Standard Operating Procedure (SOP)

Documentation and Record-Keeping for Traceability

This SOP details the procedures for **documentation and record-keeping for traceability**, ensuring accurate and comprehensive recording of product history and movement. It covers proper data entry, maintenance of traceability logs, compliance with regulatory requirements, and secure storage of records. The purpose is to facilitate efficient tracking of products through the supply chain, enhance accountability, and support quality control and recall processes.

1. Scope

This SOP applies to all staff involved in the handling, movement, and documentation of materials and products throughout the supply chain.

2. Responsibilities

- **All Employees**: Ensure accurate, timely, and legible data entry and record maintenance.
- **Supervisors**: Verify entries, conduct periodic audits, and ensure compliance with this SOP.
- **Quality Assurance (QA)**: Monitor compliance, maintain master records, and facilitate audits.

3. Procedure

1. **Data Entry**
   - Record all relevant product information (e.g., batch/lot numbers, production dates, quantities, movements, personnel involved).
   - Use approved electronic or paper forms for all entries.
   - Enter data promptly after each transaction or movement.
   - Ensure all entries are clear, legible, and free from unauthorized alterations.
2. **Traceability Logs**
   - Maintain up-to-date traceability logs for each product and batch.
   - Ensure logs capture the full movement and transformation history from receipt of raw materials to finished goods dispatch.
   - Assign unique identifiers to all materials and products to facilitate tracking.
3. **Corrections and Amendments**
   - For paper records, cross out errors with a single line, initial, and date. Do not erase or obliterate original entries.
   - For electronic systems, use authorized correction functions and maintain a full audit trail of changes.
4. **Record Review**
   - Supervisors or designated personnel must review documentation for completeness and accuracy at regular intervals.
   - Address discrepancies immediately and document corrective actions taken.
5. **Storage and Retention**
   - Store records securely, protecting against unauthorized access, loss, or damage.
   - Maintain electronic backups as required.
   - Retain records in accordance with legal, regulatory, and company policy requirements (minimum of 5 years unless otherwise specified).

4. Compliance and Regulatory Requirements

- Follow all applicable local, national, and international regulations for documentation and traceability.
- Be prepared to make records available for audits and inspections by regulatory authorities.

5. Training

- Provide initial and refresher training for all relevant personnel on this SOP.
- Maintain training records as part of the traceability documentation.

6. References

- Company Record-Keeping Policy
- Applicable Regulatory Standards (e.g., FDA 21 CFR Part 11, ISO 22000, etc.)
- Internal Audit Procedures

7. Revision History

Version	Date	Description	Approved By
1.0	2024-06-15	Initial release	QA Manager