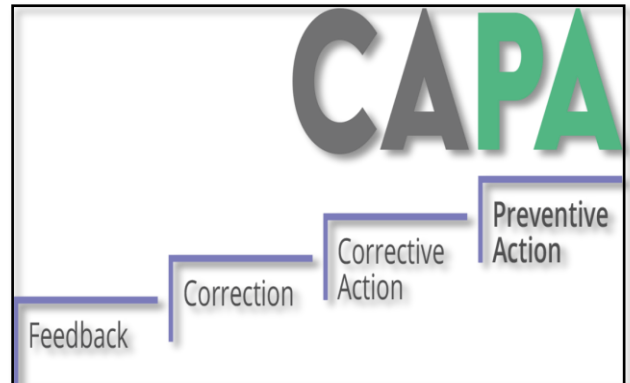


Correction-Corrective Action And Preventive Action In Pharma

Corrective and Preventive Actions (CAPA) are processes designed to improve quality and handle nonconformity as well as other undesirable situations



Introduction

Product quality is a key factor for any pharmaceutical organization and the CAPA process helps ensure that the products are of high quality.

Corrective and Preventive Actions (CAPA) are processes designed to improve quality and handle nonconformity as well as other undesirable situations.

The CAPA processes should be well defined to support an effective and efficient project management process. When working with CAPA, corrective actions are defined as actions set in motion to eliminate a nonconformity or other unwanted situations which have already occurred, and preventive actions as actions set in motion to eliminate potential nonconformities or unwanted situations.

CAPA is a mandatory part of the Quality Management System (QMS) for any pharmaceutical or medical device manufacturer reporting to the **U.S. Food and Drug Administration (FDA)**.

CAPA is also an integrated part of **ISO:13485** and Good Manufacturing Practice (GMP) for medical products.

The FDA defines the purpose of a CAPA procedure as: collecting and analyzing information, identifying and investigating product and quality problems, and taking appropriate and effective corrective and/or preventive action to prevent their recurrence

The CAPA process plays an important role in the quality management system of any pharmaceutical company. It helps to identify, evaluate, prioritize and manage nonconformities or problems related to products or processes to prevent them from recurring.

Nonconformity is nothing but the non-fulfillment of a specified requirement.

A correction is when you fix the thing that went wrong (the non-conformity) or to contain the problem.

For Example, Reworking, repair or replacement are corrections.

Corrective Action

Action to eliminate the cause of a detected nonconformity.

A corrective action (CA) deals with a nonconformity that has occurred i.e. the corrective action is performed on detected non-conformity.

The objective of CA is to prevent a recurrence

For Example: Installing the filter after an incidence of filter choking.

Corrective action is a reaction that can be made along with the correction.

Preventive Action

Action to eliminate a cause of a potential nonconformity.

Preventive action determines and eliminates the cause of potential non-conformities to prevent occurrence.

The objective of PA is to prevent its occurrence

For Example: Installing an alarm to warn you when your process is drifting out of the acceptance range.

Preventive action is proactive.

Correction	Corrective Action	Preventive Action	Nonconformity
<p>Correction - it is a onetime activity of correcting or rectifying a mistake/error. Or , repair, rework, or adjustment and relates to the disposition of an existing nonconformity.</p>	<p>Deals with a nonconformity that has occurred.</p> <p>The objective of CA is to prevent a recurrence .</p> <p>Focuses on past events Requires root cause analysis</p> <p>Eg. Installing a backup filter after an incidence of filter choking</p>	<p>Deals with potential nonconformities- no failure has yet occurred.</p> <p>The objective of PA is to prevent the occurrence .</p> <p>Focuses on potential future events . Requires risk/or trend analysis .</p> <p>Eg. Installing an alarm to warn you when your process is drifting out of acceptable range.</p>	<p>non-fulfillment of a specified requirement.</p>
	<p>Corrective Action - is the action taken to eliminate the causes of an existing nonconformity , defect or other undesirable situation, the any mistake/error to prevent it from recurring or recurrence.</p> <p>This involves understanding the root cause and eliminating it.</p>	<p>the action taken to eliminate the cause of a potential nonconformity, defect, mistake , error, or other undesirable situation in order to prevent occurrence.</p>	
<p>E.g. taking a medicine for symptomatic relief from fever</p>	<p>E.g. Identifying the actual reason for fever (viral/bacterial infection) and treating the infection</p>	<p>E.g. maintaining proper hygiene and a healthy lifestyle to build up resistance to infections</p>	

What is CAPA?

