RESEARCH ARTICLE

Corrective and Preventive Action: An Imperative Quality Management Perspective in Pharmaceutical Industry

Sneha A. Dhamne[1*], Kamlesh R. Dandagvhal[2], Prashant L. Pingale[1], Sunil V. Amrutkar[2]

[1]*Department of Pharmaceutics, GES's Sir Dr. M. S. Gosavi College of Pharmaceutical Education and Research, Nashik, Maharashtra, India*

[2]*Department of Pharmaceutical Chemistry, GES's Sir Dr. M. S. Gosavi College of Pharmaceutical Education and Research, Nashik, Maharashtra, India*

Received: 01st March, 2022; Revised: 26th March, 2022; Accepted: 14th April, 2022; Available Online: 25th June, 2022

ABSTRACT

Advancements to be made in product, process, or quality management system are through the corrective and preventive actions (CAPA) method only, to eradicate non-conformities and other undesirable circumstances. CAPA is a regulatory concept that focuses on systemic investigations to determine the root cause and explain and resolve problems while seeking to avoid their re-occurrence. Regulatory inspections offer greater importance for CAPA, and for this reason, they will highlight the systems followed in the organization and the technical skills of the people involved in different activities.

During the investigation, there is a mechanism to ensure that the nonconformities are monitored and that corrective steps are taken to ensure the product's quality. Identify the issue and consider its effect on the company's products and prestige. To investigate the possible cause and arrive at the root cause to investigate systematically.

Keywords: Corrective Action, Pharmaceutical, Preventive Action, Quality Management System.

International Journal of Pharmaceutical Quality Assurance (2022); DOI: 10.25258/ijpqa.13.2.1

How to cite this article: Dhamne SA, Dandagvhal KR, Pingale PL, Amrutkar SV. Corrective and Preventive Action: An Imperative Quality Management Perspective in Pharmaceutical Industry. International Journal of Pharmaceutical Quality Assurance. 2022;13(2):95-102.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Corrective and preventive action (CAPA) is a basic quality managing approach and it is a very important process that must be used in every quality management system for quality improvement. This system provides an ordered process for completing and documenting preventive and corrective actions (DPCA). A comprehensive, proper documented investigation will be the result, and a solution that will achieve regulatory requirements and develop regulatory requirements for every company's successful quality improvement plan. Correctly recorded actions give significant historical details for a constant improvement in quality idea, and also it is important for all products that fulfill regulatory requirements needed by a different regulatory body like International Organization for Standardization (ISO), Food and Drug Administration (FDA) and other quality system. Many CAPS investigations end with retraining being as corrective action. Non-specific suggestions probably advise that the root cause of concern has not been recognized.

Additionally, in most cases, the root cause is a representation of a market or organization plan and it is clear that retraining is not a logical end of a CAPA. Corrective action is one of the most important improvement activities. CAPA determines steps required to address the causes of problems found and aims to permanently eradicate the causes of problems that have a detrimental effect on systems, procedures, and goods. Corrective action involves identifying the causes of a particular issue and then putting in place the steps required to prevent a re-occurrence. Preventive Actions are designed to stop future concerns from arising.

When it comes to CAPA, we need to separate between three distinct individuals' topics:

- Remedial action or correction
- Corrective actions
- Preventive actions

Remedial Action or Correction

Remedial action or correction emphasizes the instant condition to delete a current undesirable non-compliance or non-compliance situation. It is essential to note that certain acts emphasize the instant condition that does not answer the root cause, but only momentarily "fixes" the issue.

**Author for Correspondence: prashant.pingale@gmail.com, ninny4907@gmail.com*

Corrective Action

The corrective Action is a response to situations of non-conformity or unwanted act. It assumes that an issue exists, and either internal or external sources have confirmed it. The initiated actions are proposed to avoid repetition, which includes subsequent stages given below:

- Correction of problem or issue
- Amend the quality system so that the procedure that caused non-conformance can be monitored and further stops the repetition of same problem.
- The documents related to the Corrective Actions provide proof that the problem was
  - ✓ Identified
  - ✓ Rectified
  - ✓ Proper measures installed

Preventive Actions

Preventive action is a systematic technique for non-conformance identification or inappropriate conditions that have not yet occurred and eliminate that condition before arising.

