Best Practices for Effectiveness Checks for CAPA

The need for periodic performance and effectiveness checks should be established and documented as part of a compliant Corrective Action & Preventive Action (CAPA) process. This is a practice that regulators look for when evaluating a firm’s Quality Management System (QMS). CAPAs are among the most important Quality systems and, when done properly, enable the firm to show due diligence and commitment to Quality.

Verifying the effectiveness of corrective and preventive actions closes the loop between identifying a problem and completing the actions to solve a problem. Even in everyday life, if you have a problem, investigate it and correct it, you should also verify that the correction actually worked. Determining the best verification approach and deciding when to conduct the verification for the wide range of problems that could occur can often prove to be elusive. In many instances, these problems are easy to fix, but some require more time and more robust, well-thought out remediation.

After a deviation or non-conformance occurs, it is up to you, the investigator, and the area impacted to develop an action plan to fix the issue. But what if you couldn’t find a true root cause? What if you really don’t understand the problem that occurred? What happens if you deem the issue a minor hiccup as opposed to a critical deviation from the norm? What if the team begins to over think the resolution? These are all common roadblocks when trying to establish an effective verification for a CAPA.

Once the CAPA has been established and the details have been determined with regard to the plan of action, the areas responsible and the due date for implementation; it is up to the Quality Unit to develop a proper effectiveness check to ensure that the CAPA is successful.
The basic purpose of a CAPA is to identify the problem and make certain it does not occur again.

Some firms struggle with using a quantitative approach in performing effectiveness checks, because some things are harder to measure than others. However, you can measure anything. For example, you can even measure entry errors for operators who are deviating from good documentation practices. This can be done by identifying area where quality records are reviewed and documentation errors are measured. You can measure by operator, type of documentation, i.e. lab record, batch record, cleaning log, by month, etc.

To help with this process, you may want to answer some of these questions:

1. Who will measure it?
2. What will be measured?
3. Where will it be measured?
4. When will it be measured?
5. How will it be measured?
6. How will measurements be analyzed?
7. Who will data analysis be communicated to?

Once these questions have been answered, you can move on to developing ways to verify CAPA effectiveness.

Some basic tools and principles can be used to help make these effectiveness checks successful.
• Trend Analysis – In the cases of human error, training, environmental monitoring excursions, cleaning deviations, testing errors, etc. trend analysis can help the auditor determine if the corrective action has remediated the issue. The auditor can review data over a pre-determined timeframe and determine if the problem or deviation has occurred again after the corrective action was implemented. In most cases, the data will show if another corrective action should be established or if the fix was successful.

• Periodic Checks – This method involves reviewing the process that was remediated in real-time. For example, if there was a CAPA implemented to improve gowning practices, the auditor can observe the newly improved gowning practices prior to the operator entering the clean room.

• Surprise Audits – Audits are intended to ensure that compliance is being maintained in a certain area. When audits are used to verify effectiveness checks, they can be done in a manner to make sure that the operators, process or equipment is following the prescribed corrective action documented in the CAPA.

• Sampling – Sampling is a successful method to verify corrective actions pertaining to environmental monitoring or lab testing. For example, if there was a deviation for an area exceeding environmental action limits and more robust cleaning practices were in place, additional samples could be taken to verify that the additional cleaning was effective.

Another vital piece to ensuring a robust and properly managed CAPA effectiveness verification is establishing the appropriate timeframes to perform the checks. When settling on a due date, it is important to give enough time for the corrective action to work while maintaining a sense of urgency to ensure the problem is fixed. Some deviations or problems may require a simple procedure update, re-training or tweaking to a piece of
equipment. However, in most cases, CAPAs are opened to address more difficult issues such as changing the facility layout, changing gowning practices, increasing sample sizes, or implementing a new piece of equipment. In these cases, it is best practice to set up several effectiveness checks over a period of time. Perhaps the first check can be done within a few weeks, but others will be spread out over the next few months.

Overall, CAPA effectiveness checks need to be robust and fix the issue at hand. They are a proven method to track, trend and remediate some of the more critical deviations that occur during manufacturing and laboratory testing. When done well, effectiveness checks demonstrate your firm’s commitment to Quality and Compliance.

About the Author: Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters, consent decrees and those wishing to improve compliance establish more robust quality systems so that the company can succeed.

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