Corrective and Preventive Action: The Closed-Loop System

Summary

The Corrective and Preventive Action (CAPA) process is a fundamental process that affects all of the control points in a company's management system. Auditors tend to look deeply into companies' CAPA process during investigations. Key questions typically asked include:

- Are CAPAs followed-up in a timely fashion?
- Do records prove that all actions have been completed successfully?
- Are all recommended changes completed and verified?
- Was the actual root cause identified? How was it validated?
- Was action taken to correct or prevent the problem and ensure it will not happen again?
- Has it been demonstrated that actions taken have no adverse effects on products or services?
- Was training performed and communications issued to assure that all relevant parties understand the situation that occurred and the changes that have been made?

To better manage the issues that launch the CAPA process, companies need to optimize their practices by implementing efficient, closed-loop CAPA processes. Every good CAPA process should have a built-in audit process to verify and validate that the CAPA system is at optimal performance. Data and evidence tracking is a critical component of action management as well, so the organization can ensure that all non-conformance information can be confirmed, monitored, measured, and, if necessary, corrected.

With nearly every ISO standard, e.g. ISO 9001, ISO 13485, ISO 14001, ISO/IEC 27001, or OHSAS 18001, organizations must determine the actions they can take to eliminate the causes of potential nonconformities.
A company's ability to rapidly correct existing problems and implement controls to prevent potential problems is essential to ensure customer satisfaction and achieve operational success. Even more, regulatory bodies, such as the Food and Drug Administration (FDA), CFR - Code of Federal Regulations Title 21 and Environmental Protection Agency (EPA), and Resource Conservation and Recovery Act (RCRA) require a corrective action program, to ensure the protection of all interested parties.

While a CAPA process must meet the necessary industry compliance requirements, it also must be effective. Otherwise, managers will find themselves in a constant state of response and the CAPA process becomes a bottleneck.

How CAPA Works: It's All About Improvement

A preventive action is created to offset a potential problem. While the preventive action process can contribute to the overall continual improvement effort, its main objective is to eliminate potential problems before they occur. Corrective actions, on the other hand, provide managers with not only the data they need to construct an effective and efficient closed loop corrective action process but can be used as input into preventive actions from lessons learned reports and data provided. Using both types of actions enables a company to transform itself from an operation that is continually reacting to failures, to one with the processes in place to prevent problems in the first place. Ultimately the company saves time and money and, most importantly, retains customers.

Corrective and preventive actions are processes that may be used to achieve continual improvement. Continual improvement reflects an ongoing effort to improve products, services, or processes. It can be incremental improvement over time or breakthrough improvement all at once. For instance, an organization's delivery processes are constantly monitored and evaluated in light of the fact that they are already considered to be effective; improvement may come in the form of making the processes more efficient. Improved efficiency could lead to a decrease in administrative and operations costs, thereby lowering the costs of goods and services and providing an opportunity to lower prices to be more competitive and win more business.

Companies that implement a closed-loop CAPA process can expect to experience satisfying and cost-effective results. See Figure 1 for an illustration of a closed loop CAPA process and how it ties in to the Plan, Do, Check, Act process. Through continuous monitoring, issues are highlighted, thereby allowing them to be addressed real-time. Consequently, the closed-loop process reduces the number and severity of issues that occur. Over time, organizations build an intelligent knowledge base and can implement additional preventive actions, thereby being more proactive, further improving processes and operations throughout their facilities. As a result, customer satisfaction improves and the bottom line moves in the right direction.

In addition to these advantages, a closed-loop CAPA process ensures that best practices are consistently applied to the processes that support compliance requirements. Properly documented actions provide managers with important historical data, which may be used to implement continual improvement plans; a well thought, integrated process can help in the capture and dissemination of operational intelligence related to these actions.