The process includes:

- Identification of the issue
- Finding the reason for issue
- Preparation of a plan to stop the repetition of same issue
- Implementation of the plan
- Review of the implemented action
- Effectiveness check of CAPA on implemented action

WHY CAPA!!

Regulatory Requirement

An active CAPA program is needed by both the FDA and ISO as an integral component of the quality system.

Customer Satisfaction

It facilitates fixing or enforcing regulation of identified issues to avoid future problems that are important for constant satisfaction with customer.

For Strong Business Practices

Quality Issues may have a major economic effect on the company.

Rectification

Any step that is taken to remove non-conformity is a correction. Corrections do not, however, deal with triggers.

CAPA PROCEDURE

CAPA have seven general phases for pharmaceutical product industries:

- Identification of the issue: It states the problem.
- Evaluation: Judge the extent and possible impact.
- Investigation: Find the main source (root cause) of the issue.
- Analysis of evaluation and investigation: Execute a detailed evaluation with relevant documents.
- Action Plan: Explain preventive and corrective action.
- Implementation of action: Implementation of the action plan.
- Follow up: Confirm, evaluate the success of plan.

Although recurrence of non-conformance is avoided by corrective action, preventive actions avoid occurrence. To avoid non-conformities, both corrective and preventive action are planned.

Preventive actions resolve future issues. In general, it is possible to think of the preventive action method as a risk analysis process.

Identification

The first stage in the procedure is to identify the issue clearly. It is necessary to explain the situation accurately and thoroughly as it occurs right now. It must cover the data source, a detailed explanation of non-conformance, and the presence of evidence as there is a problem.

Report Source: It becomes very important to record the source of the incident while conducting the investigation and implementing the action plan. Data will also be used to measure the efficacy of the quality system and make it simpler to communicate the conclusion of the activity for responsible staff or departments.

Corrections/corrective and preventive measures for a quality-related problem, risk and non-compliance should be recognized by:

- Consumer audits and regulatory checks
- In-house audits
- Grievances from customer
- Customer's returns
- Goods recalls
- Deviations from various sources
- Out of specification
- Out of calibration
- Failures of batch/rejection of batches
- Out of Trends
- Annual product quality reviews (APQR)
- Management review output
- Other GMP and non-conformances problems /findings

Explanation of the Problem: Full summary of the issue is described here. Summary must be brief, and still enough detail should be provided to ensure that the problem will be easy to understand by reading the summary.

Evidence: Listing of existing basic data which indicates there is an issue.

Evaluation

Condition identified and reported in the section "Identification" should now be investigated, the necessity for action, and the degree of action needed. It is necessary to assess the possible effect of the issue and the current threats to the organization and the consumers. Principally, it is necessary to document the causes why this problem is of concern.

Potential Impact: A detailed description is part of the assessment, especially why the issue is a concern. This may consist of the potential cost, feature, quality of product, protection, reliability and customer satisfaction effect that the issue may have.

Assessment of Risk: The severity of the issue is measured by using the results of the impact evaluation. The risk level related to the problem can affect the actions required.

Remedial Action: Based on the above impact and risk assessments, it can be decided that urgent remedial action is needed to resolve the condition before the comprehensive study is carried out and fixed solution is established. There is documentation of the actions taken. This document will be included in sections' Implementation of Action 'and' Follow Up 'of the CAPA action.

Remedial Action form: Sample form for "Remedial Action" is involved. The steps to be taken to prevent any further adverse effects should be clarified in this form.

Investigation

A protocol for investigating the issue is written in this process stage. A written plan helps to ensure completion of the investigation plan and that nothing is skipped. Protocol must contain: aimed at the steps to be carried out, the method to be followed, responsible people, and some additional necessary means.

