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White Paper:

How to Kick-Start Your CAPA Process

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The medical device industry faces the challenge of delivering safe and cost-effective products on time, every time. The pressure to put products into the marketplace is undoubtedly intensified by the strict guidelines enforced by the FDA and other regulatory bodies worldwide. Medical device companies are under obligation to meet market demands while complying fully with regulatory requirements.

Over the last couple of years, we have seen a significant increase in warning letters and consent decrees that have in some cases caused a supply chain delay or even plant closure. Every organization understands that an effective corrective and preventive action (CAPA) program is mandatory for doing business while satisfying the FDA guidelines. The bottom line is to find ways to operate effectively within a CAPA system while maintaining profitability.

Challenges of Implementing CAPA

Historically, most organizations have relied upon the wisdom and experience of their internal experts to identify root causes. Experts attempt to solve all problems using their experience of tried and true past solutions. The main pitfall of this strategy, however, is that their solution is completely dependent upon and limited by their expertise. If the root cause happens to lie outside the scope of their expertise levels, they are not likely to find it. Therefore, they must design a series of closely monitored experiments to test their hypotheses and to determine if they are on the right track in locating the root cause. The problem with designing and implementing these experiments is that they are invasive —requiring personnel, equipment, laboratory resources, down time, and funding. If the experiment is a failure, the internal experts must repeat the same costly process again: brainstorming another probable cause and conducting yet another experiment. This process can be time-consuming and lower the morale of those involved.

To the FDA and the customers who observe this trial-and-error approach, confidence deteriorates quickly. For an FDA investigator conducting an inspection, this often results in a costly, time-consuming search to assure that necessary corrective actions are based on more than expert guesses.

Fortunately, there are alternatives to this model. Today, successful companies are discovering that deductive reasoning and comparative analysis are faster, easier, and more cost-effective ways to identify root cause, test the hypothesis, and implement a corrective action. Several proprietary programs use deductive reasoning and comparative analysis. The primary focus of such processes is on improving diagnostic technique through better data collection. Data is collected using an (is-is not) observed and comparative questioning technique. A unique yet simple tool is used to synthesize the collected data into information that tells the root cause story.

During a CAPA investigation, an internal investigator may use a cause analysis process funnel following a six-step methodology. The funnel represents the steps to be taken reading from top to bottom.

Improved CAPA Investigation

Problem: Every effective investigation begins with understanding the problem. Two key ingredients to building an effective problem statement are to understand the object and defect of the problem or in other words, “What is wrong with what?” By clearly identifying the object and defect, one can launch a battery of effective investigative questions. Be careful that the object and statement of defect is not too general or vague. To say, “Stability test of product A has failed,” is far too general. It is much better to say, “Sample A has IPA solvent levels that exceed minimum specification.”

In some situations, the object may be less tangible, such as a system error in a computer operating system. Nonetheless, the investigator searching for the root cause to a problem must use specific language to define the object and defect regardless of whether it is a process, equipment, product, or human error.

Figure 1 - The CAPA process should be integrated into the quality management system.

Investigate: Years ago, Isaac Newton said that everything that is anything can be identified in four dimensions. Today's research supports Newton's theory. The primary purpose of the investigation step in the process is to ask key questions that provide insightful data in the dimensions of what, where, when, and weight. These dimensions become the basis for gathering data when using the six-step model seen in the funnel diagram. The key facts are made visible by probing these dimensions. It is important not to ask "why" at this point as this step is primarily used to gather all relevant facts, not to interpret the facts.

Compare: After collecting facts about the problem, investigators should gather points of comparison from each of the dimensions. In this sense, "comparisons" are similar data points where this problem could logically be seen occurring in time (when), location (where), and magnitude (weight). For example, if the same IV bag is manufactured on two lines and only Line 1 has the problem, then Line 2 would be a good comparison because it could experience the same problem but did not. Also, if Line 1 did not have the problem last Tuesday afternoon, then Tuesday morning would be a good "is not" comparison. Comparisons are important data sets that distinguish between what the problem is versus what it could become. These data sets are used to start the deductive process and to generate clues as to what is unique between the observed and comparative information.