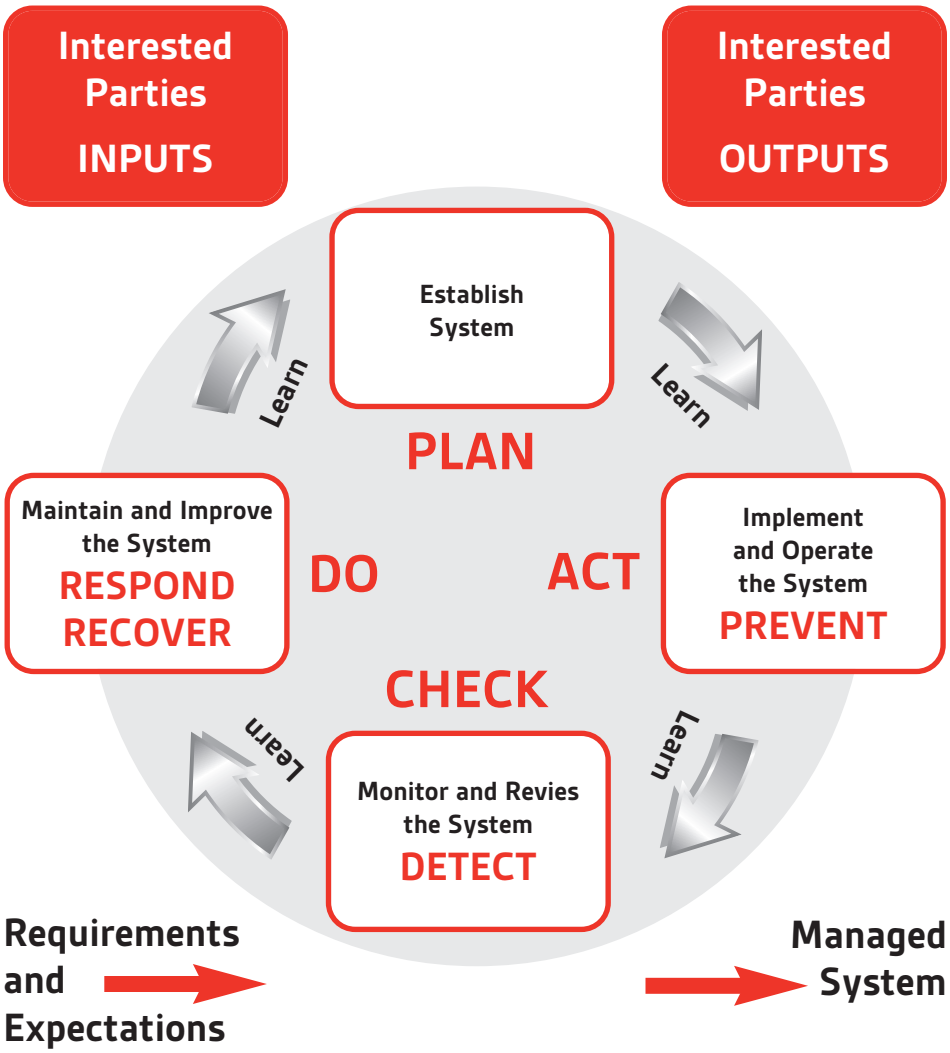

Figure 1 - Close Loop Process

Defeating Non-conformities

When implementing a CAPA process, it is important to define all of the non-conformities that could impact a company's operations. Having a good grasp of the non-conformities helps managers write procedures and design actions that will be taken when a corrective action plan is launched.

But what is a non-conformity? A non-conformity is defined as a deviation from a specific procedure, standard, stated process, or system requirement. When defining nonconformities, it is important to identify the potential severity of the impact they could have on a management system. For example, a major nonconformity could be an actual or potential deficiency that will seriously affect the management system. A minor one would be a less serious more isolated incident, such as a documentation/work instruction error or inaccuracy.

Some of the many issues related to the CAPA process are:

- Poor documentation of requirements
- Failure to document and communicate updates or process improvements following a CAPA
- Inability to trace training documents
- CAPAs that are outdated or closed without validation
- Missing or misplaced data
- E-mail sandwiches [1]
- Failure to monitor critical controls

As illustrated in Figure 2, BSI ISO 9001 field audit results over a twelve month period reveal that the majority of nonconformities are raised in the areas of **document and record** control closely followed by **monitoring & measuring**, and **improvement**. All three are closely linked, as a good CAPA system requires good documentation and continuous monitoring in order to deliver continual improvement.

A closed-loop CAPA process enables companies to avoid or minimize the occurrence of issues, as managers are better able to characterize problems and assemble the best possible cross-functional team of people to successfully tackle them.

[1] A CAPA record that is sandwiched in by multiple untraceable e-mails that should be formally documented evidence.

