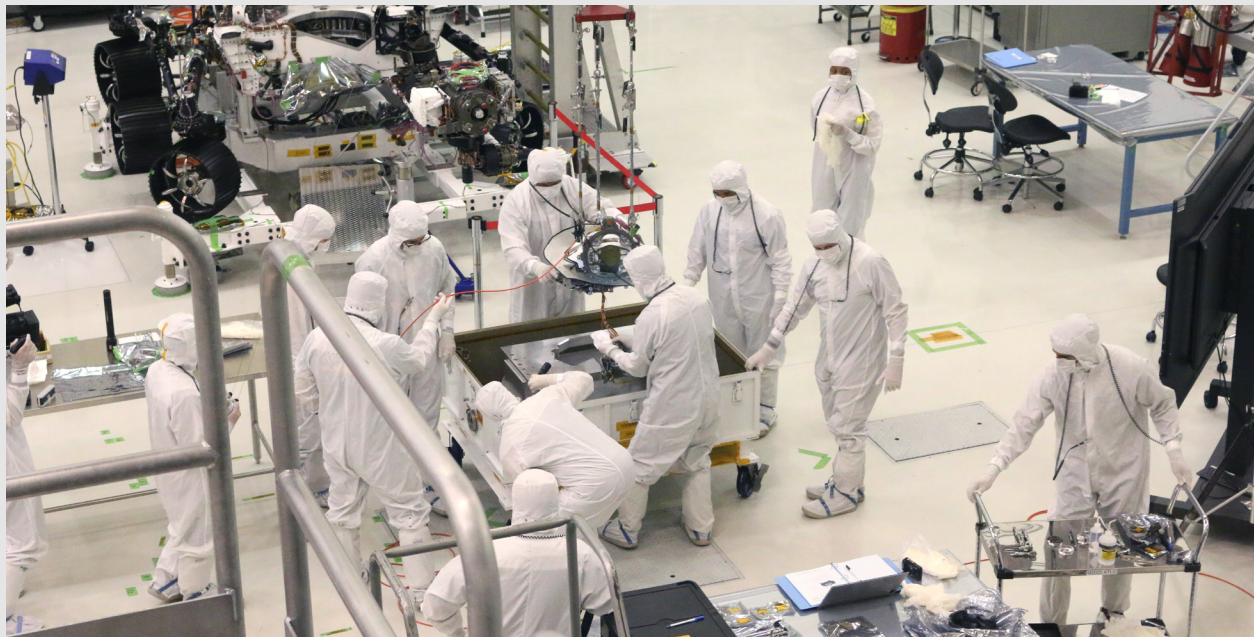


Corrective and Preventive Actions (CAPAs) Are Evolving: CAPAs for Continuous Improvement



It is no longer acceptable to respond to audits and product recalls with CAPAs that only address short term concerns. It's now all about aligning CAPAs and Continuous Improvement processes.

Companies in regulated industries have had processes for implementing corrective and preventive actions (CAPAs) in response to deviations for decades. But the focus of CAPA initiatives has shifted from 'having effective processes' to 'producing sustainable results'. The companies best positioned to accomplish this are those that align their CAPA and Continuous Improvement processes, provide employees with the necessary skills to deliver, and maintain a culture that balances quantity against quality.

The basic intent behind CAPAs hasn't changed significantly, nor have the fundamentals of how CAPA processes work. Traditionally the focus of CAPAs has been as a response to audit findings, product recalls or significant production issues. They were a means of both addressing the problem as well as demonstrating to regulatory agencies that the company's production processes are 'under control' and

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operating within designated parameters. But an increasing need to deliver as much value as possible, makes satisfying the basic intent of CAPAS insufficient. The reactive CAPA process, in addition to maintaining the status quo, must be aligned with and support the proactive Continuous Improvement process.

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Success = Impact

Companies are changing the definition of what success in corrective and preventative actions looks like. It is no longer about completing all the steps in the CAPA workflow to appease regulators and resolve a recall – it is about making the products the company produces better, safer, and more dependable for customers. Success is also about taking the time to address systemic issues to make the company's operations more consistent and effective. Not that companies didn't care about quality and doing the right thing before, but companies that thrive recognize that effective quality leads to customer loyalty and efficient quality lowers costs: key components of financial success.