Objective of the Investigation: In the investigation, the former footstep is to define a purpose of operation. Problem was identified and present situation reported, in "Identification" section. The objective of investigation is to describe the desired outcome of the corrective or preventive action. When action is complete, state what the condition will be. The description in the form may be like: "the issue will be solved, all consequences of the issue will be detected and fixed, and safety measure will be to avoid the re-occurrence of the situation".

Investigation Procedure: Detailed guidelines series is generated to explain whatever needs to be done in order to identify the problem's contribution and main reason for the issue. Depending on situation, an investigative protocol may differ.

Responsibilities/Resources: Responsibility allocation for conducting each phase of the investigation is a significant feature for the investigation. This will also define and record any additional resources that may be needed. For example, it can require specialized testing for equipment or analysis from an external agency.

Form for Investigation Procedure: Sample form for Investigation Procedure is incorporated. This is a detailed plan of action for an investigation into the issue. This form must contain complete purpose and guidelines for directing the investigation. It is also necessary to highlight the name of the individual or responsible personnel for study and the estimated day of completion.

Analysis

For analysis purpose, the procedure for investigation is now used. Purpose of the study is first to identify the root cause of the issue mentioned, but it also finds any contributing reasons. To determine the cause of the problem, this process contains gathering of related information, identifying all potential reasons, and using the available information. The difference between detected signs of a problem and the major (root) cause is very important.

Possible Reasons/Data Collection: list is created for all possible reasons. This list of possible reasons creates the base for the compilation, test data and relevant information.

Results and Data: Data collections results are recorded than ordered. It might involve a blend of results of testing and/or an evaluation of documents, practices, facility info, activities, and any further information that might contribute to the finding of the root cause of issue. Documents resulting from this must be full and discuss potential reasons formerly identified. To determine the root cause of the problem, this information is used.

Root Cause Analysis: Root cause also needs to be determined by replying to a sequence of questions 'why'? Digging deep into the condition up to the root cause for the issue is found. Analysis for the root cause is main objective to corrective actions, and successful corrective action is difficult to come up without an efficient root cause analysis.

Methods: Proper statistical and non-statistical methods may be useful for studying the non-conformity.

Related Example of statistical methods:

- Statistical Process Control (Shewhart chart) charts
- Pareto charts
- Trending of Data
- Non-linear regression and linear regression
- Experimental model (DOE: Design of Experiments) and variance study
- Pictographic techniques (circle graphs, scatter diagrams etc.)

Related Example of non-statistical methods:

- Reviews of administration
- Quality discussion with outcome
- Failure mode effect analysis (FMEA)
- Fault tree analysis/deductive failure analysis

Failure Mode Effects Analysis (FMEA)

The FMEA be determined by understanding of the procedure and product. It breaks the study of compound systems into convenient steps methodically. It offers an assessment of possible process failure modes and their possible effects on product performance. It may be introduced to facilities, equipment and can be helped to evaluate production procedure and its result on the manufactured goods or procedure.

Deductive Failure Analysis / Fault Tree Analysis

This analysis assumes product or process failure functionality. In the form of a deductive failure analysis, conclusions are depicted graphically. To fully understand their root cause, this can be used to evaluate complaints or deviations and ensure that the expected development will address the problems and does not source any other problems.

Ishikawa/Fishbone Analysis

A method to recognize the root causes of quality problems is the Fishbone Analysis. This method is an option for study,

which gives a concise lookout at the effects and reasons which generate such effects and relate to them. Ishikawa referred as a diagram of cause-and-effect because of the function of Ishikawa diagram. Ishikawa diagram is well explained in Figure 1. Some benefits of implementing an Ishikawa diagram are that it uses a systematic approach to define the root causes of an issue or quality trait, encourages the group's involvement and uses group understanding of the process, defines fields wherever data can find for other research.

