TIME TO MOVE BEYOND MEDIOCRE CAPAS AND MAKE THEM MORE EFFECTIVE

by Andy Barnett

Have you ever wondered why some of your corrective and preventive actions (CAPAs) fail to achieve the desired improvement? Wouldn't it be nice if there were a way to evaluate the CAPA before you implement it? Your organization will lose valuable time if you wait until the effectiveness check is complete, only to discover that the CAPA was not adequate. Meanwhile, your customers will continue to struggle with quality issues and the regulatory risk will increase as the issues remain unresolved.

We propose the use of our CAPA hierarchy, which will help investigators select a CAPA that is most likely to deliver the desired outcome. It can also be used by reviewers and approvers to evaluate the CAPA plan and push for better solutions. The hierarchy can give them a framework to articulate their concerns and give specific direction to improve the CAPA plan.

The five levels of the CAPA hierarchy, in order of decreasing effectiveness, are:

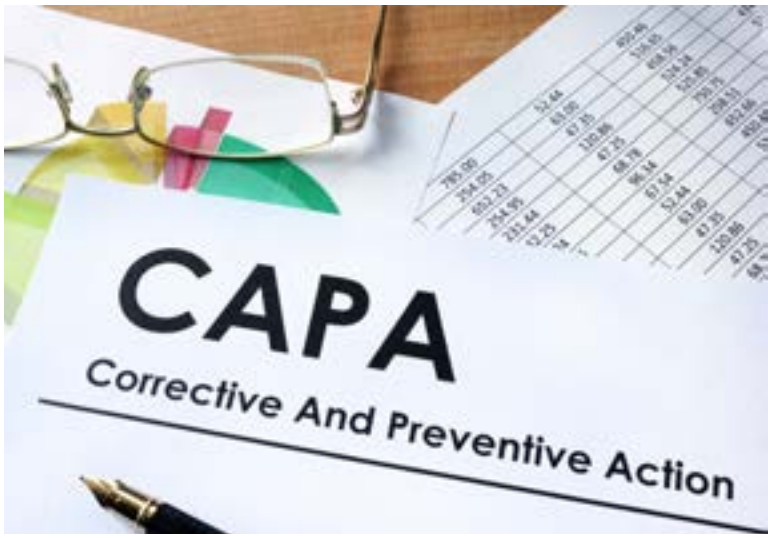
1. Elimination
2. Replacement
3. Facilitation
4. Detection
5. Mitigation

Each of these approaches is discussed below.

ELIMINATION

The most effective CAPA is to eliminate the possibility of errors. The easiest way to achieve this is to eliminate the task, if possible. A few examples include:

> Eliminating mixing errors by purchasing pre-mixed materials



> Eliminating recording errors by linking the measurement device to a printer

> Eliminating steps that are no longer necessary

> Eliminating assembly errors by using an error-proofing device (poka-yoke) such as a fixture with a special feature that prevents parts from being assembled incorrectly

As a specific example of elimination, I helped investigate a recurring complaint for an intravenous bag that was shipped to a customer without a thermal-print label. The operation had a camera that would 100 percent inspect the product and reject units with missing labels. The camera was examined at the beginning and end of each shift, and there was no evidence of camera failures. Previous investigators concluded that an operator must have picked up the rejected units, overlooked the missing label and put the product back into the production stream. In reality, every time an operator pushed the emergency stop button, both the printer and the camera would lose their memory. So the printer did not know what to print, and the camera did not know what to reject. We eliminated the problem by

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modifying the programmable logic controller (PLC) to automatically reject the in-process bags following an emergency stop.

REPLACEMENT

The second most effective CAPA is to change the current process by replacing it with a more reliable one. For example, you could add redundant sensors so that if one sensor fails, the other is still working and the product is not affected. Note that this will not completely eliminate the problem because there is a chance – however slight – that both sensors will fail at the same time.