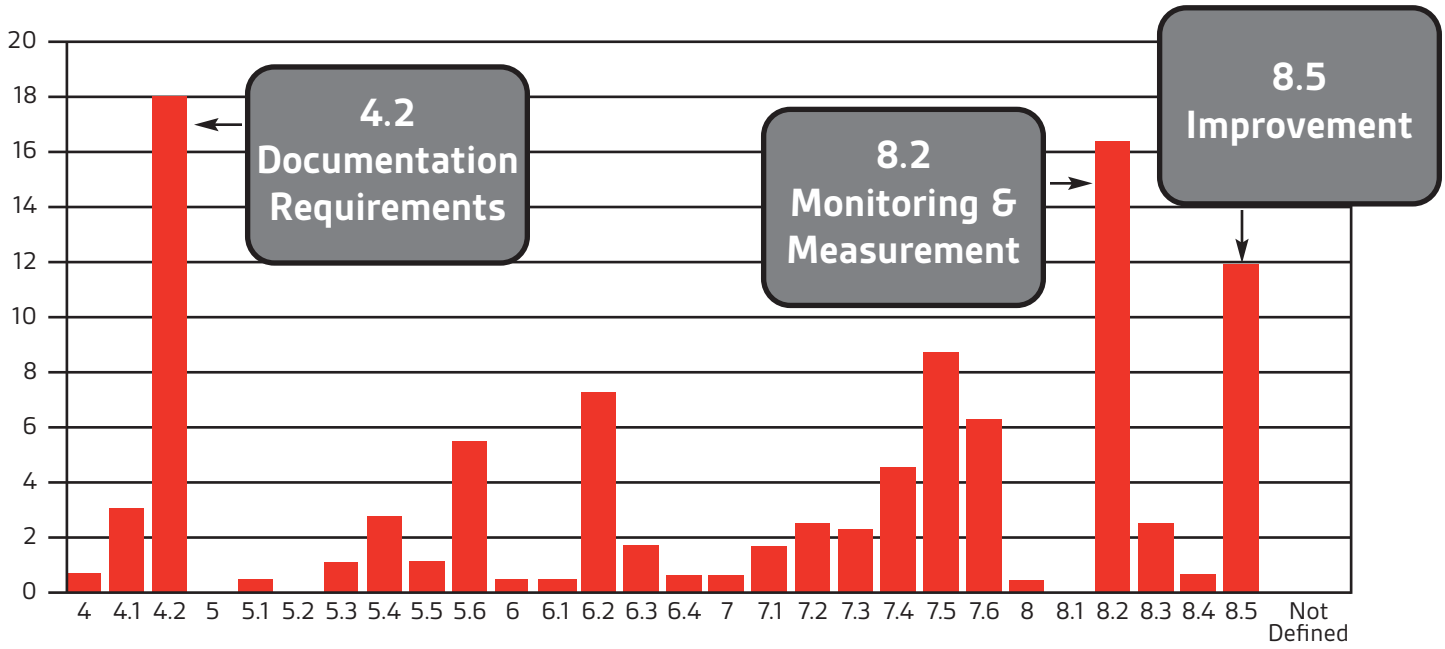

Figure 2 - Non-conformance by clause

Opening a CAPA

Some organizations open a CAPA for every event, regardless of its severity or potential impact. However, this creates bottlenecks because employees become so focused on their CAPAs that they find it difficult to focus on their other day-to-day responsibilities. It also creates a feeling of chaos and concern that "the sky is falling"; continuous improvement suffers by trying to keep up with CAPAs.

ISO 9001:2008 simply states that when planned results are not achieved, appropriate corrective action shall be taken. It goes on to say that when managers are determining suitable actions, they would be wise to consider the type and extent of monitoring or measurement they plan to undertake. This is similar for many other ISO standards.

Any actions taken should be appropriate to each process related to the problem and should be considered in relation to their impact on conformity to product requirements and the effectiveness of the management system. If the system is monitoring wrong or contaminated data, companies basing actions and assigning resources to implement those actions could find themselves wasting resources and money.

Risk assessment is a good way to avoid this effect. Risk matrices[2] help managers and teams to clearly define risk, severity, and potential impact. They also help determine which procedures, designs, and controls best define expected performance. The higher the risk, the more likely it will be necessary to launch a corrective or preventive action. An example of high risk situations are those associated with medical device nonconformities. In fact, the in vitro diagnostics (IVD) and the Medical Device (MD) Directives would require risk based investigations for CAPAs especially if they are related to complaints and reportable events. Thorough investigations are mandatory for the FDA, Health Canada, and other competent authorities, such as the Federal Financial Institutions Examination Council and Federal Deposit and Insurance Corporation in the financial industry and the Environmental Protection Agency in the environmental sector. These are only just a few examples where an industry sector regulation mandates a specific CAPA process.

