch a CAPA, they can leverage standardized formats in the EQMS instead of having to start from scratch. During the documentation, investigation and root cause analysis stages, the EQMS guides stakeholders through each of the necessary steps to facilitate initial capture of all relevant details related to the quality issue at hand.

During plan implementation, EQMS capabilities including digital data capture, standardized workflows/documentation and process automation serve to align CAPA stakeholders in collectively moving forward. The most advanced EQMS solutions feature dashboards, status reports, alerts, notifications, and escalations that keep teams and management aware of late tasks and review requests.

In addition, corrective action management software with automated effectiveness checks and compliance verification provides the quality manager confidence in CAPA program ISO and GxP alignment.

Strategy 3: Link all decisions and actions to data

With cloud-based solutions, system integration, digital data capture and advanced analytics (AI, ML), today's quality managers have credible and actionable insights at their fingertips to inform and guide the CAPA process from start to completion.

Take a data-driven approach at every stage to determine what went wrong, develop a plan to effectively address the issue, confirm successful issue resolution, and monitor processes to ensure it doesn't happen again.

EQMS Integration Fosters Collaboration

An EQMS that serves as a single solution to replace manual and legacy quality systems serves to consolidate all core quality management and regulatory compliance management processes.

Cloud-based integration with enterprise business systems, including ERP, PLM, LIMS, CRM, CMMS, and internally developed applications and databases, enables stakeholders across departments and functions to work collaboratively within the EQMS.

With shared workstreams, documentation and data, stakeholders to a CAPA can more effectively and efficiently work toward resolution. The quality manager has real-time visibility into the process and can intervene when needed to remove obstacles and drive progress forward, as needed.

“Success and failure are related to underlying organizational processes and systems as causes of failure rather than blaming individuals because CQI is process-focused based on collaborative, data-driven, responsive, rigorous and problem-solving statistical analysis.”[7]

Accurate data is key to the CAPA effectiveness check. To that point, a common pitfall is performing this step too early or too late in the CAPA cycle. A quality manager should avoid leaving CAPA open for too long, but they also don't want to close it too soon before they've validated that those actions taken are effective.

Therefore, it is best practice to perform the effectiveness check 60-90 days from completion. A strong data foundation and analytics capabilities will guide the quality manager in determining whether the issue has been resolved or if further action is needed.

Lastly, data analysis is also critical to continuous improvement of the CAPA program and overall quality management system. Never lose sight of the fact that quality management is a process, not a project. No matter how well thought out and detailed, there is always room for improvement. An EQMS with key performance indicators (KPIs), trending, and reporting tools can help determine CAPA program effectiveness and identify areas for enhancement.

Building CAPA Team Competencies

Regardless of the tools or technologies implemented, from manual, paper-based diagrams and matrices to automated, electronic solutions and advanced analytics, a successful CAPA ultimately goes back to the people involved, their understanding of their roles and responsibilities and their dedication to effective issue resolution.

Therefore, quality managers should prioritize stakeholder training that builds competence and confidence in the end-to-end process and any methodologies and solutions employed.

Conclusion

Effective quality management, including targeted and efficient issue identification and resolution, are essential for companies across all industries. Where CAPA programs often fail are in stakeholder engagement and accountability.

While tools and technology solutions have emerged to help quality managers and their teams navigate the process – from detailed documentation through to the effectiveness confirmation – in the end, the effectiveness of the CAPA process comes down to the individual stakeholders involved.

Quality managers who build their CAPA programs and teams on a foundation of stakeholder engagement and accountability and guide their processes with advanced technologies, credible data and advanced analytics, position their companies for short-term quality improvements and long-term QMS success.

The industry-wide criticality of CAPA

CAPA is a core component of quality management across many industries, including life sciences, food and beverage, technology, manufacturing, and energy and utilities.

AssurX Enterprise Quality Management Software (EQMS) and Enterprise Energy Compliance System (ECOS) is trusted by companies worldwide to help improve quality, reduce risk, and maintain compliance with industry-specific regulations and standards.

AssurX cloud-based CAPA management software integrates with core business systems (ERP, PLM, LIMS, CRM, CMMS) offering quality management workflow standardization, process automation, digital data sharing, and the application of advanced analytics to surface actionable, impactful insights.

References

1 Embedding 'smart quality' culture and capabilities in the organization, McKinsey & Company, January 10, 2022, https://www.mckinsey.com/industries/life-sciences/our-insights/embedding-smart-quality-culture-and-capabilities-in-the-organization

2 The 8 Quality Management Trends You Need to Prepare for in 2024, Gartner on-demand webinar, https://www.gartner.com/en/webinar/445839/1051178

3 The 8 Quality Management Trends You Need to Prepare for in 2024, Gartner on-demand webinar, https://www.gartner.com/en/webinar/445839/1051178

4 Embedding 'smart quality' culture and capabilities in the organization, McKinsey & Company, January 10, 2022, https://www.mckinsey.com/industries/life-sciences/our-insights/embedding-smart-quality-culture-and-capabilities-in-the-organization

5 Endalamaw A, Khatri RB, Mengistu TS, Erku D, Wolka E, Zewdie A, Assefa Y. A scoping review of continuous quality improvement in healthcare system: conceptualization, models and tools, barriers and facilitators, and impact. BMC Health Serv Res. 2024 Apr 19;24(1):487. doi: 10.1186/s12913-024-10828-0. PMID: 38641786; PMCID: PMC11031995, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11031995/

6 2024 Industry Trends: Quality + Compliance, Clarkson Consulting, https://clarkstonconsulting.com/wp-content/uploads/2024/01/2024-Quality-Compliance-Trends.pdf

7 2024 scoping review of CQI published in BMC Health Services Research