Standard Operating Procedure (SOP)

Corrective and Preventive Action Implementation

This SOP details the process for **Corrective and Preventive Action Implementation**, including identification of non-conformities, root cause analysis, development of corrective actions, verification of effectiveness, documentation procedures, and continuous improvement strategies. The purpose is to ensure systematic resolution of issues, prevent recurrence, and enhance overall quality and compliance within the organization.

1. Purpose

To provide a systematic approach for identifying, correcting, and preventing non-conformities, ensuring continuous improvement and compliance with regulatory and organizational standards.

2. Scope

This SOP applies to all employees and processes where non-conformities may be identified or improvements can be implemented.

3. Responsibilities

- **Employees:** Identify and report non-conformities and suggest preventive actions.
- **Department Managers:** Oversee root cause analysis, develop and implement corrective/preventive actions.
- **Quality Assurance:** Facilitate investigations, maintain records, and verify effectiveness.
- **Senior Management:** Support resources allocation and continuous improvement strategies.

4. Procedure

1. **Identification of Non-conformities**
    - Non-conformities may be identified through audits, inspections, customer complaints, or routine operations.
    - Document all identified issues using the Corrective and Preventive Action (CAPA) form.
2. **Root Cause Analysis**
    - Assign a responsible party or team.
    - Use appropriate tools (e.g., 5 Whys, Fishbone Diagram).
    - Document findings and contributing factors.
3. **Development of Corrective and Preventive Actions**
    - Develop actions to correct the immediate problem and to prevent recurrence.
    - Assign action items, responsible persons, and realistic deadlines.
4. **Implementation**
    - Communicate action plan to relevant parties.
    - Implement corrective and preventive actions as per the plan.
5. **Verification of Effectiveness**
    - Review the situation after the actions have been implemented.
    - Verify and document that the non-conformity has been resolved and recurrence prevented.
6. **Documentation and Recordkeeping**
    - Maintain all CAPA records, investigation details, action plans, and verification results.
    - Ensure documents are readily accessible for audits and reviews.
7. **Continuous Improvement**
    - Periodically review CAPA activities for trends.
    - Update procedures and training to reflect lessons learned and improvements.

5. Documentation

Document	Description	Retention Period
CAPA Form	Record of non-conformity, root cause, action plans, and verification	5 years
Investigation Reports	Details of root cause analysis	5 years
Action Plan Logs	Tracking corrective and preventive actions	5 years

6. References

- Quality Management Manual
- Internal Audit SOP
- Regulatory requirements (e.g., ISO 9001, FDA 21 CFR Part 820)

7. Revision History

Version	Date	Description	Approved By
1.0	2024-06-01	Initial release	Quality Manager