CAPA stands for Corrective Action and Preventive Action, a system for analyzing, correcting, and preventing issues. It outlines procedures to solve the issue, it also analyzes the cause of the problem to prevent its recurrence.

CAPA is the abbreviation for corrective and preventive actions. The term refers to the improvements to an organization's processes to mitigate undesirable situations like product nonconformities and is typically used in connection with quality assurance.

CAPA can provide a structure for organizations to follow to find the cause of a problem, solve it, and identify ways to prevent the problem from occurring in the future. Thus, organizations **correct** the issue and **prevent** it going forward.

For example, Corrective Action and Preventive Action (CAPA) can investigate the misprinting problem in a pharmaceutical manufacturing environment. The CAPA initially proposes corrective actions to solve the misprinting problem and then investigates the cause to prevent recurrence in the future.

Corrective Action (CA) vs Preventive Action (PA)

Corrective action is a kind of extension of the **Root Cause Analysis (RCA)** approach. Step 1 of CA is to identify the root cause of the issue following a report of a nonconformity. Step 2 is to eliminate the root cause to prevent the nonconformity from recurring.

Preventive action is when you identify and remove potential sources of nonconformities before an undesirable situation has the chance to occur.

PA follows a similar design to the **lessons learned/read-across approach**. It emphasises the sharing of information across the organisation so that problems can be taken care of efficiently.

To put it simply, you could describe corrective as reactive, and preventative as proactive.

The purpose of an efficient CAPA process

CAPA is designed to ensure quality and continuous improvement, which is especially important in the pharmaceutical and medical device industry since / because lack of process can have fatal consequences.

CAPA is one of the most essential regulatory areas for both the FDA and ISO in pharmaceutical quality systems and for industries producing medical devices.

The CAPA system is always a part of the regulatory compliance audit and around 30-50 percent of non conformances cited quoted by the FDA are due to inadequate implementation of CAPA. So that the FDA can withdraw the certification that's necessary to be able to sell on the U.S. market.

However, an efficient CAPA process can also help create value for the company, as it is effective in uncovering and solving quality problems. Solving the wrong problem or having recurring quality problems can be expensive for a company.

An efficient CAPA is a comprehensive procedure that collects and monitors information about existing and potential quality problems and allows for analysis and investigation of issues to identify root causes, and initiate actions to fix the problem.

What Should Trigger CAPA?

Not every deviation or nonconformance requires a CAPA.

An unnecessary CAPA can result in additional costs, processes slowdowns, and inefficient usage of the organization's resources.

There are certain situations, that when they occur, can trigger a CAPA.

Non conformances or Deviations	Customer Complaints	Audit Findings
Non-conformance or deviation is the failure to fulfill the associated	Customer complaints help identify product deficiencies after it is released	The main objective of the pharmaceutical audits is to