In addition to predicting problematic events, risk assessment may suggest monitoring a particular aspect of a process or product. The results of the monitoring may yield measurements and analysis that help managers' spot trends that in turn will justify the opening of a CAPA. In many companies, the compilation of results is aided by software tools that provide a framework for the analysis that is critical to an effective CAPA process.

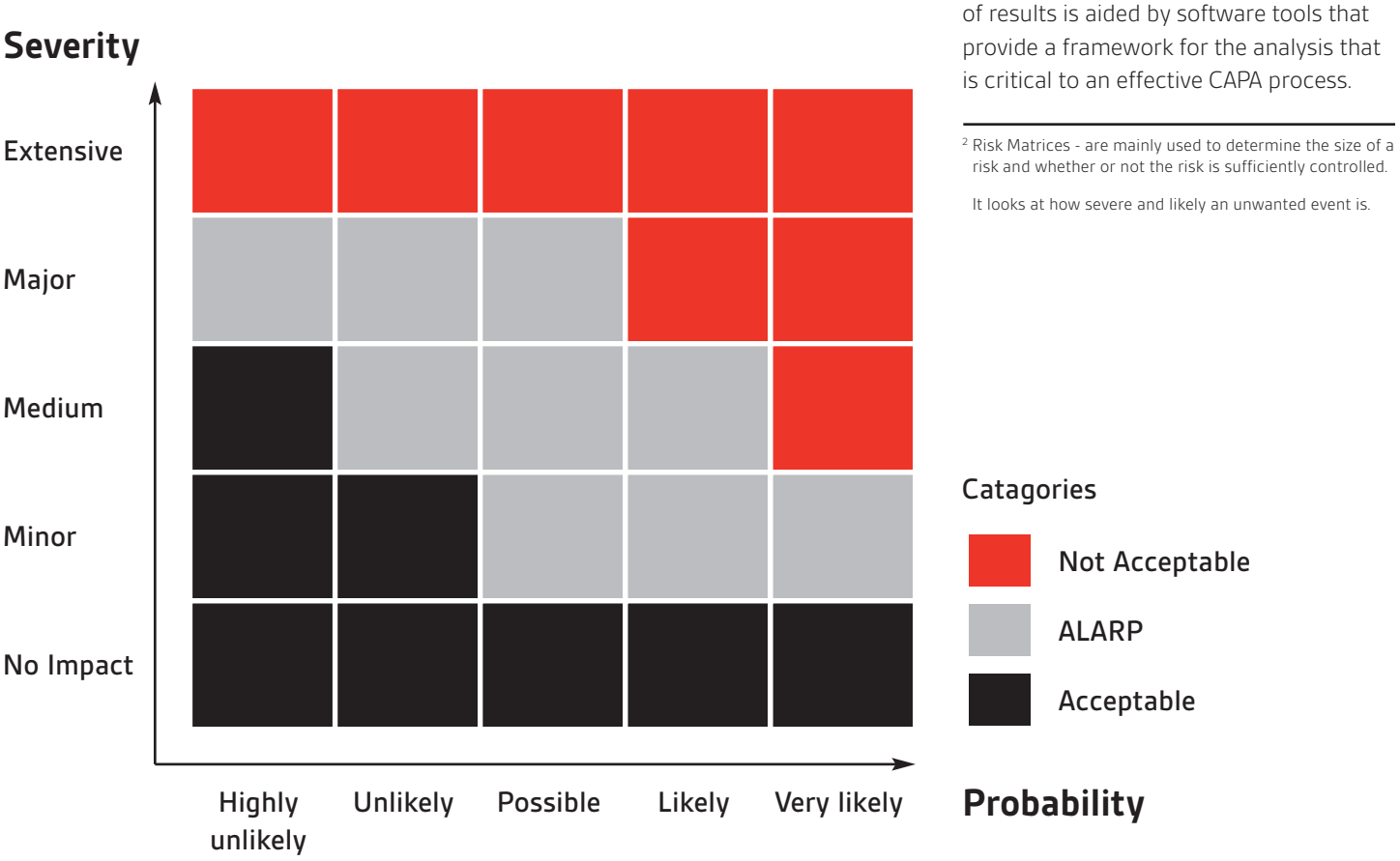

Figure 3 Example Risk Matrix

[2] Risk Matrices - are mainly used to determine the size of a risk and whether or not the risk is sufficiently controlled.