The building blocks of an effective CAPA/Continuous Improvement strategy

A modern CAPA strategy may be defined and mandated from above, but effective processes are as much about people and culture as they are about boxes and lines. Quality must be embedded into the culture of the organization. The people, the processes, and the culture must all be aligned to focus on producing quality, learning from mistakes, and doing what it takes to continuously improve.

People

Quality starts when the people in your organization understand their roles and have the skillsets needed to proactively identify issues in their environment, implement corrective and preventative actions to address deviations, and also address the systemic causes that are at the root of deviations and inefficiencies. The core set of skills needed to contribute effectively to CAPA and Continuous Improvement is straight forward:

Root Cause Analysis – Employees need the ability to look at the environment surrounding a deviation, separate out the symptoms from the underlying causes, and identify true cause.

Decision Making – Once causes are known or improvement opportunities have been identified, employees need to choose actions to correct causes, prevent recurrences, and remove inefficiencies within the constraints of the broader business environment.



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Risk Management – When choosing and then implementing actions, employees need to protect the impact the action is intended to make, whether the action be corrective, preventive, or a process improvement.

What is not straight forward is aligning these skills across an organization and supporting people in applying these skills appropriately.

CAPA and Continuous Improvement efforts span different parts of the organization, so it is important to have a common approach and language, or terminology, to improve communication and prevent misunderstandings. If one group's approach does not match another's, there will be inefficiencies when escalating or collaborating on resolving issues. This also has implications when companies want to track deviations or risks across the organization. If different groups use different language when describing deviations, it will be hard to see trends. If different groups use different baselines or rating systems when measuring risk, similar issues can be looked at very differently.

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Another benefit of having a common approach is that it is easier for people to document and explain how they reached their conclusions. In addition to the internal benefits discussed above, people also need to be able to present their findings to regulatory agencies. When an auditor questions the conclusions of an investigation, the choice of corrective or preventive actions, or a risk assessment and the counter-measures taken, being able to tell the story with clear, consistent documentation saves time and avoids unnecessary regulatory scrutiny.



While the value of these skills, used across organizations and with regulators is not new, what has changed are expectations for use and an increase in data. People do not enter the workforce with the all the skills necessary to interpret and use information to drive Continuous Improvement and CAPAs. While some companies address this by relying on a small team of trained experts to lead CAPA and Continuous Improvement initiatives, modern organizations are achieving greater impact by developing these skills in-house and broadly across their workforce—instead of hiring for them.

The companies that benefit most from skill development, build a case for the need for change and then present training within the context where the skills will be applied. This approach allows employees to not only learn the foundational skills but also how they will apply them in their workplace. Furthermore, companies can improve skill retention and accelerate adoption by building a culture that is committed to learning and supports new skills with coaching and mentoring.

Processes

Having a solid foundation of these core skills, broadly developed across your organization creates value when they are used within the context of processes that directly impact product throughput and quality. These include product management processes for manufacturing and testing and knowledge management processes that include validation, continuous improvement for proactive change, CAPA for reactive change, and change control.

Standard operating procedures provide guidance for how work should be done. In the life sciences and other regulated 4. Improve the process industries, they are also the basis for demonstrating to 5. Control process to sustain regulatory agencies that your methods promote safety, improvements consistency, and effectiveness (all very important if your customer's life depends on your product). SOPs are only as effective as the process they describe; and must be executed consistently in order to achieve repeatable results. Good SOPs also include KPIs to monitor these elements; KPIs that are appropriate (based on the process), informative (provide meaningful insights) and well understood. Just as with product management processes, many knowledge management processes (validation, Continuous Improvement, CAPA, and Change Control) are also guided by SOPs. Knowledge management processes have a greater impact when people follow them consistently, however skill and behavior differences can lead to inconsistent adoption. (See sidebar for an overview of the basic CAPA and Continuous Improvement processes). Knowledge management processes should include a structured approach and defined methods, require clear and consistent documentation for supporting conclusions, and be applied with a consideration for the long-term impacts of the actions you take in the near term.