<p>requirements and can occur both in products and processes. Non-conformance can also result due to an inability to meet the requirements of a customer. It can be identified during the manufacturing process or if a defective product is returned to the manufacturer.</p>	<p>to the market. The communication mode can be written, oral, or electronic. The defect can indicate a product's inability to fulfill its desired effectiveness, quality, results, or performance. Every manufacturer must maintain a complaint handling system for receiving, reviewing, and evaluating complaints. The manufacturer is also responsible for processing the complaints promptly, documenting complaint reviews and investigations as well as sharing information across relevant departments and regulatory bodies.</p>	<p>inspect whether the existing quality system is in line with the established quality system requirements. There are two types of audits – internal and external audits. An internal audit is performed by a team of the same manufacturing organization. However, they must be from another department and should not be interested in the department being audited. On the other hand, external regulatory and standardization organizations perform external audits.</p>
<p>For example, manufacturing requires a specific temperature for carrying out a specific process. However, quality personnel detects the temperature deviation and find out that this deviation is occurring for a very long time. This problem is a non-conformity and triggers a CAPA.</p>	<p>For instance, if a pharmaceutical manufacturer receives a complaint of an empty pocket in a tablet blister pack, it should trigger a CAPA.</p>	<p>For example, if during an audit, particles are found in injectables filling operation, it will result in non-conformance. Since this is a serious issue, it would require a CAPA.</p>

Regulatory Guideline

CAPA is most commonly used in highly regulated industries and is a mandatory part of a QMS for any pharmaceutical or medical device manufacturer reporting to the U.S Food and Drug Administration (FDA) or who is compliant with ISO:13485 Medical Devices as well as European Pharmaceutical GMP and IATF. Procedures for corrective actions are also mandatory in the QMS for the majority of ISO management systems.

1. ICH Q10 PHARMACEUTICAL QUALITY SYSTEM

➤ Section 3. CONTINUAL IMPROVEMENT OF PROCESS PERFORMANCE AND PRODUCT QUALITY

➤ Subsection 3.2 Pharmaceutical Quality System Elements

➤ Point No. 3.2.2 Corrective Action and Preventive Action (CAPA) System

➤ The pharmaceutical company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. A structured approach to the investigation process should be used with the objective of determining the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, in line with ICH Q9. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

➤ Table II: Application of Corrective Action and Preventive Action System throughout the Product Lifecycle

Pharmaceutical Development	Technology Transfer	Commercial Manufacturing	Product Discontinuation
Product or process variability is explored. CAPA methodology is useful where corrective actions and preventive actions are incorporated	CAPA can be used as an effective system for feedback, feed forward and continual improvement.	CAPA should be used and the effectiveness of the actions should be evaluated.	CAPA should continue after the product is discontinued. The impact on product remaining on the market should be considered as well as other products which

into the iterative design and development process.			might be impacted.
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2. PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart B—Organization and Personnel 21 CFR 211.22 Responsibilities of quality control unit

➤ (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

3. PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart J - Records and Reports 21 CFR 211.192 Production record review

“Any unexplained discrepancy shall be thoroughly investigated. The investigation shall extend to other batches ...that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include conclusions and followup.”

4. 21 CFR 820 CURRENT GOOD MANUFACTURING PRACTICE (CGMP) REQUIREMENTS FOR MEDICAL DEVICE MANUFACTURER.

MEDICAL DEVICES PART 820QUALITY SYSTEM REGULATION

21 CFR Part 820 is a set of regulations from FDA that outlines the current good manufacturing practice (CGMP) requirements that medical device manufacturers in the United States must follow with regards to their quality system.

➤ 820.90 - Nonconforming product: “The evaluation and any investigation shall be documented.”

➤ 820.100 - Corrective and preventive action:

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

➤ 820.198 - Complaint files : “Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated.”

5. Volume 4, EU Guidelines for , Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use , Chapter 1 , Pharmaceutical Quality System

➤ A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that:

- ❖ The results of product and processes monitoring are taken into account in batch release, in **the investigation of deviations**, and, with a view to taking preventive action to avoid potential deviations occurring in the future.
- ❖ An appropriate level of **root cause analysis should be applied during the investigation of deviations**, suspected product defects and other problems.
- ❖ Appropriate **corrective actions and/or preventative actions (CAPAs)** should be identified and taken in **response to investigations**.
- ❖ A review of all batches that failed to meet established specification(s) and **their investigation**.
- ❖ A review of all **quality-related returns, complaints and recalls** and the **investigations** performed at the time.

Correction-corrective action and preventive action are the 3 key definitions used in the pharmaceutical industry while investigating.

6. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

- ❖ reviewing nonconformities (including complaints);
- ❖ determining the causes of nonconformities;
- ❖ evaluating the need for action to ensure that nonconformities do not recur;
- ❖ planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- ❖ verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- ❖ reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken shall be maintained.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

- ❖ determining potential nonconformities and their causes;
- ❖ evaluating the need for action to prevent occurrence of nonconformities;
- ❖ planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- ❖ verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- ❖ reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained.

7. The Joint IPEC - PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients

8.5.2 Corrective Action

The excipients manufacturer should establish, document and maintain procedures for:

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- ❖ determining the root causes of nonconformities,
- ❖ ensuring that corrective actions are implemented and effective,
- ❖ implementing and recording changes in procedures resulting from corrective action.

8.5.3 Preventive Action

The excipients manufacturer should establish, document and maintain procedures for:

- ❖ initiating preventive actions to deal with problems at a level corresponding to the risks,
- ❖ implementing and recording changes in procedures resulting from preventive action.

8. As per PIC/S PE 009-17 (Part I) 25 August 2023 GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS PART I

Chapter 1 PHARMACEUTICAL QUALITY SYSTEM

PHARMACEUTICAL QUALITY SYSTEM

1.4 A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that:

(xiv) ***An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems.*** This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked, if present. ***Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles;***

ROOT CAUSE ANALYSIS AND CORRECTIVE AND PREVENTATIVE ACTIONS

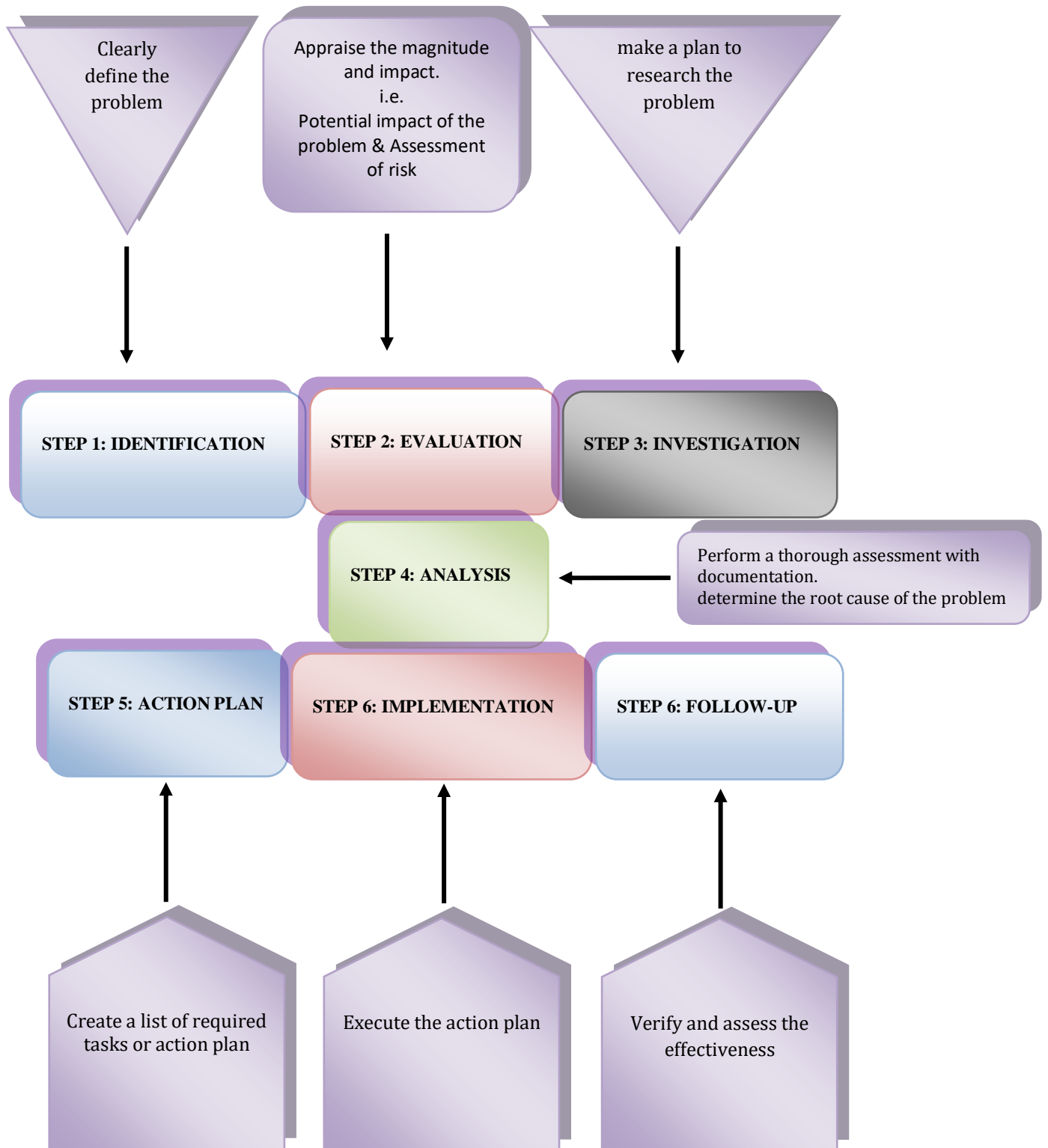
8.18 ***Appropriate CAPAs should be identified and taken in response to a quality defect.*** The effectiveness of such actions should be monitored and assessed.

