IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 1, September 2025
Impact Factor: 7.67

Role of Corrective and Preventive action (CAPA) in Pharmaceutical Quality Management System

Ms. Bhakti Santosh Gurav[1], Dr. Sachin V Datkhile[2], Ms. Komal Gaikwad[3], Mr. Omkar Gosavi[4], Ms. Komal Aher[5], Ms. Divya Deshmukh[6]
Department of Pharmaceutical Quality Assurance[1-6]
Samarth Institute of Pharmacy Belhe, Pune, Maharashtra, India

Abstract: *Corrective and Preventive Action (CAPA) forms an essential element of the Pharmaceutical Quality Management System (QMS). Its primary aim is to drive continuous improvement by systematically identifying, analyzing, correcting, and preventing quality issues in processes and products. This review explains the importance of CAPA within pharmaceutical QMS, covering regulatory perspectives, implementation approaches, common challenges, and overall benefits. It also highlights how CAPA strengthens compliance with Good Manufacturing Practices (GMP) and emphasizes the need for effective root cause analysis, proper documentation, and verification of outcomes to ensure success*

Keywords: CAPA, Quality Management, GMP, Corrective Action, Preventive Action, Root Cause Analysis, Continuous Improvement.

I. INTRODUCTION

The pharmaceutical industry places the highest importance on product quality and patient safety. To achieve this, companies operate under Quality Management Systems (QMS) such as those outlined in ICH Q10. Within these systems, Corrective and Preventative Action (CAPA) is a system of quality procedures required to eliminate the causes of an existing nonconformity and to prevent recurrence of nonconforming product, processes, and other quality problems. Corrective Action: A corrective action is to eliminate the cause of a detected non-conformity or other undesirable situation. Preventive Action: A preventive action is a process to eliminate the cause of a potential non-conformity or other undesirable situation.

Corrective and Preventive Action (CAPA) is a cornerstone because it provides both corrective measures for existing issues and preventive strategies to reduce future risks. CAPA ensures that problems are not only addressed but also studied systematically to prevent recurrence, thereby safeguarding compliance and reliability in pharmaceutical manufacturing.

CAPA in the Pharmaceutical Industry

In pharmaceutical operations, CAPA offers a structured framework to handle deviations and risks. The process typically includes identifying issues, performing root cause analysis (RCA), preparing an action plan, implementing measures, verifying effectiveness, and documenting the entire activity. Regulatory bodies such as ICH, USFDA, EU GMP, and ISO 9001 all require CAPA as a compliance element.

- Corrective Action: The action taken to eliminate the causes of non-conformities or other undesirable situations, so as to prevent recurrence is known as corrective action Example :- If a batch of tablets failed a dissolution test due to improper drying, correcting the drying process parameters is a corrective action.
- Preventive Action: The action taken to eliminate the cause of a potential nonconformity or problem before it occurs, in order to prevent its occurrence is known as preventive action. Example :- Training operators on proper equipment cleaning procedures to avoid contamination issues in future batches.
- Thus, CAPA provides a dual approach: reacting to existing issues while proactively preventing future risks.

DOI: 10.48175/IJARSCT-28977

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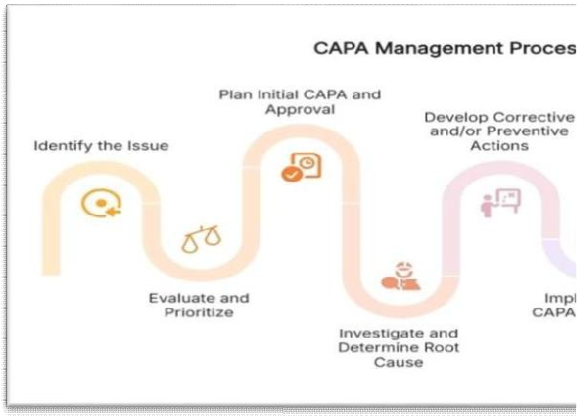
- The purpose of corrective and preventive action is to collect and analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.
- Manufacturers should consider that their corrective action and preventive action documentation can demonstrate to FDA that the manufacturer's quality system is effective and enables the manufacturer to identify problems quickly and implement effective corrective and preventive actions (or not).

CAPA Process in the Pharmaceutical Industry

The CAPA procedure follows a systematic approach to ensure issues are properly handled and prevented from recurring.

- Identification of the Issue: The first step is to clearly identify and define the problem, such as customer complaints, audit findings, deviations, or adverse events observed in the product, process, or system.
- Evaluation and Prioritization: Once identified, the issue is evaluated for its impact on product quality, patient safety, and compliance. Based on severity and urgency, the issue is prioritized for timely action.
- Preparation of an Initial CAPA Plan: A structured plan is then created, outlining the specific steps to be taken, deadlines for completion, allocation of responsibilities, and the necessary resources.
- Root Cause Investigation: A thorough investigation is carried out to determine the true underlying causes using appropriate root cause analysis tools, rather than just addressing the symptoms.
- Development of Corrective and Preventive Actions: Based on the investigation, effective corrective measures are proposed to resolve the current issue, while preventive actions are designed to avoid similar problems in the future.
- Implementation of the CAPA Plan: The identified corrective and preventive actions are executed according to the plan, ensuring proper coordination among all responsible departments.
- Verification of Effectiveness: After implementation, checks are performed to confirm whether the actions have successfully resolved the problem and that no recurrence is observed.
- Documentation and Closure: All details of the CAPA process including investigations, actions taken, and effectiveness checks are documented in a CAPA report. Once complete, the CAPA is formally closed.
- Trending and Continuous Review: Finally, quality data is periodically monitored and trended to identify recurring patterns or new risks. These reviews are presented during management meetings to ensure ongoing regulatory compliance and to drive continuous improvement in processes and products.



