SOP Template: Management of Sterilization Failures and Corrective Actions

This SOP details the **management of sterilization failures and corrective actions**, encompassing the identification, documentation, and investigation of sterilization process failures, implementation of immediate containment measures, root cause analysis, corrective and preventive actions, staff training and competency requirements, monitoring and validation procedures, and continuous improvement strategies. The objective is to ensure effective sterilization processes, maintain product safety and quality, and comply with regulatory standards.

1. Purpose

To establish a systematic approach for managing sterilization failures, including immediate action, investigation, corrective and preventive measures, ensuring product safety and regulatory compliance.

2. Scope

This SOP applies to all sterilization processes, equipment, and personnel involved in the preparation and release of sterile products.

3. Responsibility

- All staff involved in sterilization procedures
- Quality Assurance (QA) personnel
- Supervisors and Department Heads

4. Definitions

- **Sterilization Failure:** Any deviation from established sterilization parameters, or detection of viable microorganisms in final product.
- **Corrective Action:** Steps taken to eliminate causes of identified non-conformities.
- **Preventive Action:** Measures implemented to prevent recurrence of failures.

5. Procedure

1. **Identification of Failure**
    - Monitor and document all critical parameters for each sterilization cycle.
    - Investigate process deviations or positive biological indicators, chemical indicator failure, or physical parameter deviation.
2. **Immediate Containment Measures**
    - Quarantine affected products and equipment immediately.
    - Stop release and use until investigation is completed.
3. **Documentation**
    - Complete failure documentation form, including cycle data, equipment logs, product details, and observed deviation.
    - Notify QA and relevant authorities as applicable.
4. **Investigation and Root Cause Analysis**
    - Conduct thorough investigation using root cause analysis tools (e.g., Fishbone Diagram, 5 Whys).
    - Review sterilization records, equipment status, staff performance, and related process steps.
5. **Corrective Actions**
    - Implement corrections as soon as cause is determined (e.g., equipment repair, process adjustment).
    - Re-process, re-sterilize, or dispose of affected products as per policy.
6. **Preventive Actions**
    - Review and revise protocols, SOPs, and training materials as needed.
    - Enhance monitoring procedures and equipment maintenance schedules.
7. **Staff Training and Competency**
    - Conduct training and assessment for all staff involved in sterilization.
    - Document competency and retrain as appropriate.
8. **Monitoring and Validation**
    - Re-validate sterilization process following corrective actions.
    - Increase monitoring for a defined period post-implementation.
9. **Continuous Improvement**

- Review incidents and outcomes periodically for trend analysis.
- Implement process improvements based on findings.

6. Records

- Sterilization logbooks and cycle reports
- Failure investigation and corrective action forms
- Training and competency records
- Equipment maintenance and validation reports

7. References

- Applicable local and international regulatory guidelines (e.g., FDA, WHO, ISO 13485)
- Internal Quality Management System procedures

8. Revision History

Revision	Date	Description of Change	Approved by
01	[Insert Date]	Initial release	[Name/Signature]