It looks at how severe and likely an unwanted event is.

Responding to a CAPA

Once a CAPA has been opened, a cross-functional team should be assembled to respond to the event and clearly define the (potential) problem. Team members should consider the source of the information and data. They also must obtain or draft a detailed description of the problem and consult any documentation and/or data that provides evidence that a problem exists. The team then must evaluate the situation to determine both the need for action and the level of action required.

When evaluating the problem the team should consider the potential impact of the problem in terms of its risk to the company and its customers, as well as any immediate action that may be required. They also must determine and document why the problem is a concern and what impact it may have on the company and its customers. Typical concerns can include costs, functions, product quality, safety, reliability, and customer satisfaction.

The potential impact and risk assessment may indicate the need for some kind of immediate action to remedy the situation for the short term until a permanent solution is developed and implemented. If the remedial action solves the problem adequately, the CAPA can be closed. However, the team must document the rationale for its decision and complete appropriate follow-up to validate effectiveness of the action.

It is important to document the specific source of the information that is gathered by the team. The information collected helps with the investigation and developing an action plan. It also helps the team evaluate the effectiveness of the action and communicate how a problem has been resolved. Some sources of good information include service requests, customer complaints, internal audits, and staff observations. Trend data also can be gathered from Quality Assurance (QA) inspections, process monitoring, and risk analysis. The data gathered must be properly organized and shared through some sort of relational database. This data, when properly organized and disseminated, becomes operational intelligence that may be leveraged by the entire organization to help improve performance.

Defining the Root Cause

A problem statement is a clear concise description of the issues that need to be addressed by the assembled team, and not just a byproduct of a quick brainstorming session. The description must contain enough information so that the specific problem statement can be easily understood. Data supporting the statement also must be easy to translate. The problem statement may have to be reviewed several times until the entire team is clear and in agreement about the task at hand.

Next, the team must conduct a detailed investigation of the circumstances that created the problem by performing root cause analysis. Eliminating the root cause is the only way to prevent the problem from recurring. Many problem-solving techniques help in this phase of the process. The most popular techniques include use of process mapping, Fish Bone, and the Five Whys.

The 5 whys have been criticized in the past because it is very basic:

- Tendency for the team to stop and address symptoms rather than going on to lower-level root causes.
- Inability to go beyond the team's current knowledge - cannot find causes that they do not already know.
- Lack of support to help the team ask the right "why" questions.
- Results are not repeatable - different people using 5 Whys come up with different causes for the same problem.
- Tendency to isolate a single root cause, whereas each question could produce or uncover different associated root causes.

These can be significant problems when the method is applied through deduction only. On-the-spot verification of the answer to the current "why" question before proceeding to the next is recommended to avoid these issues.