Cause and Effect Diagram (Ishikawa Diagram): The Ishikawa diagram defines possible variables that may affect the target quality attribute and then classifies the variables based on possibility, magnitude, and detectability using the study of FMEA or similar methods based on previous information and initial experimental results. To determine the effect of the higher ranked variables, obtain a better understanding of the mechanism, and establish a proper control strategy, experimental design or other experimental methods could then be used.

Form for Problem Analysis

A form for "Problem Analysis" is included. This form is not compulsory, but is intended to be used to disclose details relating to the issue's study. For information found during the study, the form may be used as a gathering point and any supporting details or documents may be attached to the same.

Action Plan

The correct plan for fixing the situation (or avoiding a potential occurrence) is calculated by using the study's results and establishing an action plan.

Actions to be completed: Review all the actions and exercises required to be completed to either fix the present situation or stop potential issue. It's very necessary to take a systemic approach for a CAPA program to succeed. Ensure and recognize all the steps needed to resolve the whole thing relevant to the condition.

Changes to document or Specification: List documents will be updated and explain the changes in general terms.

Modifications to Method, Procedure, or System: If any improvements to methods, operations, or facilities need to be made, they are listed. Sufficient information must be involved so that what must be done is well known. It is also important to clarify the expected impact of the modifications.

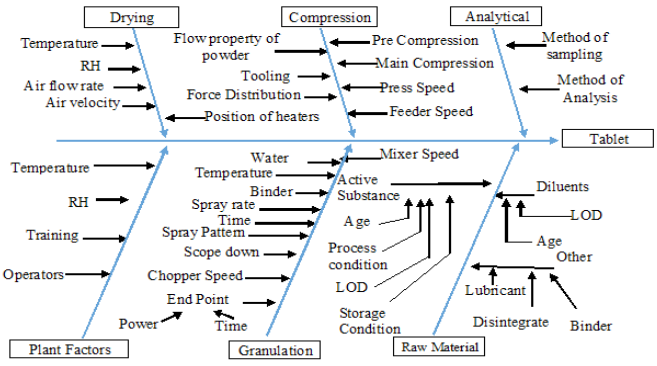

Figure 1: Ishikawa Diagram in Tablet Manufacturing

Training of Employee: Employee training is an essential element of almost all progress achieved and should be part of the action plan.

Form for Action Plan: A sample form of the 'Action Plan' is involved. This should involve a collection of formal instructions explaining all the tasks that need to be carried out to resolve the issue and prevent recurring this. This involves corrective and preventive steps, document changes, training, etc. The individual or individual responsible and the estimated completion date should also be recorded on the form.

Implementation of Action

Implementation of action for Proposed corrections/corrective and preventive steps requiring process changes, working methods, processes or apparatus must be applied employing the proper change management procedure.

The preventive and corrective course of action that has been developed is now being executed. Initiated, completed, and reported all the necessary tasks recorded and described in the action plan.

Implementation Summary: The tasks that have been done as needed in the "Action Plan" should list and summarize. The division must include a detailed record of the steps taken to address issue and assure that it doesn't repeat. It involves variations, preventive steps, control of procedures, employee training, etc.

Documentation: Listing of revised documentation and other specifications. Usually, a final written CAPA action report will be added to the documents. This will require the modifications of the variations for the follow-up.

Follow Up

The next basic stage in the CAPA method is to evaluate the actions taken. It is important to answer several key questions:

- Were all the goals of this CAPA fulfilled? (Did the actions fix or avoid the issue and are there assurance that there won't be the same problem again?)
- Whether all the suggested variations have been completed and checked?
- Has adequate coordination and training been established to ensure that the situation and the improvements that have been made are recognized by all relevant employees?
- Is there any risk that there might have been any other adverse impact on the product or facility from actions taken?

Results Verification

Checking the implementation and completion of all changes, controls, training, etc. is essential. The documentation that has been completed is essential to record. Relevant data should have been recorded to indicate that all acts were conducted effectively.

