SOP: Resolution and Corrective Action Implementation Process

This SOP details the **resolution and corrective action implementation process**, focusing on identifying issues, determining root causes, developing and executing corrective actions, monitoring effectiveness, and ensuring continuous improvement. The objective is to promptly resolve problems, prevent recurrence, and enhance overall operational quality and compliance through systematic follow-up and documentation.

1. Purpose

To establish a systematic approach to resolving issues, implementing corrective actions, and ensuring continuous improvement in operational processes.

2. Scope

This SOP applies to all employees involved in identifying, reporting, investigating, resolving, and documenting issues across operations.

3. Definitions

Term	Definition
Issue	Any deviation, nonconformity, or problem requiring resolution.
Corrective Action	Action taken to eliminate the cause of a detected issue and prevent recurrence.
Root Cause	The primary underlying reason for the occurrence of an issue.

4. Responsibilities

- **Employees:** Report issues promptly using designated channels.
- **Supervisors/Managers:** Oversee root cause analysis, development, and implementation of corrective actions.
- **Quality/Compliance Team:** Facilitate process, monitor effectiveness, maintain documentation, and ensure compliance.

5. Procedure

1. **Issue Identification and Reporting**
    - Recognize and document any problem, deviation, or nonconformity.
    - Report the issue using the approved form/system within one business day.
2. **Initial Review and Triage**
    - Supervisor/Manager reviews the report for clarity and completeness.
    - Assign priority level based on severity, impact, and urgency.
3. **Root Cause Analysis**
    - Assemble a cross-functional team to determine the root cause using tools such as the 5 Whys or Fishbone Diagram.
    - Document all findings and discussions.
4. **Development of Corrective Actions**
    - Identify and evaluate possible corrective actions (including risk assessment).

- Select best solutions to eliminate root cause(s) and assign responsible parties and deadlines.

5. **Implementation of Corrective Actions**
   - Communicate the plan to all affected stakeholders.
   - Implement corrective actions as per schedule.
6. **Verification and Effectiveness Monitoring**
   - Monitor implementation and evaluate the effectiveness of corrective actions.
   - Conduct follow-up checks after a set period and adjust actions if necessary.
   - Document outcomes and lessons learned.
7. **Closure and Documentation**
   - Once resolved and effectiveness verified, mark the issue as closed in the tracking system.
   - Retain records for future reference and audits.
8. **Continuous Improvement**
   - Regularly review trends, recurring issues, and process outcomes.
   - Incorporate lessons learned into training and SOP updates as needed.

6. Documentation and Records

- Issue Report Forms
- Root Cause Analysis records
- Corrective Action Plans
- Verification and Follow-up Records
- Closure Reports

7. References

- Applicable regulatory standards (e.g., ISO, FDA, internal QMS)
- Organizational policies and procedures

8. Revision History

Version	Date	Description	Author
1.0	2024-06	Initial template release	[Your Name/Department]