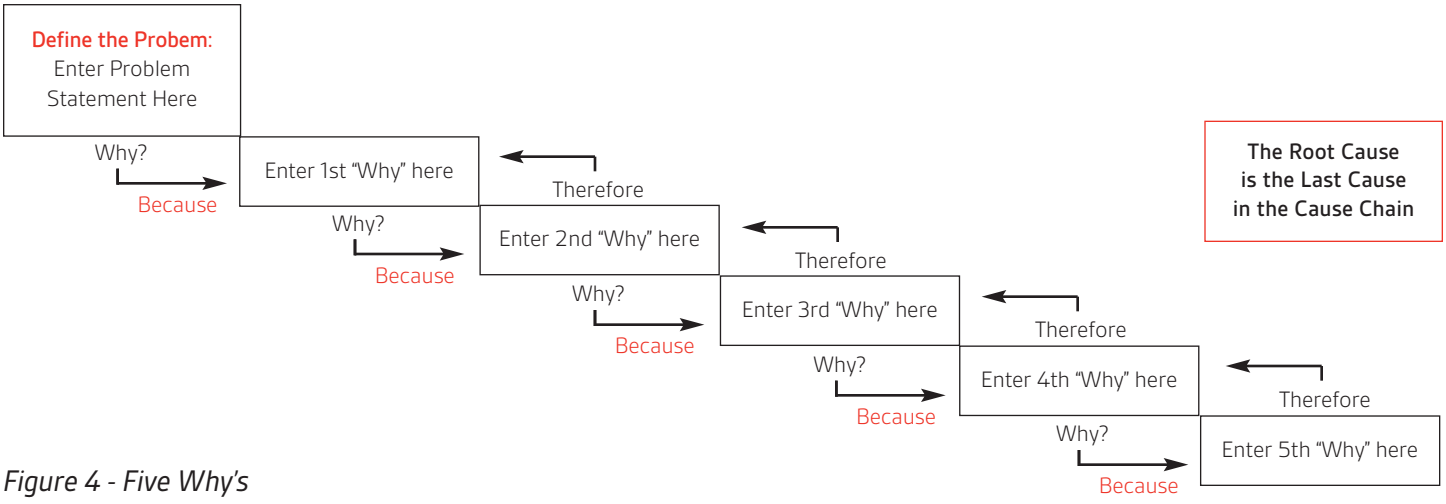

Figure 4 - Five Why's

The Fishbone diagram on the other hand is considered a more holistic approach to problem solving and root cause analysis. Causes in the diagram are often categorized, such as to the 5 M's, (Machine, Manpower, Machines, Methods, and Measurements). Cause-and-effect diagrams can reveal key relationships among various variables, and the possible causes provide additional insight into process behavior.

Causes can be derived from brainstorming sessions. These groups can then be labeled as categories of the fishbone. They will typically be one of the traditional categories mentioned above but may be something unique to the application in a specific case. Causes can be traced back to the actual problem.

Root Cause Analysis requires asking a series of questions to identify all of the possible causes that could explain why the problem occurred. It also helps to identify why the problem was not noticed earlier. Then, all causes should be verified.

Once the root cause is established, the team should work together to create a list of required tasks and implement pre-production, process or design experiment programs to quantitatively confirm that the prescribed solution actually will resolve the problem. It is important to note if employee training should be part of the action plan. To be effective, all modifications and changes must be communicated to all persons, departments, suppliers, etc. that were or will be affected. Automated tools can facilitate these communications to stakeholders and also ensure that communications are received and acknowledged.

Solution

The next step is implementing the solution. It is important to confirm and verify that all of the required tasks described in the action plan are initiated, completed, and documented. At the same time, necessary changes to documents, processes, procedures, or other system modifications must be described in a clear and concise manner and should specify the desired outcome of any changes. As one may imagine, in complex processes, discovering the potential impact of an action plan may be difficult. In this instance, a programmed tool with a comprehensive search function can ease the discovery process and help ensure that affected areas are uncovered, considered, and addressed.

Once the long term permanent action is in place, the team needs to ensure that it has records of all actions taken. It also must have a plan in place to follow-up, verify, and assess the effectiveness of the solution it has implemented after a pre-determined period of time. The team also should implement preventive measures such as modifying management systems, operation systems, practices, and procedures to prevent reoccurrence of this nonconformity and all similar types of problems.

As this is not a "one size fits all" process, it is up to the team to determine the verification method and timeline required. In some cases (depending on your industry) your customer contract may dictate a specified amount of time that processes must be monitored during and after corrective action.