Actions Effectiveness/Results

One more significant element of any CAPA action is ensuring that the steps taken have been successful. Comprehensive review should be carried out to ensure that the root cause of the issue has been addressed, and subsequent problems have been rectified, proper controls have been developed, and sufficient observing of the condition is in place. This assessment may also involve an examination to assess if any other adverse effects may result from the actions taken. It is important to track this investigation and the findings.

It is important for all companies to document the whole procedure covered in a corrective or preventive action from the identification of the issue to its effective conclusion, but it is essential for meeting existing regulatory requirements.

Verification and Closure of CAPA

- After completing the activities, the head of department will confirm completion and execution of the proposed CAPA, along with the related actions.
- QA will check and certify the execution and completion of the CAPA by reviewing the related documentation.
- Changes suggested by means of a significance of CAPA will be the reference for change control via SOP (Standard Operating Procedure); It is specified the same way in the CAPA format.
- Entire change management system, deviations, variations, incident reports that give rise to CAPA shall be controlled by means of CAPA.
- All improvements to facilities, capital procurement requirements, significant changes to the quality plan and compliance with regulatory obligations arising from CAPA shall be discussed by means of the form of CAPA.
- Kept record of each CAPA.
- QA must send one copy of the finalised CAPA to Department heads of different departments involved in the activity.
- During management review meeting, QA will collect the CAPA details and send summary to the management.
- Same will be check/verify by Management in a management review meeting on the same quarterly basis.
- Information and documentation collected from CAPA-related internal audits, external/customer audits and regulatory audits shall be deemed to be secret. They shall be provided for regulatory review only if authorized by the technical director and the head of QA.

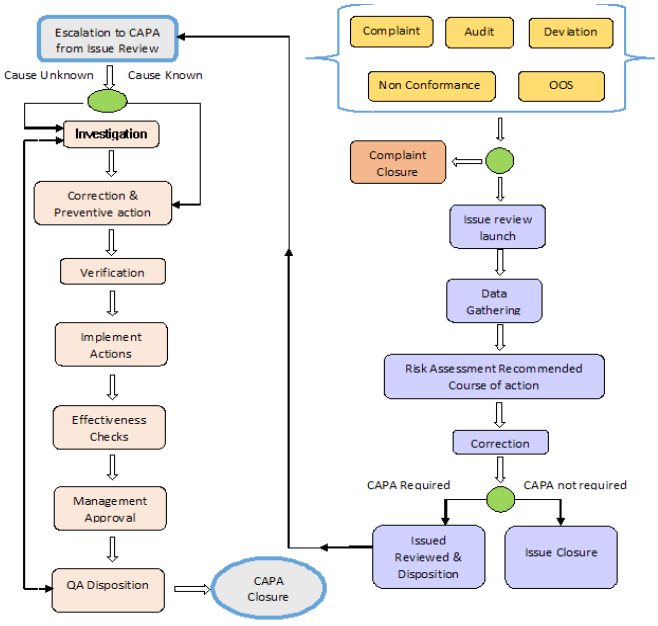

Figure 2: CAPA management system and its effectiveness

CAPA MANAGEMENT SYSTEM

CAPA refers to two distinct requirements for documented 'Corrective Action' and 'Preventative Action' procedures that should form part of your med tech Quality Management System. CAPA Management system and necessities of CAPA management system is well explained in Figure 2.

CAPA APPLICATION FOR THE WHOLE LIFE CYCLE OF THE PRODUCT

Development of Pharmaceuticals

Variability of goods or processes is discussed. In the iterative design and development phases, the CAPA approach is useful in implementing preventive actions and corrective actions.

Tech Transfer/Technology Commercialization (TT)

CAPA can be used as an effective mechanism for feedback, feed-forward, and continuous growth.

Commercial Manufacturing

CAPA should be used and it is important to determine the effectiveness of the acts.

Discontinuation of Product

After the product is discontinued, CAPA can continue. It is important to consider the impact or the effects on the product existing in the market, as well as on other goods which may be affected.