Other examples of replacement include:

- Designing a more robust screen for milling machines so they don't break as often
- Installing mechanical limiting devices or modifying PLC programs so that the process cannot exceed a specified range
- Using bar code scanners

In fact, hospitals implemented the use of bar code scanners many years ago to reduce patient medication errors. The medication order is scanned and the patient wrist band is scanned. If the bar codes do not match, the medication is not administered. Of course, this does not eliminate all medication errors, just the errors that may occur at the final delivery step in the hospital room.

FACILITATION

The third CAPA in our hierarchy is facilitation, which can make a process easier to perform and therefore make mistakes less likely to occur. Examples of facilitation include:

- Using "visual factory" techniques such as 5S and color coding to make mistakes obvious. Many electronics manufacturers have adopted color coding. The green plug goes in the green socket, the red plug goes in the red socket and so forth. Imagine what you could do with colored signs and storage bins.
- Redesigning forms so that they are easier to complete and omissions are easy to see. If you place all the data entry boxes to the right side of the form, omissions will be easier to spot and correct.
- Streamlining processes to reduce material handling. Every movement is an opportunity to make a mistake. Reducing the number of opportunities to make errors will ultimately reduce the overall frequency of errors.
- Simplifying procedures. Strive for simple action statements, arranged in sequential order. Avoid conditional statements and look-up tables. Add a flow chart. Add pictures. Provide specific directions on what to do if a process upset occurs.

DETECTION

In our experience, numerous companies use improved detection as the default CAPA activity. The intent is to catch the non-conformance as soon as possible after it occurs, preferably before the product moves to the next step in the process. Please don't misunderstand: Detection is essential. You cannot afford to allow non-conformances to get shipped to the customer. However, detection should be viewed as necessary, but not sufficient. Detection is inherently weaker than the hierarchy options listed above. Why? Because detection does not prevent defects; it merely prevents defects from escaping to the customer. Detection does not address the underlying root cause. CAPAs for improved detection should always be supplemented by at least one action that is intended to reduce the frequency of failure.

Detection can be improved by adding audible alarms or lights if a process is out of tolerance. A better approach would be to automatically shut down the process or add an interlock so that the process cannot move to the next step.

MITIGATION

The final CAPA strategy is mitigation, which can minimize the impact of an error and is the weakest form of corrective action. For most pharma companies, the product design is constrained. It is likely that the only way to mitigate is to sort or rework. Sort and rework should be viewed as in interim action that affects only

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the current batch, and is therefore not a permanent solution. This is true even if you have an automated re-inspection system. Simply put, rework is a crutch.

Sometimes you can combine detection and mitigation, such as installing a metal detector with a link to the conveyor. If metal is detected, the conveyor stops or the material is diverted to a scrap bin.

CONCLUSION

We encourage you to review a sample of your past CAPAs and apply the CAPA hierarchy. How many CAPA actions fall into the detection and mitigation categories? These are the least effective actions you can take. You may be surprised by the result.

After you roll out the CAPA hierarchy in your organization, you can use it to critique investigation reports and CAPA plans prior to approval and implementation. If the CAPA actions are limited to detection and mitigation, the investigation report approvers should push back and require the investigator to add actions that are higher up on the hierarchy. You can anticipate the expected results prior to execution. Failed effectiveness checks should become rare events.

The CAPA hierarchy is just one small element of NSF's comprehensive offerings on root cause analysis and human error reduction. To learn more about our training programs, please contact **uspharma@nsf.org**.

ABOUT THE AUTHOR

For over 20 years, Andy Barnett has worked with clients in the pharmaceutical, medical device, biologic and biotechnology industries to develop quality assurance and regulatory strategies for compliance with U.S. FDA regulations. His particular expertise includes providing statistical support for process development, process characterization and optimization; assisting with remediation activities, especially corrective actions and process improvement; and providing training in root cause, corrective actions and statistical methods for process improvement.

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