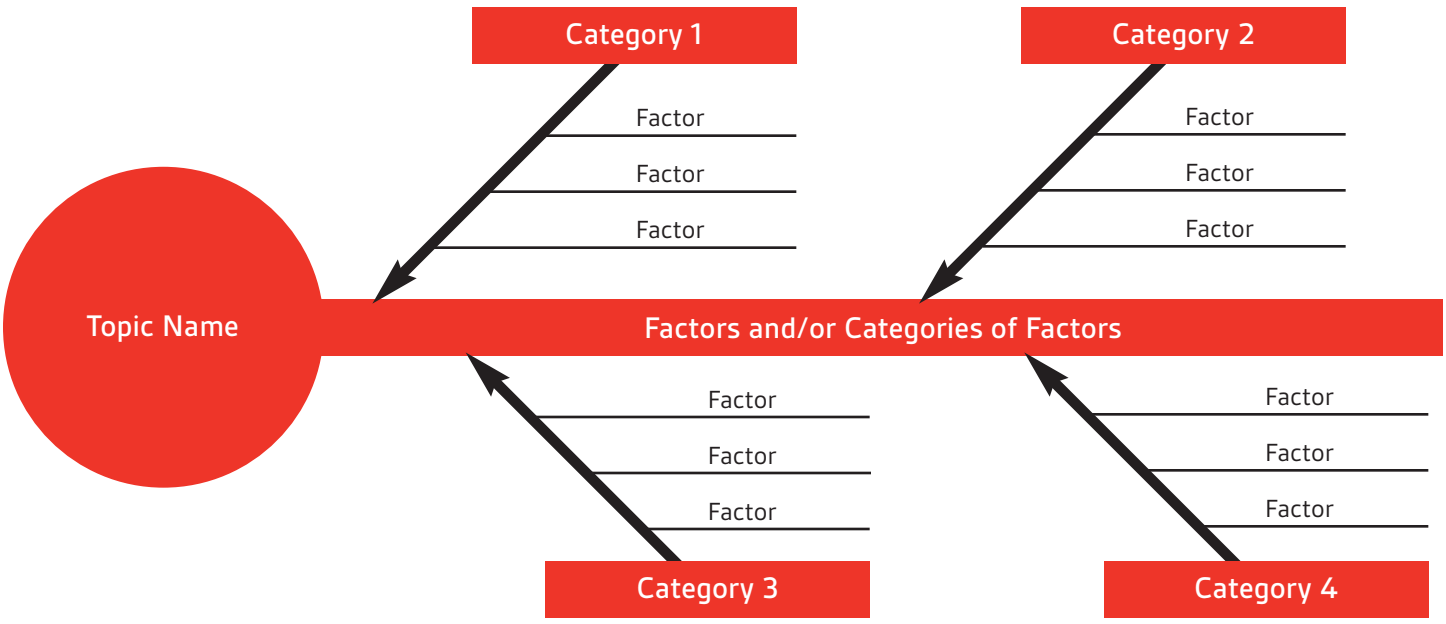

Figure 5 - Fishbone Diagram

Unleashing the Power of CAPA with a Closed-Loop System

The objective of a Closed-Loop system is to utilize CAPA opportunities by systematically converting them into inputs that connect to specific tasks that are assigned to process owners to be carried out until closure, verified and then redirected back into the CAPA system for final disposition and/or continuous monitoring. The CAPA process will provide feedback to managers for necessary process improvements. This in turn enables them to continuously improve how they proactively address and prevent nonconformities.

Checking the effectiveness of a closed-loop CAPA process has to be structured and diligent. CAPA data must be easy to access and analyze, while having a continuous feedback loop. Automating forms-based processes like CAPA, facilitates compliance and saves companies' time and resources; with automation, the concerns of regulators, auditors, and other stakeholders may be easily addressed.