Clues: After having established the data in the "Investigate" and "Compare" columns, the next step in the process is to ask, "Why?" The cause analysis Process shows that effective investigations are best understood by asking, "What is unique or different" between the observed "is" information and the contrasting comparison "is not" information. These unique differences frequently direct the investigator in finding the root cause of the problem. Use the four key dimensions of what, where, when, and weight to explain why the problem is occurring in the investigative facts and not occurring in the comparison.

Causes: Armed with several clues, CAPA investigators naturally ask, "What about these differences, changes, or clues would account for the nonconformance or the out-of-spec (OOS) problem?" It is at this point in the process where the previous experience of the investigator will be utilized to interpret the facts and make connections as to which clues would best explain the nonconformance.

Test: Instead of trying to support the likely cause with an experiment, it is more effective to try and eradicate the hypothesis in a destructive or logic test. If then, after being unsuccessful in the attempt to eliminate the hypothesis, it would appear that the root cause to the problem has been isolated. In order to explain why the problem was occurring under the observed circumstances but not the comparative circumstances, the reasonableness of the cause must be tested. It is vital to eliminate any causes that do not match the data. A key question to ask would be, "If this is the right cause, does it explain why I see my observed facts and not the comparative facts?"
Correct: Once the root cause has been determined, there are four primary actions that may be taken. Depending on schedule, resources, safety, customer demands, or other key criteria, consider the following actions:

- **Adaptive** - Action that allows the adaptation or ability to live with the problem situation and still operate within daily objectives.

- **Interim/Correction** - Action that alleviates the immediate effects of the problem and buys time before a corrective action is implemented.

- **Corrective** - Action that eliminates the problem permanently.

- **Preventative** - Action that anticipates potential problems and eliminates the most likely causes of the problem so they are less likely to occur in all areas of operation.

Ask the question, "How will I best address the issue in order to resolve the root cause?" Corrective action is generally the best course to pursue.

Investigation Case Study
The following case example will demonstrate the six process steps as outlined in the process funnel:

A medical device manufacturer in the U.S. has been implementing a method for improving all aspects of its business operations. Early in 2002, the company began deploying cause analysis as a process, which assisted in scrutinizing problems more effectively. The company began training employees to follow the cause analysis method and also certified cause analysis process advisors internally who are specifically trained to lead groups through difficult investigations and pinpoint root cause. Under the direction of these advisors, many problems have been solved and a number of non-conformance CAPAs have been closed.

In February 2003, customer complaints were received regarding "fractured tubing" on a vendor-supplied tubing cartridge, which is one of the disposable components utilized in a blood processing system. A nonconformance CAPA report was opened, and a cause analysis process was used to determine what was causing the problem. As a team was dispatched to investigate this problem, one member noted that they had seen a similar problem five years earlier but that it had gone away. They also noted that the problem was getting worse, as the number of complaints went from three in February to 12 in early March. Costs were increasing due to the company having to inspect 100 percent of these parts on the floor, requiring additional labor.

Manufacturing and quality engineers were sent to the supplier of this part to better understand what was going on and to collect data. After returning, the following data was placed into a cause analysis worksheet.

The problem was defined by answering the questions in the four key dimensions: what, where, when, and weight. Under closer examination, a combined effect of two variables taken from the clues column seemed to account for what was occurring, with the tubing fractures. During the assembly process, one end of the tube is dipped in solvent (glue) and is then pushed into the socket on the tubing cartridge. The tube was wrapped around the cartridge while the other end is secured to the cartridge with tape. If the tube was allowed to sit 20 to 40 seconds after socket bond attachment was made prior to taping it in place, and if it was pulled on while securing it with tape, the tube fractured at the socket bond due to the assembly stress. This cause could not be discounted by testing against the assembled facts seen on the worksheet. Further examination of failed parts verified that this was indeed the cause.