PROCEDURES FOR HANDLING AND INVESTIGATING COMPLAINTS INCLUDING POSSIBLE QUALITY DEFECTS

8.9 When a quality defect investigation is initiated, procedures should be in place to address at least the following:

- i. The description of the reported quality defect.
- ii. The determination of the extent of the quality defect. The checking or testing of reference and/or retention samples should be considered as part of this, and in certain cases, a review of the batch production record, the batch certification record and the batch distribution records (especially for temperature-sensitive products) should be performed.
- iii. The need to request a sample, or the return, of the defective product from the complainant and, where a sample is provided, the need for an appropriate evaluation to be carried out.
- iv. The assessment of the risk(s) posed by the quality defect, based on the severity and extent of the quality defect.
- v. The decision-making process that is to be used concerning the potential need for risk-reducing actions to be taken in the distribution network, such as batch or product recalls, or other actions.
- vi. The assessment of the impact that any recall action may have on the availability of the medicinal product to patients/animals in any affected market, and the need to notify the relevant authorities of such impact.
- vii. The internal and external communications that should be made in relation to a quality defect and its investigation.
- viii. ***The identification of the potential root cause(s) of the quality defect.***
- ix. ***The need for appropriate Corrective and Preventive Actions (CAPAs) to be identified and implemented for the issue, and for the assessment of the effectiveness of those CAPAs.***

The 7 steps of CAPA



Define the problem. It can be a description of a potential or actual problem. If the problem has already occurred, be specific in describing the incident. Clearly state what should have occurred versus what actually occurred. Describe how this issue was uncovered.

Determine the risk level of the problem. To assess risk, evaluate the probability of occurrence versus the severity of the problem. Describe the potential impact of the problem as it relates to subject safety, data integrity, protocol compliance, the University, etc.

Establish a written procedure for conducting an investigation of the problem. Describe the steps to be taken and who will be responsible for conducting them. Include the methods of root cause analysis to be used, such as "5-Whys", "Fishbone/Ishikawa Diagram", etc., interviews to conduct, and documents to review and collect. This procedure should be a systematic process such that nothing is overlooked or discounted. Outline the various areas that will be reviewed as part of this investigation. For example, personnel, equipment, supplies, written procedures, training processes, etc. should be reviewed as they relate to the problem. Describe how information gathered during the investigation will be documented.

