Kepner-Tregoe

Recall Remediation

How to successfully manage a recall and prevent future problems

At one time or another everyone has heard the mantra, “The customer is always right!” When a company is in the midst of a regulatory recall and its new “best friend” is the FDA, the company must clearly understand that the FDA is their customer AND it is imperative to get the recall “right.”

There have been a number of recent, visible recalls that have laid waste to companies who did not meet FDA standards. What a company does both publicly and with the regulatory agencies is critical to an organization’s ability to survive and thrive. This is a true test of resilience as the FDA is not the only concern. People who buy the company’s products could be the ones to decide their fate.

The FDA and other regulatory agencies maintain intense regulatory scrutiny of companies who do not decisively address audit findings. The result is not only closer scrutiny of the company subjected to the recalls, but to other sites or business units as well. These actions on the part of the FDA make it very clear that they mean business.

However, there are effective courses of action an organization can take to successfully manage current recall status and prevent future recalls.

Assessment of Key Performance Indicators (KPIs)

A company scorecard of metrics for investigations and Corrective Action Preventative Action (CAPA) is the starting point for the remediation efforts. Each company does this in different ways and to varying levels of sophistication. In order to assess the scale and scope of the recall, an organization needs to review the measures, metrics, and trends from the past two years to determine the extent of the recall. Some of the data points needed include:

- Number of open investigations and CAPAs
- Reportable vs. non-reportable incidents (counted by level)
- Time to close investigations and CAPAs
- Resources required to close investigations and CAPAs
- First-time fix rates
- Mean time to resolution (tracked by person hours)

In order to launch a remediation effort, this information must be quickly accessible and available to all involved in the remediation effort. This is crucial for proper analysis of KPIs.

Current workflows that impact the recalled product also need to be reviewed. These should include troubleshooting methodology, performance environment and performance support work flows as well as the standard operating procedures (SOPs) for investigations, CAPAs and investigation training. This information, along with the metric information above, will serve as a basis for verifying the improvements recommended at the conclusion of the project.

Investigation Assessment

Consistency, stability and capability of business processes are necessary to reduce variations caused either by common causes or by incursion of external factors or special causes. Analysis of the current business and investigation processes regarding the use and implementation of CAPA methods - and root cause analysis (RCA) tools - will identify a framework to address quality events in a holistic fashion. This will reduce the time required to complete investigations and provide a blueprint for future CAPAs to be transparent and traceable and can be adopted at other sites throughout the company.

To achieve this, a company should start with a structured review of the organization's SOPs against past investigations in a "should vs. actual" analysis to judge outcomes. This structured review includes analyzing the SOPs as compared to the written investigations, as well as reviewing the actions of the employees involved. By this approach, the gaps and shortcomings not found in typical audits can be identified and addressed.

CAPA Assessment

To continue with the recall remediation, it is important to assess the company's CAPAs. That process begins with a review of the SOPs. Once this is complete, a company should meet with its CAPA approval team to identify the gaps between the SOPs and the actual work flows that drive CAPAs as described by the CAPA approval team. This meeting will yield valuable data that will help a company zero in on the "sweet spot" for improving their CAPAs. It is important to note that there typically is a gray area associated with how to choose the most effective and efficient corrective action, among the many that are available. For these decisions, companies should consider working with outside vendors, who can look at these potential actions with an objective mindset, thus removing any emotional elements.

RCA Tool Assessment

Integrity of the RCA tools used in investigations is essential for achieving scalability, repeatability, improved hit rate, and ensuring the use of the least amount of resources. Consequently, a review of current RCA tools and the training programs that utilize these tools will help identify weaknesses and/or limitations that can hinder the level of results. This is essential to keep problems from reoccurring.

Often times, companies use multiple tools to assess RCA, which can result in experts racing down parallel paths towards the same goal - determining the root cause. However, these experts are separated by "virtual walls" because they typically work in different functional areas of the company, and the effect of separation results in redundant work and little synergy. One solution to this remediation problem is to establish a companywide RCA tool chest where employees receive training and have access to the basic set of RCA tools, such as "5 Whys," Fishbone and Kepner- Tregoe (KT) Problem Analysis. Then, as investigations unfold and possibly become more complex, experts of particular RCA tools get assigned to the investigation team so they can apply the more complex set of tools.

In the remediation effort, looking at the interaction between quality investigations and manufacturing production will greatly increase the probability of effectively addressing issues. Finally, continuous improvement in the use of RCA tools and methods will only guarantee a reduction in recalls if the current RCA tools are in line with training programs. A review of training manuals and seminars is a key element in any remediation effort.

Assessment of Roles and Responsibilities

Understanding the people performance and the dynamics of team performance in current investigations and CAPAs is THE most overlooked area during remediation efforts. Our work with companies indicates this is often overlooked in standard audits. Yet, when performing a review and remediation of a company's Investigation/CAPA processes, this is where most of the time is spent.

All meetings associated with investigations and CAPAs, such as CAPA In-Process Status Reviews, Investigation Reviews, Disposition Meetings and Problem-Solving, should be recorded in order to obtain a summary picture. Once this is achieved, interviews should be conducted with operators, quality control analysts, supervisors and quality assurance personnel, to get a better understanding of why people are not getting the appropriate performance during investigations.

The results and trends from those interviews should be explored and clarified with focus groups. Once completed, a full, and comprehensive picture may begin to emerge regarding the rewards and consequences the workplace and the quality or the lack of quality of feedback given to employees. It may also reveal the encouraging consequences management offers the organization to get to root cause and close out CAPAs effectively.

The Performance Environment is an area where the majority of systemic failures can be found. Looked at another way, performance systems, if designed correctly, and with individual levers pulled appropriately, are the most significant area that WILL ensure a reduction in the likelihood of recalls AND drive dramatic improvements in a company's "in-process" investigations. Effective performance systems are the silver bullet for recall remediation. These need to be in place at both leadership and operational levels.

Conclusion

In the end, recall remediation is hard work. Somewhere, in all those previous audits, were the nuggets of information and "ah ha" moments that, if exposed earlier would have kept the recall from happening. Somewhere during your past efforts, the blinders were left on and issues were looked at through rose-colored glasses. Now, things have gone sideways in the worst possible way for the company. All procedures, processes and SOPs need to be seen through a new set of eyes with renewed passion to get to the bottom of what is happening. Unfortunately, in a recall those new eyes are now many pairs of eyes, some within the company and many outside of the company. The rush to judgment by many will be uninformed and very damaging, unless the company takes the time to start over and drive the remediation effort across all aspects of the business.

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.