The company reviewed in the cause analysis worksheet noted several likely causes that might possibly account for the tubing fractures. By examining how each clue would explain the tubing fractures, the company investigators were able to discover the most probable causes. The mold was changed to add five ribs to preserve the arc of the tubing and reduce the stress at the socket bond ensuring that even if an operator pulled upon the tube accidentally, it would not stress fracture. By using this corrective action, a serious problem was eliminated. This medical device manufacturer continues to solve the types of problems that every manufacturer encounters, through fast and effective investigation techniques such as cause analysis. The benefit of using cause analysis is significant. Many organizations are able to lock onto real root cause and implement corrective actions that keep the problem solved without costly reoccurrence. A common process has promoted better communication between the internal investigator and those closest to the data. Due to internal CAPA requirements to explain data logically before beginning any experiment, trial and error experiments have been greatly reduced.

Design of experiments (DOE) can now be held back and used only to verify or prove that this corrective response will work. The repositioning of DOE to a verification tool/research tool from a problem-solving tool increases speed of root cause resolution and creates less operational disruption. Another benefit is that both management and FDA can easily see the logic trail behind the investigation, corrective action, and solutions. This allows management to apply its collective wisdom, often gathered from experience, to ensure that any corrective response explains all the facts. If the corrective action and likely cause will not support the observed versus the comparative data, new clues must be sought and more data probed before an advisable action can be taken. The observed and comparative data collected leave the doors open for any conclusion to be tested quickly, a factor bound to be appreciated when focusing on speed to market, regulatory compliance, and scarce resources.

For this root cause analysis to be implemented effectively, there must be effective training, competent internal investigators, integration into ongoing procedures, and reliable documentation.

Adopting a New CAPA Investigation Model

There is an unspoken rule in any highly regulated business: “Any process that lacks discipline is doomed to fail.” For a car, forward traction occurs where the rubber meets the road. Likewise, a process that is integrated and measured throughout the organization provides forward traction. The end result is—no discipline, no process.

The following four-phase CAPA implementation brings the best results needed for forward traction:

1. Gain organization commitment.
2. Integrate root cause analysis into the quality systems.
3. Train key people.
4. Provide reinforcement and tools.

Gain organization commitment: For a new CAPA process to be embedded long-term, it must align with the business initiatives and allow the employees to solve a variety of problems. Commitment comes from two directions: top down (management) and bottom up (employees). What normally gets in the way of commitment is that each source has different

indicators of success that can confuse commitment. Top down measures employee buy-in, customer satisfaction, and market alignment that meet product and growth goals. Bottom-up evaluates what is being done, not what the management says they are after. Employees often will stay with a root cause process that works and brings results even without management commitment. Bringing process coaching top down and root cause investigating from the bottom up into alignment is critical to long-term sustainment.

Integrate root cause analysis into quality systems: Make the process establish a well-grounded method for accomplishing work within the organization. This is normally accomplished by placing forms or templates into the control of the company, basic operating procedure (BOP), and reporting systems. The cause analysis worksheet is a tool easily placed into a documentation process. The company systems need to be aligned to incorporate the desired result. If not, many people will go back to their old methods.

Train key people: Train on the new process steps at the appropriate level. Most often, the new skills cannot be implemented into the old systems, nor can the new systems and processes be properly supported using the old skills. Provide training to employees at the level each employee needs to use the new skills. For example, it is unnecessary to be taught how to build a car if all that is needed is a driver's license. Teach the right skills to those who need and will use them. Ensure that they understand the new skills and can apply them. Internal investigators need greater proficiency in cause analysis than the operators who answer investigators' questions.

Provide reinforcement and tools: There is a generally accepted rule that two weeks after a training session, the attendees forget 60 percent of what was taught. This means that the likelihood of someone continually using the new skills is low. What is needed is ongoing coaching, support, accountability for effective investigations, and reliable corrective actions.