STEP 1: IDENTIFICATION

STEP 2: EVALUATION

STEP 3: INVESTIGATION

STEP 4: ANALYSIS

Determine the root cause(s) and contributing causes of a problem by conducting a root cause analysis, such as "5-Whys", "Fishbone/Ishikawa Diagram", etc., as outlined in the written procedure established in the previous step. Collect evidence of these causes and document it. Remember there may be several causes to this problem.

STEP 5: ACTION PLAN

STEP 6: IMPLEMENTATION

STEP 6: FOLLOW-UP

Develop a Corrective and Preventive Action (CAPA) Plan to mitigate or prevent each identified cause or contributing cause of the problem. Be specific in listing each action to be completed or implemented, who will be responsible for completing each action, and a due date for each action.

Allocate resources to implement each action listed in the CAPA Plan and document the implementation

Verify that all actions outlined in the CAPA Plan were implemented, documented and that these corrective and preventive actions were effective in preventing the problem from occurring or recurring. Confirm and document the actions that were completed and if the problem has recurred. If the objectives of the CAPA Plan were achieved, then it is considered successful and the CAPA Plan can be closed. Document the CAPA closure. • If the objectives of the CAPA Plan were not met or the problem has occurred or recurred, the CAPA Plan is considered ineffective and must be revised.

A sound corrective and preventive action programme can be a powerful tools for improving product quality , streamlining production and ensuring regulatory compliance.

When CAPA is performed as a part of a regulatory requirement documentation of each step is crucial. When the CAPA is closed a report is written to ensure that the process is recorded. The CAPA process is typically managed by the Quality Assurance or Regulatory Affairs manager.

CAPA Leader

- should have Excellent communication/presentation skills.
- should have Strong analytical problem solving skills.
- should have Influence management skills; ability to work constructively across all functions of the organization.
- should have Experience in all areas of the CAPA process.
- should have Experience with quality tools and process improvement techniques.
- should have Project management experience.

Sr. No.	Steps	Description
1.	Identification	<ul style="list-style-type: none"> ➤ The first step of the CAPA process is to identify, describe and document the problem. ➤ A nonconformity incident does not necessarily trigger a CAPA. However, it is necessary to evaluate every nonconformance and assess what actions are appropriate. ➤ Nonconformance's can be identified from both internal and external sources, including, but not limited to: <ul style="list-style-type: none"> ❖ Deviation ❖ Change Control ❖ Incidents ❖ Internal quality audits Observations ❖ Customer complaints / Product Quality Complaints ❖ Product Recalls ❖ Quality Assurance inspections ❖ Staff observations ❖ Trending data ❖ Risk assessment ❖ Management review ❖ Audit findings ❖ Regulatory Inspections/Testing, Deviations

		<ul style="list-style-type: none"> ❖ Process Monitoring ❖ OOS Results ❖ OOT Results ❖ New Amendments to regulatory Guidelines ❖ Investigations ❖ Product Quality Reviews ❖ Risk Assessments ❖ Management Reviews ❖ Any Warning Letters or other Regulatory Observations ❖ Negative GMP Trends and other sources of Quality data <p>➤When a problem is discovered, a clear problem statement should be written. It is important to precisely and completely describe the situation. The problem statement should include the source of the information, evidence of the problem and a detailed explanation of the problem.[9] In this process, answering the following questions can be helpful..</p> <table border="1" data-bbox="491 1032 1509 1350"> <tr> <td>What</td> <td>Explain what happened or what you want to happen</td> </tr> <tr> <td>When</td> <td>When did the problem occur/was discovered?</td> </tr> <tr> <td>Where</td> <td>Where was the problem found? (process, region, department, etc.)</td> </tr> <tr> <td>Who</td> <td>Who is affected by the problem?</td> </tr> <tr> <td>How much</td> <td>How much of a process, product, batch, etc. is affected?</td> </tr> </table>	What	Explain what happened or what you want to happen	When	When did the problem occur/was discovered?	Where	Where was the problem found? (process, region, department, etc.)	Who	Who is affected by the problem?	How much	How much of a process, product, batch, etc. is affected?
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2.	Evaluation	<p>➤Here evaluate the problem to determine why it's of concern, and the impact and risk associated with the problem.</p> <p>➤And evaluate the possible impact on costs, function, product quality, safety, reliability, customer satisfaction, etc.</p>										
3.	Investigation	<p>➤In this step you should measure the gravity of the problem. You should determine the scope and boundary of the problem.</p> <p>➤An understanding of immediate actions is prepared.</p> <p>➤The following questions are helpful to understand what immediate steps are taken and why.</p> <ul style="list-style-type: none"> ❖ What actions are taken immediately to fix the problem? (to record briefly the actions taken and by whom?) ❖ How long did it take to fix the problems? (to determine incident lost time) 										

