SOP Template: Raw Material Traceability and Documentation Process

This SOP defines the **raw material traceability and documentation process**, detailing procedures for tracking raw materials from receipt through production to ensure product quality and compliance. It covers methods for recording material origin, batch numbers, storage conditions, and handling instructions, as well as maintaining accurate and accessible documentation to support audits, quality control, and regulatory requirements.

1. Purpose

To establish a standardized approach for maintaining traceability of all raw materials received, stored, and used in production, and to document relevant information to ensure quality, compliance, and effective recall capability if needed.

2. Scope

This procedure applies to all personnel involved in receiving, storing, handling, and documenting raw materials in the facility.

3. Responsibilities

- **Purchasing Department:** Ensure all raw materials are acquired from approved suppliers and that Certificate of Analysis (COA) and relevant documents are received.
- **Receiving Personnel:** Inspect incoming materials, verify documentation, label materials, and enter details into the inventory system.
- **Warehouse/Storage Staff:** Store materials according to designated requirements and monitor storage conditions.
- **Production Staff:** Record batch numbers and quantities of materials used during production processes.
- **Quality Assurance:** Review documentation, conduct audits, and verify traceability during routine checks.

4. Procedure

4.1 Material Receipt

- Receive raw materials only from approved and qualified suppliers.
- Inspect materials for damage, contamination, and conformity with purchase orders.
- Verify and collect accompanying documents (COA, shipping records, etc.).
- Assign and label each batch with a unique batch/lot number.
- Enter the following into the inventory management system:
  - Supplier Name
  - Date of Receipt
  - Material Name and Description
  - Batch/Lot Number
  - Quantity Received
  - Storage Location
  - Relevant Documentation References (COA, etc.)

4.2 Storage and Handling

- Store raw materials in designated areas with proper environmental controls (temperature, humidity, etc.).
- Maintain clear labeling at all times (batch/lot number, name, storage instructions).
- Monitor storage conditions and document any deviations immediately.

4.3 Material Issuance to Production

- Record the batch/lot number and quantity of material issued to each production batch.
- Document the date and person responsible for issuance and use.
- Ensure â€œFirst-In-First-Outâ€ (FIFO) or â€œFirst-Expire-First-Outâ€ (FEFO) protocols are followed.

4.4 Documentation & Record Keeping

- Maintain all documents electronically and/or in hard copy as required.
- Archive records for the minimum period defined in company policy or applicable regulation.
- Ensure documentation is accessible for audits, traceability investigations, and quality reviews.

5. Documentation and Forms

Document/Form	Description	Retention Time
Raw Material Receipt Log	Log of all incoming raw materials with relevant details	5 years
Batch/Lot Tracking Form	Tracks movement and use of each batch/lot	5 years
Storage Condition Log	Records of temperature, humidity, and inspections	2 years
COA and Supplier Documents	Certificates and qualification/approval evidence	5 years

6. References

- Company Quality Manual
- Regulatory Guidelines (e.g., FDA, ISO 22000, GMP)
- Supplier Qualification SOP

7. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-12	Initial version	Quality Manager