Change Control System

Corrective steps and preventive measures to thoroughly assess, authorize and correctly apply these changes; the organization must have an efficacious change management or change control mechanism. The change management framework ensures that development of quality is performed in a timely and successful way. This must have a significant level of confidence that the alteration does not have unintended consequences.

The proposed change should be evaluated by an expert team who contributes sufficient expertise and experience from related fields (e.g., pharmaceutical development field, Production, Quality departments, regulatory businesses and Therapeutic) to confirm that the modification is technologically correct.

Quality System CAPA–More than only Corrective Action

For a complete quality management program, a CAPA quality system is absolutely necessary. The preventive action, corrective action program is the means through which

unexpected issues are dealt with, remedied and avoided from ever happening again. If an organization expects to achieve its target of zero defects, a CAPA framework is necessary fragment of ISO compliance, and is important element of TQM practices. Preventive measures may be anything, but some common ones are: writing a new procedure and providing everyone with training, recording the training provided, and inspecting every other equipment at the plant that plays a similar responsibility to ensure that it does not have a similar problem, performing routine maintenance audits, etc.

In a true CAPA system, there is a formalized process to "close the loop" to ensure that all preventive and corrective steps have been finalized, that they perform as they were intended to perform, and that the organization can be assured that the same issue will never have to be addressed again. The CAPA system is one of the easiest methods to find, repair, and remove faults from the system. Fixing it once and neglecting the root cause means that the issue will come up again. And every time it comes back, it will be as expensive to repair as it was the first time.

CAPA TEMPLATE

Case Study 1

Company logo, name	Corrective and preventive action	Doc. No.: QMS /CAPA/1

CAPA No.

Reference: Deviation/ Incident/OOS/OOT/ Market Complaint/Change Control No. -----

Initiator (Name and Emp.ID): ---------

Description of Problem:

- Admin log in observed in Batch audit trial
- During Quality Review by QA Team, it was noticed that the Batch login was found on Track and Trace system by vendor in administrator login (admin)

Initiator Department:	Area/location:
Product Name:	B. No.:
Instrument/Equipment Name (If applicable): _____	Instrument/Equipment ID (If applicable): _____

Root Cause summary: from the detail investigation by using investigation tool i.e., Brain Storming. Root cause for subjected non conformity was attributed to method, and there is a no procedure for handling of computerized systems by External agencies or vendors.

Remedial Action (Immediate action taken):

- Batch processing was stopped and informed to Section Head and section in charge of IPQA (In-process Quality control).

Corrective Action: Awareness Training is imparted to all concerned person.

- Preventive Action: New SOP for handling computerized system by external agencies / vendors in which directives shall be given to handle the computerized system by external agencies.
- Previous audit trials report of Track and Trace system shall be evaluated for involvement of vendor login during operation.

Task 2 (HOD / Designee Review and Comments by user department):

- Proposed CAPA is acceptable. New SOP for handling of the computerized system by external agency / vendor to be prepared.
- Separate report to be prepared for evaluation of the involvement of vendor during operation.

Task 3 (Evaluation by QA Co-ordinator):

- CAPA is reviewed and found satisfactory. Directive shall be given to handle the computerized system by external agencies /vendor through new SOP.
- The machine access form for external agencies to be incorporated in the stated SOP.
- Additionally, review of Audit trial report for Track and trace system for the involvement of vendor in commercial batches accordingly separate report shall be prepared with evidence of implemented action.

Task 4 (Cross functional department review and comments):

- Maintenance: Proposed CAPA acceptable. Further involvement of vendor / external agencies shall be done through the proposed SOP.
- IT: Proposed CAPA is reviewed and acceptable. To ensure that vendor agencies login shall be done through executed Annexure of proposed SOP.