Regulatory Expectations Related to CAPA

FDA 21 CFR Part 211 – CAPA

- 211.22(d): QC unit ensures investigations & CAPA.
- 211.192: Batch records reviewed; CAPA for deviations.

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- 211.100(a): CAPA for container/closure defects.
- 211.180(e): CAPA must be documented.
- 211.192(b): Deviations investigated; CAPA to prevent recurrence. ICH Q10 –CAPA
- Section 3.2.2: Requires CAPA system for complaints, recalls, audits.
- Linked with ICH Q9: Root cause analysis + risk-based documentation.

EU GMP – CAPA

- Chapter 1 (1.4xiv): Documented CAPA system for deviations & defects.
- Chapter 8 (8.16): CAPA for complaints, recalls, adverse events.
- Use risk-based RCA; monitor CAPA effectiveness. ISO 9001:2015 – CAPA
- Section 10.2: Process for nonconformities & corrective action.
- Requires root cause analysis, risk evaluation, corrective measures.
- Effectiveness must be verified & documented.

Role of CAPA in Handling Quality Events

- Problem Identification: CAPA ensures that deviations, complaints, audit findings, OOS/OOT results, or recalls are properly captured and documented.
- Root Cause Analysis: It drives systematic investigation to find the true cause of quality events rather than treating symptoms.
- Corrective Action: Helps resolve the immediate issue and prevent recurrence of similar nonconformities.
- Preventive Action: Identifies potential risks and implements proactive measures to stop issues before they occur.
- Documentation & Compliance: Ensures all activities are recorded, meeting regulatory expectations (FDA, ICH, EU GMP, ISO).
- Effectiveness & Continuous Improvement: CAPA checks whether implemented actions are effective and supports ongoing improvements in product safety

Tools Supporting CAPA

1. Root Cause Analysis Tools:

- Fishbone Diagram: Organizes potential causes of an issue into categories such as materials, methods, machines, manpower, measurement, and environment.
- 5 Whys: Uses repeated questioning ("Why?") to trace the problem back to its true origin.
- Pareto Analysis: Applies the 80/20 principle to identify the small number of causes responsible for the majority of problems.

2. Risk Assessment Tools:

- Failure Mode and Effect Analysis (FMEA): Assesses potential failure modes in a process by evaluating their severity, likelihood, and detectability, producing a Risk Priority Number (RPN) to guide corrective efforts.

3. Electronic CAPA Management Systems:

- Many companies now use electronic systems to automate CAPA documentation, tracking, and reporting. These systems improve transparency, ensure accountability, reduce errors, and strengthen compliance.

Challenges in CAPA Implementation

- Inadequate Root Cause Analysis: Many times, investigations stop at superficial causes (like human error) without identifying the true root cause.

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- Poor Documentation: Incomplete or unclear CAPA records create compliance gaps during audits and inspections.
- Delayed Implementation: Actions are often not completed within timelines, leading to repeated issues.
- Ineffective Actions: Corrective or preventive measures may not fully resolve the issue or prevent recurrence.
- Lack of Resources & Training: Limited manpower, time, or knowledge can weaken CAPA execution.
- Weak Effectiveness Checks: Failure to properly verify outcomes reduces confidence in CAPA success.
- Over-Reliance on Retraining: Using training alone as a solution without addressing process or system gaps.
- Trend Analysis Neglected: Not using data to identify recurring patterns of deviations

Benefits of a Strong CAPA System

- Prevents Recurrence: Corrective actions ensure problems are solved permanently.
- Prevents Occurrence: Preventive actions stop potential issues before they happen.
- Improves Product Quality: Strengthens processes, reduces errors, and ensures consistent quality.
- Enhances Compliance: Meets FDA, ICH, EU GMP, ISO requirements and avoids regulatory observations.
- Supports Patient Safety: Eliminates risks that could harm patients.
- Drives Continuous Improvement: Regular reviews and trending promote better systems over time.
- Reduces Costs: Avoids waste, recalls, and rework by addressing issues effectively.

II. CONCLUSION

CAPA is a cornerstone of the Pharmaceutical Quality Management System, essential for safeguarding product quality, compliance, and patient safety. Its success depends on accurate root cause analysis, timely execution, thorough documentation, and effective verification of actions. A well-established CAPA system not only resolves current issues but also prevents future ones, enabling a culture of continuous improvement within pharmaceutical organizations.

A strong CAPA system strengthens compliance with global regulations such as FDA 21 CFR Part 211, ICH Q10, EU GMP, PIC/S guidelines, and ISO 9001. One of the major contributions of CAPA is safeguarding patient safety by ensuring that products are free from defects, deviations, or risks that could compromise health. At the same time, CAPA also benefits the manufacturer by reducing waste, avoiding recalls, saving costs, and improving overall efficiency of operations

In conclusion, a well-designed and effectively executed CAPA system ensures regulatory compliance, improves product quality, enhances patient safety, reduces costs, and builds long- term trust with stakeholders. Therefore, CAPA should not be seen merely as a regulatory requirement but as a strategic approach that connects quality, safety, and efficiency. Its role in the pharmaceutical quality management system is indispensable, making it a cornerstone for both present and future success of the industry.

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