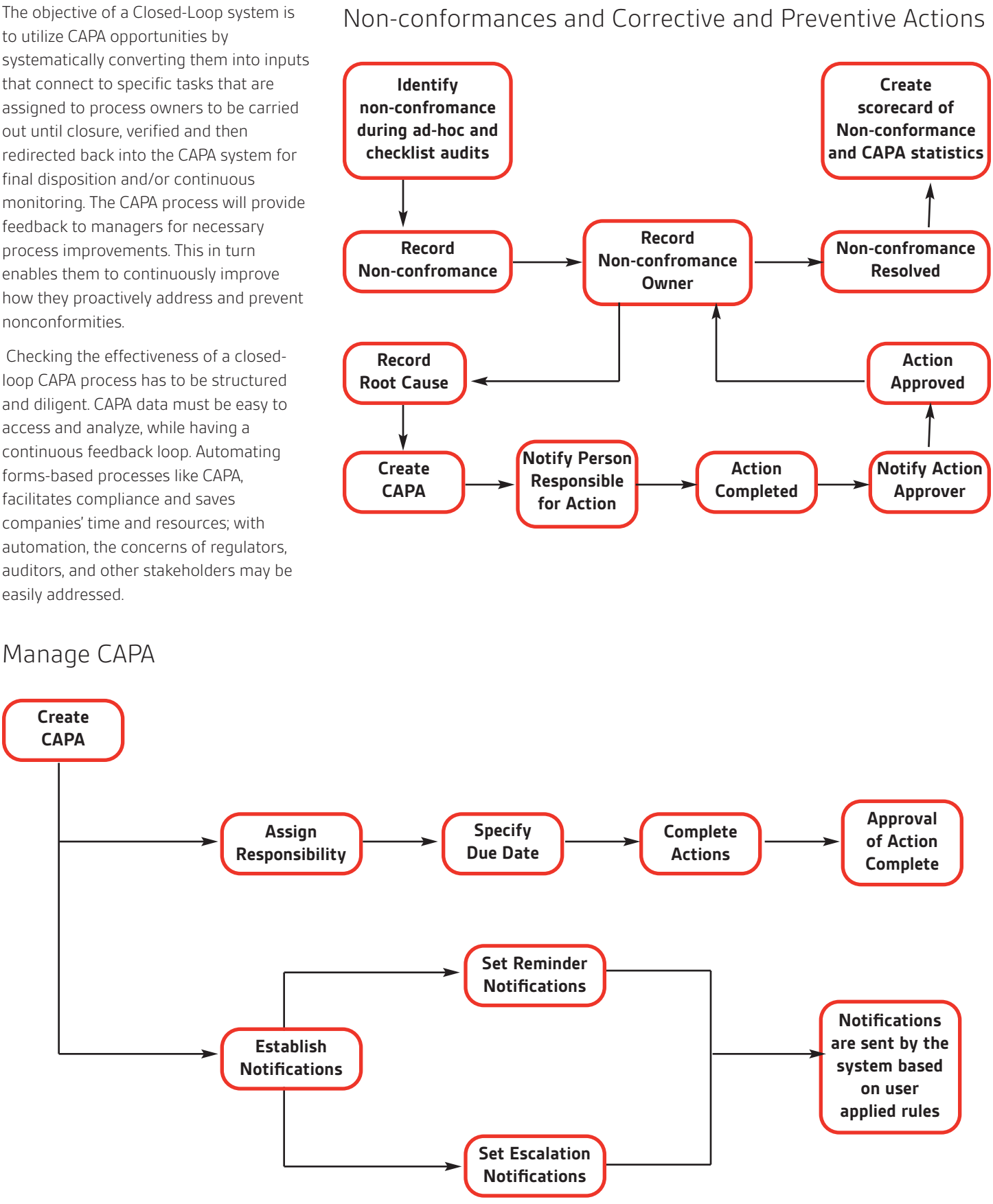

Figure 6: Example automated Closed-Loop CAPA

Conclusion

Without a closed-loop system, the ability for the CAPA process to effectively communicate is compromised. As a result, risk increases because there is no logical flow that can be followed. While any regulated company can ill-afford to work in such an environment, virtually every organization has to uphold customer, internal and industry standards

In an optimal approach for a closed-loop system, resources are managed as a series of interconnecting processes. The system identifies, understands, and manages processes that have interrelationships. Inputs and outputs of the system are also monitored to ensure the process is meeting its expected performance. This optimal approach takes a certain amount of automation to be effective. An example of a workflow element of an automated closed-loop system is shown in Figure 4. We can see that key processes are integrated and tracked to ensure that responsibility and tasks are assigned, root cause analysis is captured, and the final action plan is documented, implemented, and verified. Key owners are established, notified and documented as are the start dates and due dates. Automatic reminders and escalation notifications ensure the process and tasks are on track.

While implementing a closed-loop CAPA process can be an expense for companies, the cost of inaction is higher (i.e. ad hoc investigation of incidents, unclear assignment of accountability, assets over or under protected, and fines or suspensions levied by regulatory authorities).

One way to contain costs is to subject both preventive and corrective actions to the same closed-loop process. Furthermore, preventive actions, in particular, need to be thoroughly investigated and justified, both at the time of implementation and on a regular basis going forward, in order to avoid unintended consequences that could lead to non-conformities.

Manually meeting the requirements of a closed-loop system is a very daunting task, which may tax resources in a manner that can lead to the deterioration and disuse of the CAPA process. An enterprise level, role-based, automated software tool will encourage stakeholder participation in the CAPA process; the facts and figures associated with CAPA will become operational intelligence; and the organization's operational intelligence quotient can greatly improve, thereby improving the likelihood of implementing and sustaining a top-notch, close-loop CAPA process.

By leveraging intelligence to drive operational excellence, companies are relying on automated closed-loop systems to implement a systematic and consistent CAPA process across the organization for increased transparency, effectiveness, and efficiency.

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