Task 6 (Implementation of CAPA):
- As per proposal of CAPA new SOP for Handling of the computerized system by external agency /vendor is prepared and made effective.
- Training was imparted on new SOP for Handling of the computerized system by external agency /vendor.
- Updation of SOP index.
- Comprising report for detail evaluation of evaluation and review of track and trace system and another computerized system has been prepared. Wherein assessment of the impact of vendor/external agency involvement in commercial batches was performed.
- Conclude that all proposed activities are implemented.

Task 7 (Review of Implemented action by QA Co-ordinator):
- As per the proposed actions awareness training was imparted to all concerned persons related to the observation of Administrator (vendor) login in the audit trial report.
- New SOP for Handling of the computerized system by external agency /vendor was prepared and made effective after the completion of training.
- In addition to past audit trial reports generated on the track n trace systems, a detailed report has been prepared wherein impact of vendor involvement in commercial batches was checked and found satisfactory.
- Detailed evidences are attached.
  CAPA is implemented, and the initiator will provide the effectiveness of the implemented actions.

Task 8 (Effectiveness Check of CAPA on implemented action):
- As a part of post-effectiveness checks on implemented actions; the intervention of vendor to access the computerized system is reviewed.
- All procedure followed as per SOP (Handling of the computerized system by external agency /vendor). No abnormality and similar type of incidence have been noticed till date.
- Executed annexure for the effectiveness check is attached for reference.
- Part of effectiveness check separate report was prepared, contains past audit trial review of track n trace system for evaluation of vendor in commercial batches and no involvement of vendor in commercial batches.
- Post-implementation of CAPA effectiveness was checked on …. equipment in…section. It revels to vendor login in the system as per effective SOP.
- From the above actions it concluded that the implemented CAPA is effective.

Task 9 (Verification of Effectiveness checks by QA Co-ordinator):
- All the activities pertaining to the CAPA is implemented.
- Post-implementation of subjected SOP; intervention of vendor to access computerized system is reviewed.
- All procedures were followed as per SOP and abnormality was noticed.
- Vendor login on computerized systems was checked for the effectiveness checks found satisfactory.
- After the implementation of CAPA there were no such incidence observed.
- It concludes that the implemented CAPA is effective and can be closed.

Task 10 (Evaluation and Closure of CAPA by QA Head):
- The CAPA is implemented effectively and it is closed.

Attachments:
1. CAPA Proposal 2. Evidence of implemented action 3. Annexure of evaluation of effectiveness checks 3. Training records as an evidence

Case Study 2

Company Logo, Name	Corrective and Preventive Action	Doc. No.: QMS /CAPA/1

CAPA No.

Reference Deviation/ Incident/OOS/OOT/ Market Complaint/Change Control No. -----

Initiator (Name & Emp.ID): ---------

Description of Problem:
- In ….. Tablet (Strength…, Batch Number….), overprinting details on carton was debossed as "LOT" for batch number instead of "B.No."
- Printing format requirement as per sales text or BOM (Bill of material) Alternative text, Specification) is B.No. XXXX EXP MM/YYYY
- Actual format debossed on carton is LOT XXXX EXP MM/YYYY

Initiator Department: Area/location:

Product Name:	B. No.:
Instrument/Equipment Name (If applicable): _____	Instrument/Equipment ID (If applicable): _____

Root Cause Summary: During investigation, the Concern packing supervisor and QA officer verified the Batch coding details as per sales text but skipped to verify the details of description for batch no. hence "LOT" debossed instead of "B.NO".
Further, the batch details mentioned in the BPCR are written against the sale text, and stereos are issued against the details mentioned BPCR. However, the procedure is not defined in the SOP to refer the sale text information.

Remedial Action (Immediate action taken): The deviation (problem) is immediately reported to section head and IPQA (In Process Quality Assurance) in-charge.

Corrective Action: SOP, which is related to packaging Instruction to be revised to incorporate instruction

Preventive Action: Retraining to be imparted to all concern persons on SOP Verification of Batch coding details against the sales text during specimen approval.

