SOP Template: Deviation, Non-Conformance, and Corrective Action Handling

This SOP details the processes for managing **deviation, non-conformance, and corrective action handling**, including identification, documentation, evaluation, and root cause analysis of deviations and non-conformances. It outlines responsibilities for corrective action implementation, verification of effectiveness, and continuous improvement measures. The goal is to ensure product quality, compliance with standards, and prevention of recurrence through systematic handling and resolution of issues.

1. Purpose

To provide a systematic approach for the identification, documentation, evaluation, investigation, and resolution of deviations and non-conformances, and to ensure corrective actions are implemented to prevent recurrence.

2. Scope

This SOP applies to all personnel involved in the manufacturing, quality control, and related functions where deviations and non-conformances from standard requirements can occur.

3. Definitions

Term	Definition
Deviation	An unplanned departure from an approved procedure, process, or specification.
Non-Conformance	Failure to meet specified requirements for a product, process, or system.
Corrective Action	Action taken to eliminate the cause of a detected non-conformity or deviation to prevent recurrence.
Root Cause Analysis	Systematic process to identify the fundamental reason for a deviation or non-conformance.

4. Responsibilities

- **All Employees:** Promptly report deviations or non-conformances.
- **Supervisors/Managers:** Initiate documentation, assess the issue, and assign investigation.
- **Quality Assurance (QA):** Review, approve, and monitor the handling of deviations and corrective actions.
- **Root Cause Analysis Team:** Conduct in-depth analysis and propose corrective actions.

5. Procedure

1. **Identification:**
    - Any staff member who identifies a deviation or non-conformance must notify their supervisor immediately.
2. **Documentation:**
    - Initiate a *Deviation/Non-Conformance Report* including:
        - Description of the event
        - Date, time, location
        - Personnel involved
3. **Evaluation:**
    - Supervisors/QA assess the potential impact on product/process quality and regulatory compliance.
4. **Root Cause Analysis:**
    - Assign a team to investigate using appropriate tools (e.g., 5 Whys, Fishbone Diagram).
    - Document findings and potential root causes.
5. **Corrective Action Implementation:**
    - Develop an action plan addressing the root cause(s).
    - Assign responsibilities and deadlines for completion.
    - Document all actions taken.
6. **Verification:**
    - QA verifies effectiveness of corrective actions within a defined period.

    - Review recurrence data if available.
7. **Closure:**
    - Compile all documentation for QA approval and closure.
8. **Continuous Improvement:**
    - Trend analysis and regular reviews to detect systemic issues and improvement opportunities.

6. Documentation and Records

- Deviation/Non-Conformance Reports
- Root Cause Analysis Reports
- Corrective Action Plans
- Verification and closure records

All documentation must be retained according to company record retention policy and regulatory requirements.

7. Review and Revision

- This SOP is to be reviewed annually or as required by regulatory changes or process improvements.
- Revisions must be documented, approved, and communicated to all relevant staff.

8. Appendix: Forms and Templates

- Deviation/Non-Conformance Report Form
- Root Cause Analysis Worksheet
- Corrective Action Plan Template