Every organization needs a reinforcement process. A valuable tool for that reinforcement would be to have a cause analysis process advisor on board. Cause analysis process advisors are employees who are selected based upon their credibility, dependability, and experience within the organization to solve problems. These selected individuals receive a high level of specialized training in the cause analysis process, as well as internal consulting and team skills. These process advisors become an additional pair of hands for managers and teams when investigating out-of-specification occurrences.

Once key employees are trained in root cause analysis, it behooves an organization to equip them with the appropriate software solution as a tool for conducting the investigation and implementing corrective action. The system should be flexible enough to recreate a company's existing paper-based forms to accelerate the process. It should tie all quality processes together, from the initial nonconformance to corrective action, for a closed-loop problem-solving approach.

MasterControl and PathWise Partnership

MasterControl Inc., the leading maker of integrated quality management software solutions for regulated industries, and PathWise, an innovator in the development of management solutions and training programs for companies in the life sciences sector, have formed a partnership to provide a one-stop CAPA solution.

Companies can improve their investigative process and data input through PathWise's proven analytical methods for investigating root cause, performing corrective action, evaluating a CAPA system's effectiveness, and preventing future problems. The PathWise methods are particularly effective in managing complaints, nonconformances, out of specifications, and deviations.

Performing the proper investigation and implementing a corrective action quickly is easier with an integrated software solution such as MasterControl CAPA™ and MasterControl Forms™. These closely related applications offer out-of-the-box configurations that can be used as is or customized to help manage forms-based quality processes such as CAPA, audits, out of specifications, nonconformances, deviations, and customer complaints. They can be integrated with MasterControl Documents to link all forms-based workflow processes with document control, change management, and

training. When CAPA is initiated, the system will trigger a change in engineering, SOP, and other documents, as well as new training on the change.

In the future, risk schedules will be incorporated to aide in knowing if the seriousness will require a CAPA investigation and the ensuing documentation and management review necessary to meet FDA regulations.

Conclusion

In order to solve problems every organization must know how to conduct an effective investigation, identify root causes, and implement workable corrective action in a timely manner. An effective CAPA process requires training internal investigators, who can also coach others in the organization, to employ critical thinking. The process must provide a common model and language within the organization, which allows investigators to master the process quickly and easily. Once a common language is in place, it anchors the logic behind investigations and brings unity to problem solving.

Equally critical is selecting the appropriate software solution for a consistent, thorough, and efficient investigation when it has been decided that software is part of an organization's solution. The overall goal is to implement a repeatable, standardized, and complete process that can tackle CAPAs and ensure compliance.

About the Author and PathWise

Ken Peterson is the founder of PathWise Inc., an education and consulting firm specializing in developing process control and analytical thinking skills. Peterson is responsible for coordinating the development of programs and services that build better CAPA management systems. He consults routinely on quality, problem solving, innovation, risk management, and entrepreneurship.

PathWise, founded in 1992, is a CAPA training and consulting provider to such companies as Baxter Laboratories, Varian Medical, Canadian Blood Services, Johnson & Johnson, Boston Scientific, Stryker, and Fuji Medical. PathWise has offices throughout North America and staff on faculty at the Association for the Advancement of Medical Instrumentation (AAMI), Barnett International, and PDA, and staff serving on boards and committees in various professional organizations. To learn more, visit PathWise at www.gopathwise.com or call (801) 222-9988.

About MasterControl Inc.

MasterControl Inc. has been at the forefront of providing quality management software solutions since 1993. Hundreds of companies worldwide use MasterControl to help ensure compliance with FDA regulations such as 21 CFR Parts 11, 210-211, 820, 606; ISO quality standards such as ISO 9000, ISO 13485, ISO 14000; and Sarbanes-Oxley Act requirements. In addition to providing off-the-shelf products, MasterControl also offers comprehensive technical and customer support, including product training, implementation, and validation services.

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