Task2 (HOD / Designee Review & Comments by user department): Concern packing supervisor and QA officer missed out on verifying the batch coding details against sales text. There are no discrepancies in Batch No. details. Hence the identity of Batch No. is maintained.

Task3 (Cross functional department review & comments): The Deviation is acceptable. No impact on the quality.

Task4 (Evaluation by QA Co-ordinator): The packing and QA supervisor has skipped to verify the description details for the batch number as mentioned in the sales text. The identity is maintained as batch number is correctly mentioned on the blister, carton, and labels.

Task5 (Pre-approval by QA HOD): Batch can be released as there is no impact on product quality.

Task6 (Implementation of CAPA): Retraining has been imparted to all concerned persons on SOP Verifying batch coding details against the sales text during specimen approval.

Task 7 (Review of Implemented action by QA Co-ordinator): As per the proposed actions, awareness training is imparted to all concerned persons.

Task 8 (Effectiveness check of CAPA on implemented action): As a part of post effectiveness checks on implemented actions, the SOP for verifying Batch coding details is revised for updated procedure.

Task 9 (Verification of Effectiveness checks by QA Co-ordinator): all the activities pertaining to the CAPA is implemented
- Post-implementation of subjected SOP Verification of Batch Coding is revised.
- After CAPA implementation, no such incidence is observed and conclude that the implemented CAPA is effective and can be closed.

Task 10 (Evaluation and Closure of CAPA by QA Head): The CAPA is implemented effectively and it is closed.

Attachments:
1. CAPA Proposal 2. Evidence of implemented action 3. Annexure of evaluation of effectiveness checks

CONCLUSION

CAPA is one of the many essential tools for every product and service to ensure quality and continuous improvement. It offers a high degree of confidence that all regulatory and quality criteria are often met by the product or services. In the future, the introduction of CAPA in industry will help to recognize the root cause of non-compliance and avoid further harm, as It plays a major part in quality risk control.

REFERENCE

1. Jain SK, Jain RK. Investigations and CAPA: Quality System for Continual Improvement in Pharmaceutical Industry. International Journal of Research in Pharmacy and Pharmaceutical Sciences. 2017;2(6):47-54.
2. Rompicherla NC, Paul E, Ganesh A, Narayanan AV. The Significance of Quality Metrics in a Pharmaceutical Quality Management System - A Case Based Study. Indian Journal of Pharmaceutical Education and Research. 2020;54(3):798-808.
3. Raj A. A Review on Corrective Action and Preventive Action (CAPA). African Journal of Pharmacy and Pharmacology. 2016;10(1):1-6.
4. Tashi T, Mbuya VB, Gangadharappa HV. Corrective action and preventive actions and its importance in quality management system: A review. International Journal of Pharmaceutical Quality Assurance. 2016;7(1):1-6.
5. Zhang L., Zheng Q. Research and Analysis on Corrective and Preventive Action of Chinese Pharmaceutical Enterprises. Chinese Journal of New Drugs. 2015;24(17):1968-1974.
6. Motschman TL, Moore SB. Corrective and Preventive Action. Transfusion Science. 1999;21(2):163-178.
7. Domínguez CR, Mares JI, Hernández RG. Hazard Identification and Analysis in Work Areas Within the Manufacturing Sector Through the HAZID Methodology. Process Safety and Environmental Protection. 2021;145:23-38.
8. Venkatesh MP, Philip A, Gangadharappa HV. Corrective Action and Preventive Action: Management and Applications in Pharmaceutical Industry. International Journal of Pharmaceutical Sciences Review and Research. 2017;46(2):184-189.
9. Kumar KB, Kumar P. Corrective and Preventive Action-A Route Cause Analysis in Manufacturing Quality System: Review. Innovare Journal of Sciences. 2016;4(2):1-4.
10. Carey CC. United States food and drug administration. In Clinical Engineering Handbook. Academic Press. 2020;1:764-773.
11. Teasdale A, Elder D, Nims RW. ICH quality guidelines. (Wiley Online Library 2017).