The CAPA system is the cornerstone for a Quality Management System, especially in the Pharmaceutical Industry, and the backbone and driver for Quality improvements. The CAPA system feeds the Quality System to improve processes, procedures, organization and business in a structured, well-documented and actionable way.

There is a strong link between QUALITY and OPERATIONAL EXCELLENCE, as a well-established CAPA system will result in a high Return on Investment (ROI) and benefits for the business, for instance:

- Improved safety and security
- Improved customer satisfaction
- Increased productivity, as a smarter process might require less personnel
- Infrastructure efficiency gains
- Better product quality
- Avoiding cost of regulatory non-compliance (fines, business closure, reputational and brand damage)

Most companies have recognized that how a quality system is maintained and monitored is critical to its effectiveness. The risk-based CAPA requirements demand a well-documented system that determines the root cause of non-conformances, system failures or process problems, corrects the problems, and prevents them from recurring. The documentation must identify why something went wrong—or why it may go wrong—and what has been done to make sure it does not happen again.

Because CAPA systems are documented indicators of problems and how they are resolved, CAPA systems are a primary target and scrutinized at every audit or regulatory inspection.

**CAPA DEFINITIONS**

When it comes to CAPA we must segregate between three (3) different subjects:

- Correction or Remedial Action
- Corrective Action (CA)
- Preventive Action (PA)

**CORRECTION**

In the first instance, correction or remedial action focuses on the immediate situation in order to eliminate an existing non-conformance or undesirable situation. It is very important to note that those actions that focus on the immediate situation do not tackle the root cause but just “fixes” the problem temporarily.

**CORRECTIVE ACTION**

A Corrective Action is a reaction to a non-conformity or undesirable situation that has already happened. It assumes that a non-conformance or problem exists and has been reported by either internal or external sources. The actions initiated are intended to prevent the recurrence, which included the following steps:

- Correct the problem
- Modify the quality system so that the process that caused it is monitored to prevent the recurrence
- The documentation for a corrective action provides evidence that the problem was
  - Recognized
  - Corrected
  - Proper controls installed

**PREVENTIVE ACTION**

A Preventive Action is a proactive approach and process for detecting non-conformances or undesirable situations that have not yet happened and prevents them before occurring. The process includes:

- Identify potential problems or non-conformances
- Find the cause of the potential problem / non-conformance
- Develop a plan to prevent the occurrence
- Implement the plan
- Review the actions taken and the effectiveness in preventing the problem

From a business perspective, Preventive Actions are much more powerful than Corrective Actions as they are proactive rather than a reactive approach.

**HOW TO IMPLEMENT A CAPA SYSTEM**

The most efficient way to implement a sustainable and robust CAPA system is by applying a closed loop system,
like the one described below (Figure 1), which is based on the following process steps:

- Identification
- Evaluation
- Investigation
- CAPA Implementation
- Verification

IDENTIFICATION

Non-conformities requiring CAPA can arise from various situations and can include, but are not limited to, internal audits, external audits, regulatory inspections, customer complaints, staff observations, trending data risk assessments, process performance monitoring, management review, etc.

During this initial step of the process it is important to list the specific information available that demonstrates that the problem does exist. This description should be concise, but with sufficient information to assure that the problem is well detailed and can be easily understood from reading the explanation. Key areas to focus on are:

- What EXACTLY went wrong?
- How often has it occurred?
- How big is the problem?
- What impact does the event create?
- Who has more information?

Common pitfalls at this stage are, for instance, failing to confirm understanding, accepting opinions as facts, failing to record information thoroughly and accurately, and most commonly jumping to problem solving mode too soon.

EVALUATION

Once the Identification phase is closed, the non-conformance is required to be assessed in terms of the potential impact, for instance in related to quality, safety, reliability, costs, or customer satisfaction. Utilizing a risk assessment tool, such the matrix in Figure 2, is a recommended and suitable tool.

Additionally, remedial actions might need to be implemented during this phase until the investigation is closed and the corrective action defined and implemented.

INVESTIGATIONS AND ROOT CAUSE ANALYSIS (RCA)

With the further knowledge gained through the first two steps of the process, it is now time to prepare the investigation plan by reviewing the circumstances related to the issue. By applying certain techniques as described in Table 1, a list of all possible causes can be created. This will form the basis for collecting relevant information and further evidences, like test data, that will be required to drill down to the root cause of the issue.

It is important to consider all possible causes (and not only focusing on one), the appropriate associated information and supplementary data to determine the root cause of the non-conformance.

It is strongly recommended to consider equipment, materials, personnel,
procedures, design, training, software, and external factors, and list all possible root causes to define which data must be collected for the assessment.

Brainstorming sessions, Process Mapping, Value Stream Mapping, Interviews and applying the 5 Whys are the most common techniques.

However it is imperative to recall that "we can’t solve problems by using the same kind of thinking we used when we created them." (Albert Einstein)

Therefore, approaching the problem from a different angle, involving a team and exploring different and/or new options is the key for an effective Investigation and root cause analysis.

**CAPA IMPLEMENTATION**

After the investigation is closed and the potential root cause identified, the CAPA implementation is next. In order to proceed, a CAPA plan should be developed and should include, as appropriate:

- All actions to be completed, for example review of other batch records
- Required documents (e.g., SOPs) to be changed
- Process / Procedure changes
- Process changes should be described in sufficient detail so that it is clearly understood what needs to be done (avoid generic statements)
- The expected outcome must be clarified and described
- Employee training
- Monitors / Controls to be implemented to prevent the problem to reoccur

The CAPA plan must also identify the person responsible for completing each task, including time lines and further resources needed, if applicable.

**SUMMARY**

CAPA systems are not only a regulatory requirement; they make good business sense to life science companies. Companies must ensure that appropriate corrective actions include both short-term actions to address the immediate problem and long-term actions to prevent the recurrence of a problem. In order to successfully manage the CAPA system, companies need to simplify their procedures, and to filter and prioritize the corrective and preventive actions. Senior management must allocate proper resources to identify and remove the root causes of recurring problems.

The most complex CAPA issues may be found in non-routine channels, such as customer surveys. Companies have to uncover and rectify the tough-to-spot problems, before they trigger an FDA warning letter.

By removing the root causes of recurring problems, companies will benefit twice – by meeting the regulatory expectations as well as business requirements.

**TABLE 1: INVESTIGATIONS AND ROOT CAUSE ANALYSIS TECHNIQUES**

<table>
<thead>
<tr>
<th>FIVE WHYS</th>
<th>INTERVIEWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAINSTORMING</td>
<td>SURVEYS</td>
</tr>
<tr>
<td>PROCESS MAPPING</td>
<td>QUESTIONNAIRES</td>
</tr>
<tr>
<td>VALUE STREAM MAPPING</td>
<td>HISTOGRAM</td>
</tr>
<tr>
<td>BAR CHART / PIE CHART</td>
<td>CONTROL CHART</td>
</tr>
<tr>
<td>PARETO CHART</td>
<td>FLOW CHART</td>
</tr>
<tr>
<td>FISHBONE (ISHIKAWA) DIAGRAM</td>
<td>RUN CHART</td>
</tr>
</tbody>
</table>

**VERIFICATION**

One of the most fundamental steps in the process is to provide evidence that the CAPA has finally been implemented successfully. This assessment must allow answering several key questions:

- Has the root cause been tackled appropriate to prevent the issue from recurring?
- Have all defined actions and changes been completed and verified?
- Are proper controls in place?
- Is there any chance that the solution implemented has any adverse effect on the product, process, or service?
- Is everything well documented?
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