Increasingly, automation is causing disruption in the knowledge management processes. The nature of modern manufacturing and testing processes makes it possible to achieve higher levels of consistency, more accurate measurement of KPIs, and greater efficiency. However, the speed of automation quickly amplifies the impact of sub-optimized processes and other problems. The digitization of production also increases the ability to measure anything. In the past, companies were limited by not having enough data to support their CAPA and Continuous Improvement efforts. Now information overload and 'noise' can cause distraction and distortion of the relevant data and meaningful signals being generated. Key to overcoming data overload and profiting from the pace of modern manufacturing is ensuring that people have the skills to use data efficiently and, in part, it relates to having robust, data-driven CAPA and Continuous Improvement processes. Data-driven processes promote recommendations that consider not only the activities in the process, but also the configuration of the workflow (setup & calibration), material inputs and/or environmental factors. When this is the case both the CAPA process Effectiveness Checks and the Continuous Improvement Control Step can focus on leading, rather than lagging, KPIs as indicators of performance success.

Basic Continuous Improvement

1. Define customer needs
2. Measure current process
3. Analyze improvement opportunities
4. Improve the process
5. Control process to sustain improvements

Basic CAPA Process

1. Understand the problem
2. Describe the problem
3. Mitigate initial effects/risks
4. Identify true cause
5. Assess additional risks
6. Choose CAPA
7. Assess CAPA risks
8. Implement corrective and preventive actions
9. Conduct effectiveness checks

Cultural alignment for impact



Companies need to align their people and their processes with the understanding that the goal of the CAPA process is not to demonstrate that everything is fine, rather, it is to find areas for improvement. It is easy for individual employees to forget this as they strive to complete their daily tasks. That is why management culture is so important - setting the right examples and expectations about the role of quality improvement in the organization. Culture is something that is unique to every organization and develops over time, but here are a set of statements that can be used to test whether your company's culture is supportive of the CAPA process and its value to the Continuous Improvement process (or whether you may have some work to do).

1. Management views investigations as an opportunity to improve
2. People are rewarded for finding impactful opportunities
3. People are provided time and resources necessary to conduct thorough investigations
4. Your process generally aligns to the 80/20 Rule (80% of investigations are closed within 5 days)
5. Product quality is rewarded equally as product quantity

The more "no" answers, the more likely your company's culture views CAPAs as "hot potatoes" and people respond with "bad, get it off my plate". The more "yes" answers, the more likely your company culture views CAPAs as opportunities to improve. Because CAPAs represent real business challenges that need attention, the focus should be on resolution not shame and blame.

Modern companies understand the strategic importance of CAPAs that produce sustainable results and drive continuous improvement of the product management processes that improve quality. Despite changes in expectations, processes, and technology, the need for a management culture that actively encourages quality-minded behavior and supports appropriate skill development has not changed.

Conclusion

As expectations, processes, and technology evolve, the necessary components for successful CAPAs and Continuous Improvement are effective employees, efficient product and knowledge management processes, and a supportive culture. To have effective employees, companies must support them in mastering the skills they need to not only maintain existing product management processes, but also to use knowledge management processes to find cause when there are deviations and identify appropriate solutions when there are opportunities for improvement. To have efficient processes, companies must align how these processes are conducted and documented across their organizations and establish leading, rather than lagging, KPIs to assess the efficacy of their corrective actions, preventive actions, and improvement solutions. To engender a supportive culture, companies must acknowledge the time and effort required to reach sound conclusions, provide people with the necessary resources to do so, and reward those who persevere.

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John Ager works with clients in both manufacturing and service industries, often in highly regulated sectors. He leads teams and coaches individuals through solving problems and implementing operational improvements to achieve strategic goals. He specializes in improving organizational processes, subsequent change management, facilitating issue resolution and transferring critical thinking skills.

About Kepner-Tregoe



Founded in 1958, and based on ground-breaking research regarding how people think, solve problems, and make decisions, Kepner-Tregoe provides a unique combination of training and consulting services to improve quality and effectiveness while reducing overall costs. The KT methodology is used at every level of client organizations: to implement strategy, achieve continuous improvement, increase customer satisfaction, and drive effective issue resolution throughout the organization.