SOP: Documentation and Record-Keeping Requirements for Recalls

This SOP details the **documentation and record-keeping requirements for recalls**, encompassing the systematic recording of recall initiation, tracking of affected products, communication logs with stakeholders, verification of product retrieval, and final disposition documentation. The purpose is to maintain accurate and comprehensive records to ensure traceability, regulatory compliance, and effective management of recall processes.

1. Purpose

To establish standardized procedures for the documentation and record-keeping necessary during the recall of products, ensuring thorough traceability, regulatory compliance, and operational integrity throughout the recall process.

2. Scope

This SOP applies to all personnel involved in the initiation, coordination, execution, and closure of product recalls.

3. Responsibilities

- **Recall Coordinator:** Ensure proper documentation of all recall activities and maintain records.
- **Quality Assurance:** Review, verify, and archive recall-related documentation.
- **Affected Department Heads:** Provide necessary records and support traceability efforts.

4. Documentation & Record-Keeping Requirements

Document Type	Description	Retention Period	Responsible Party
Recall Initiation Record	Document containing recall notification, date/time of initiation, reason for recall, and products affected.	10 years	Recall Coordinator
Product Tracking Log	Detailed list of lots/batches, quantities, distribution dates, customers/locations affected.	10 years	Recall Coordinator
Stakeholder Communication Log	Records of all communications with regulatory authorities, customers, suppliers, and internal teams.	10 years	Recall Coordinator
Product Retrieval Verification	Evidence of retrieval, including returned product quantities, condition assessments, and reconciliation.	10 years	Quality Assurance
Corrective Action Records	Documentation of product disposition (e.g., destruction, reprocessing), corrective actions taken, and closure of recall.	10 years	Quality Assurance

5. Procedure

1. **Initiate Recordkeeping:** Upon recall initiation, immediately begin a recall file for the affected product(s).
2. **Document All Activities:** Record decisions, actions taken, and communications as they occur using designated logs and templates.
3. **Maintain Traceability:** Ensure all recalled product units can be traced throughout the supply chain, and record all movements.
4. **Verification and Reconciliation:** Verify every retrieval, return, or destruction of the product. Document exceptions or discrepancies.
5. **Archive and Protect Records:** After recall closure, archive all files securely for the defined retention period, ensuring confidentiality and accessibility for audits.

6. Record Storage and Security

- Store records in a secure, access-controlled environment (physical or digital).
- Backup digital records regularly and restrict access to authorized personnel only.
- Ensure protection against damage, loss, or unauthorized alteration.

7. References

- Relevant local, national, and international regulations (e.g., FDA, EMA, ISO).
- Company Recall Policy.
- Internal Quality Management System documentation.

8. Revision History

Date	Version	Description	Author
2024-06-15	1.0	Initial release.	QA Department