DO YOU HAVE A ROBUST AND COMPLIANT CAPA SYSTEM?

by Mehul Patel and Andy Barnett

LET'S FIND OUT.

Pharma biotech companies around the globe are struggling to juggle numerous priorities and challenges. One of their biggest struggles is to effectively manage CAPAs.

1. Do you use a scored risk assessment process to determine the need for an investigation and CAPA?
2. Do fewer than 10 percent of your investigations conclude human error as the root cause?
3. Do you maintain and use metrics on how your CAPA system is performing?
4. Do you perform effectiveness checks that include objective and measurable criteria?
5. Do fewer than 25 percent of your CAPAs need extensions?

Unless you answered YES to all of the questions, your CAPA system may not be as robust and compliant as you think.

SYMPTOMS OF AN INEFFECTIVE CAPA SYSTEM

Pharma biotech companies that lack robust and compliant CAPA systems may be struggling with one or more of the following common problems:

> Employees focus on closing the CAPA to release the batch rather than applying a systemic approach to resolve and remediate the problem and prevent it from happening again

> CAPA actions address symptoms but do not fix the underlying root causes

> There is a lack of expertise in developing, implementing and maintaining (and sometimes enhancing) a CAPA system that integrates compliance into business practices and quality systems

> The CAPA system may be good but personnel do not use, or do not have the knowledge and expertise on to effectively use, the CAPA system to improve profitability by decreasing the cost of quality

> The CAPA system doesn't use effective checks and thereby results in unintended consequences

> The CAPA actions add unnecessary complexity and inevitably lead to non-compliance with local procedures

CAPA ADVICE

Not just for tracking

A CAPA system is not just a formal tracking system, it is the central component that encompasses all of the mechanisms and data sources that a sound quality system uses to monitor the quality of people, processes, product and problems. The CAPA system is an overarching umbrella – all control points flow through to the CAPA system.

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Goldilocks and CAPAs

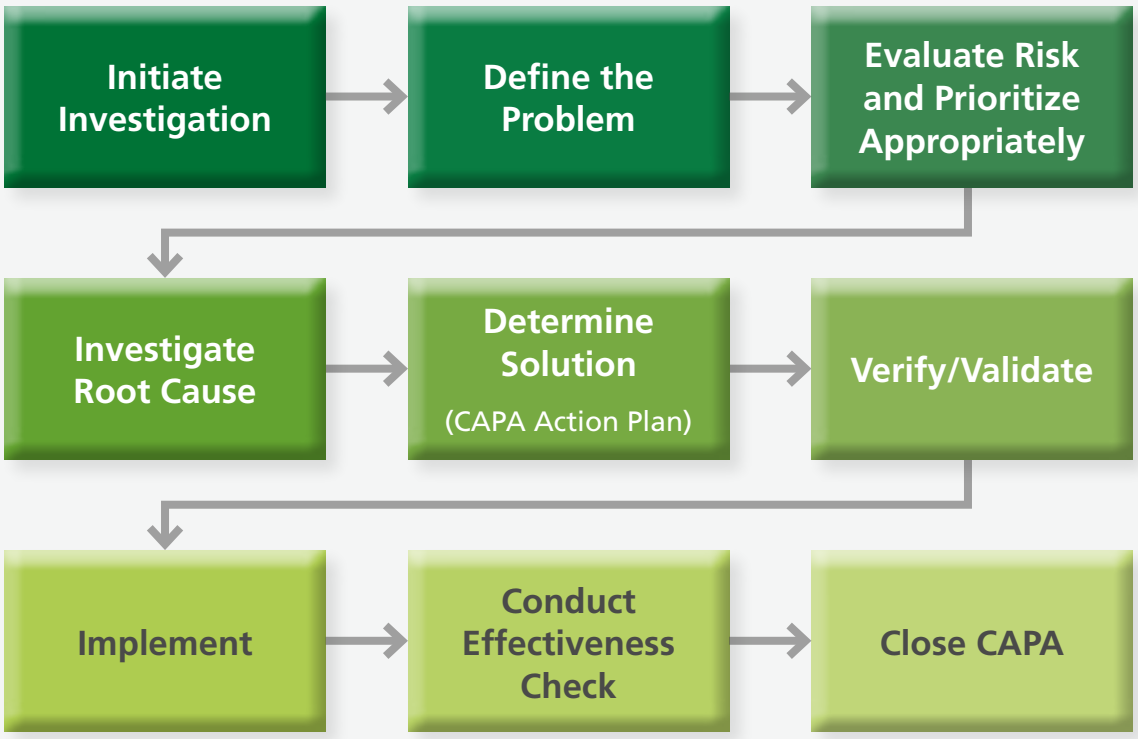
We have come across several companies that seem to be reluctant to open another CAPA for fear of overwhelming the system. This may result in under reporting of CAPAs which is a missed opportunity to fix problems and drive improvement. There is perception that having too many CAPAs is a bad thing and indicative of poor control over the pharmaceutical quality system. There is a fine line between having too many vs. not enough CAPAs, so one should strive towards a Goldilocks model – where you have the number of CAPAs that are just right. A facility must have appropriate mechanisms in place to determine when a situation merits issuance of a CAPA. It must be understood that not all investigations will result in a CAPA. One example may be an investigation in which the root cause has not yet been determined. Some companies in this situation will initiate a CAPA anyway, which is not value added. CAPAs initiated at this stage will divert resources to complete the action plans but will not reduce failure rate. Sometimes it is necessary to wait until there are several non-conformances before a pattern that points to the root cause can be identified.

