Standard Operating Procedure (SOP)

Corrective and Preventive Action (CAPA) Procedures

This SOP details **Corrective and Preventive Action (CAPA) procedures**, encompassing the identification, documentation, and investigation of non-conformities, root cause analysis, implementation of corrective actions, verification of their effectiveness, and the establishment of preventive measures to avoid recurrence. It aims to enhance process quality, ensure compliance with regulatory standards, and promote continuous improvement within the organization.

1. Purpose

To define the process for identifying, documenting, evaluating, investigating, correcting, and preventing non-conformities to ensure continual improvement and regulatory compliance.

2. Scope

This SOP applies to all departments and employees involved in processes where non-conformities may occur within the organization.

3. Definitions

- **CAPA:** Corrective and Preventive Action
- **Non-conformity:** Deviation from a procedure, process, or regulatory requirement
- **Corrective Action:** Action to eliminate the cause of a detected non-conformity
- **Preventive Action:** Action to eliminate the cause of a potential non-conformity

4. Responsibilities

- **All Employees:** Report non-conformities as identified.
- **Department Heads/Supervisors:** Review, assign, and track CAPA activities.
- **Quality Assurance (QA):** Oversee CAPA process and maintain records.

5. Procedure

1. **Identification of Non-conformity:**
    - All personnel must report non-conformities immediately using the CAPA form or system.
2. **Documentation:**
    - Record all relevant details: description, date, location, person(s) involved.
3. **Investigation & Root Cause Analysis:**
    - Assigned personnel or team investigates to determine the root cause using tools such as the 5 Whys, Fishbone Diagram, or other appropriate methods.
4. **Corrective Action:**
    - Develop and implement action(s) to address the root cause and prevent recurrence.
    - Assign responsibility and set deadlines for completion.
5. **Verification of Effectiveness:**
    - Quality Assurance/Responsible Supervisor verifies that corrective actions are implemented and effective.
6. **Preventive Action:**
    - Identify and implement measures to prevent potential similar non-conformities in other processes or areas.
7. **Documentation & Record Retention:**
    - Ensure all CAPA records are complete and retained according to applicable record retention policies.

6. Documentation Requirements

- CAPA Form or electronic system entry describing the issue, analysis, actions taken, responsible persons, and verification results.
- Supporting evidence (photos, reports, communication, etc.).

7. Related Documents

- Non-Conformance Report (NCR)

- Root Cause Analysis Worksheet
- QA Audit Reports
- Document Control SOP

8. Revision History

Version	Date	Description	Author
1.0	2024-06-XX	Initial release	[Name]