SOP: Deviation and Non-Conformance Reporting Guidelines

This SOP establishes **deviation and non-conformance reporting guidelines** to ensure systematic identification, documentation, and resolution of any deviations from established procedures, standards, or specifications. It covers the process for reporting non-conformances, assessment and investigation, corrective and preventive actions, communication protocols, and continuous improvement measures to maintain product quality and compliance with regulatory requirements.

1. Purpose

To define a uniform process for the identification, documentation, investigation, and closure of deviations and non-conformances to ensure compliance with quality and regulatory standards.

2. Scope

This SOP applies to all personnel responsible for performing tasks that could impact product quality, safety, or compliance at [Company Name/Facility].

3. Definitions

- **Deviation:** Departure from an approved procedure, standard, or specification.
- **Non-Conformance:** Failure to meet specified requirements such as regulatory guidelines, internal or external standards.
- **CAPA:** Corrective and Preventive Action.

4. Responsibilities

- **All Employees:** Promptly report deviations and non-conformances.
- **Supervisors/Managers:** Ensure thorough documentation, assessment, and timely resolution.
- **Quality Assurance (QA):** Oversee process, review reports, coordinate investigations, and ensure closure and reporting to management and regulatory authorities as required.

5. Procedures

1. **Identification & Initiation**
    - Any observed or suspected deviation or non-conformance should be reported immediately using the approved reporting form/system.
2. **Documentation**
    - Record all relevant information (date, time, personnel, equipment, description, and impact assessment).
    - Assign a unique identifier or reference number to each case.
3. **Assessment & Investigation**
    - Assess severity and potential impact on product quality and compliance.
    - Initiate a root cause investigation and document findings.
4. **Corrective & Preventive Actions (CAPA)**
    - Define and implement corrective actions to address immediate concerns.
    - Identify and implement preventive actions to avoid recurrence.
5. **Communication & Review**
    - Maintain clear communication with affected stakeholders throughout the process.
    - Management and regulatory agencies must be notified as required.
6. **Closure & Verification**
    - Ensure all actions are documented, completed, and verified.
    - Close the case and retain documentation as per record-keeping policies.

6. Documentation and Records

- Deviation/Non-Conformance Reporting Forms
- Investigation Reports
- CAPA Documentation

- Communication Records

All records must be maintained in accordance with [Company] record management policies and applicable regulatory requirements.

7. Continuous Improvement

- Regular review and analysis of reported deviations/non-conformances for trend identification.
- Implementation of process improvements based on trend analysis.
- Periodic SOP review and updates to reflect current best practices and regulatory expectations.

8. References

- [List applicable regulations, standards, company policies and related SOPs, e.g., FDA CFR, ISO 9001, internal quality manual, etc.]

9. Revision History

Version	Date	Description of Change	Author	Approval
1.0	[Date]	Initial Release	[Name]	[Name/Title]