		<ul style="list-style-type: none"> ❖ Has this happened before? (to identify history or trend on similar incidents) ❖ What actions were taken before? (to record any changes made previously) ❖ Which area of the processing line has been impacted? ❖ Are immediate actions sufficient to fix the issue?
4.	Analysis	<ul style="list-style-type: none"> ➤ In this step, the investigation procedure is used to determine the root cause of the problem . ➤ This is done by collecting all relevant data and investigating all possible causes through a Root Cause Analysis (RCA). ➤ A RCA is a systematic approach to finding the underlying (main) cause of a problem. ➤ When a root cause is properly managed, the problem doesn't recur. ➤ The most typical tools include, 5xwhy and the fishbone diagram. ➤ 5xwhy is a simple and very popular tool for RCA. ➤ To find the root cause, one has to ask what caused the problem, and question the answer five times. ➤ The 5x why approach can quickly be adapted and applied to most problems. There are three fundamental elements to effectively using the 5xwhy: <ul style="list-style-type: none"> ✓ a clear statement; ✓ honesty and the competencies for answering the questions; ✓ determination to find the problem. ➤ The second method is the fishbone diagram (also known as the Cause and Effect Diagram),which can be used by itself or together with the 5xwhy. ➤ The fishbone diagram is used to identify different elements that could be the root cause, including sub-elements. The fishbone diagram is useful if many factors affect the problem.
5.	Action plan	<ul style="list-style-type: none"> ➤ When the root cause is identified, an action plan needs to be developed. ➤ The action plan determines which actions will be initiated, how, by whom, when and so on. ➤ The documentation of the actions that are initiated is important in order to have an effective follow-up. The Examples of actions that can be initiated include: documentation/forms/instruction changes; procedural changes; employee training; or new equipment. ➤ A monitoring system or controls also need to be implemented to prevent the problem

		from recurring.
6.	Implementation	<ul style="list-style-type: none"> ➤ Once the corrective and preventive action plans are prepared, implement the action plan. ➤ Documentation of each of the determined actions is important to ensure all actions are completed. ➤ When a plan has been completed, all activities should be verified by a party independent of the individual who has completed the task. ➤ A frequent problem observed by the FDA is that the corrective and preventive actions were not implemented. ➤ It is therefore important to define clear responsibility and apply a tracking system to verify the implementation.
7.	Follow-up	<ul style="list-style-type: none"> ➤ The final stage of corrective and preventive action process is to periodically follow up the effectiveness of the actions implemented earlier and prepare a schedule to revisit the corrective and preventions and check if the plans were not deviated from the target. ➤ At stage of Follow up it should measure the root causes have been eliminated completely from the process.
8.	CAPA Closure	➤ All actions must be completed and assessed for effectiveness prior to CAPA closure.
	Is the CAPA effective	<p>Once the CAPA is complete, a good effectiveness check should demonstrate that the CAPA did in fact achieve what was intended. It should be clear:</p> <ul style="list-style-type: none"> • who is doing this check, • what will be checked, • where will the data/information be recorded and tracked, • when will the data/information be checked, • if the data qualitative or quantitative data, • who will gather the data/information, • how the data/information gathered will be used to determine the effectiveness, • if further action is required, • how will the outcome be communicated to the right people?