How long is too long?

Once the root cause is identified, evaluate the CAPA. Some CAPAs will be quick and easy to implement whereas the others may have long lead times, e.g. equipment redesign. If the CAPA will remain open for a longer period of time, the CAPA system should track the status and document the milestones. It is not good practice to leave a CAPA open long with no indication of activity. Time flies and at times a CAPA deadline is missed. The first solution to this problem is to set realistic timelines for completion; too many of us are overly optimistic about the time needed to implement improvements. However, when it becomes clear that the deadline will not be met, it is a good idea to include a system for CAPA extensions. It is recommended that you have an escalating level of approvals for extensions – for example, the first extension requires department approval while the last extension may require executive level approval. The system should have the ability to capture status information and milestones as well as rationale for the extension and the risk of not closing as per the original date.

CAPA ESSENTIALS

The CAPA process can be simplified as below:



Pharma biotech companies can improve their CAPA processes by:

- Implementing a CAPA system that is simple, easy to follow, risk-based and easily integrated throughout the organization
- Implementing a standard set of root cause analysis tools
- Using data analysis tools and processes within the CAPA system
- Configuring data so similar problems can be categorized to facilitate trending and further data analysis
- Determining the frequency of data analysis and metric review
- Identifying adverse trends in real time and intervening before they deteriorate into non-conformances

During the course of CAPA process, if you discover a new piece of information or come across a new learning, evaluate and communicate it. Also ensure that it cascades through and eventually gets implemented to other products, quality systems, and across the organization as appropriate.

DEATH BY CAPA (OVERKILL EFFECT)

While trying to develop or enhance a robust and compliant CAPA system, companies sometimes overdo things and end up adding unnecessary elements in their CAPA system. These elements start strangling the company and thereby cause the death by CAPA effect.

Companies needs to be very careful as they can easily fall into this overkill trap. They can suffer death by CAPA by having either too many CAPAs or an overly complicated system. An effective system requires a balanced approach. You do not want to develop a CAPA program that ends up requiring a CAPA!

To avoid death by CAPA:

- Use a risk-based filter and prioritize events according to size, scope and severity
- If possible develop and use a scoring system
- Adequately train qualified personnel
- Get advice from experts

ABOUT THE AUTHORS

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Cite as: NSF International. August 2017. Do You Have a Robust and Compliant CAPA System? NSF: York, UK.

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LPH-469-0817