SOP: Change Request and Deviation Management

Document Number:	[SOP-XXX]
Effective Date:	[YYYY-MM-DD]
Version:	1.0
Prepared By:	[Name/Department]
Approved By:	[Name/Department]
Next Review:	[YYYY-MM-DD]

1. Purpose

This SOP defines the **change request and deviation management** process, encompassing the identification, documentation, assessment, approval, implementation, and monitoring of changes and deviations in projects or operations. It aims to ensure systematic control, risk assessment, and communication of changes to maintain product quality, compliance, and operational efficiency while minimizing potential negative impacts.

2. Scope

This SOP applies to all employees, contractors, and stakeholders involved in initiating, managing, or affected by change requests and deviations across [site, department, or organization name].

3. Definitions

- **Change Request (CR):** A formal proposal to modify any aspect of a project, process, or documented system.
- **Deviation:** Any unplanned departure from an approved procedure, specification, or standard.
- **CAPA:** Corrective and Preventive Action taken to address deviations and their root causes.

4. Responsibilities

- **Initiator:** Identifies and documents change requests or deviations.
- **Department Manager/Supervisor:** Reviews, assesses, and endorses CRs and deviations for further action.
- **Quality Assurance (QA):** Assesses risk, ensures compliance, and approves/rejects actions.
- **Responsible Department:** Carries out approved changes or corrective actions.
- **All Personnel:** Report any potential or actual deviation as soon as identified.

5. Procedure

1. **Identification**
    - Recognize and document any required change or observed deviation using the respective form (Appendix I/II).
2. **Documentation**
    - Complete the Change Request or Deviation Report in full, providing all necessary background, proposed solution(s), and impact analysis.
3. **Assessment & Classification**
    - Manager and QA review the submission for classification (Critical, Major, Minor) and potential regulatory or quality impact.
    - Conduct a risk assessment.
4. **Approval**
    - Obtain approvals from responsible departments and/or QA before any action is taken.
    - Document all decisions and justifications.
5. **Implementation**
    - Implement changes or corrective actions as approved.
    - Document solutions/action steps and responsible parties.
6. **Verification & Close-Out**
    - Verify successful implementation and effectiveness.
    - QA/QC signs off the closure.
7. **Communication**
    - Communicate changes and deviations, including resulting corrective actions, to all affected parties.

8. **Documentation & Record Keeping**
    - Maintain all records for a defined retention period in compliance with regulatory requirements.

6. References

- [List any applicable regulatory references, company policies, or related SOPs]

7. Appendices

- **Appendix I:** Change Request Form (template)
- **Appendix II:** Deviation Report Form (template)
- **Appendix III:** Risk Assessment Checklist