Standard Operating Procedure (SOP): Batch Tracking and Traceability Documentation

This SOP details the **batch tracking and traceability documentation** process, covering the systematic recording of batch information, product identification, and tracking from production to distribution. It includes procedures for maintaining accurate records, ensuring compliance with regulatory requirements, enabling efficient recall management, and supporting quality control and supply chain transparency. The aim is to enhance product safety, accountability, and customer confidence through precise traceability throughout the product lifecycle.

1. Purpose

To define standardized procedures for recording, maintaining, and accessing batch tracking and traceability documentation to ensure product safety, regulatory compliance, and effective recall capability.

2. Scope

This SOP applies to all production, quality, and distribution personnel responsible for the handling and documentation of batch information throughout the product lifecycle.

3. Responsibilities

- **Production:** Accurately record batch numbers and associated production details.
- **Quality Assurance:** Audit traceability records for compliance and completeness.
- **Distribution:** Ensure batch data is linked to logistical records for outbound goods.
- **Management:** Maintain oversight of the traceability process and ensure staff training.

4. Definitions

Term	Definition
Batch Number	Unique identifier assigned to a specific production lot.
Traceability	The ability to track the history, application, or location of a product by means of recorded identification.
Recall	The process of retrieving products from the supply chain due to safety or quality concerns.

5. Procedure

1. **Batch Number Assignment:**
   - Assign a unique batch number to each production lot at the start of manufacturing.
   - Clearly label batch numbers on all relevant documentation and product packaging.
2. **Documentation of Batch Data:**
   - Record batch number, production date, ingredient or component lot numbers, operator identification, and equipment used.
   - Use standardized forms or electronic systems for data entry and storage.
3. **Distribution and Tracking:**
   - Link batch numbers with shipment, invoice, and customer records.
   - Maintain batch records through the entire supply chain, from raw materials to finished goods delivery.
4. **Record Retention:**
   - Store traceability records securely for a minimum period as defined by regulatory requirements (e.g., 5 years).
   - Ensure records are accessible for audits and recall exercises.
5. **Recall Management:**
   - In the event of a recall, use batch documentation to identify affected products quickly.
   - Document all recall actions and maintain records for compliance review.

6. Compliance and Review

- Conduct regular audits of batch and traceability records.
- Update procedures as required by changes to regulations or internal policy.
- Provide regular training and updates for relevant staff.

7. References

- Applicable regulatory guidelines (e.g., FDA, EU, ISO standards)
- Internal quality management system documents

8. Document Control

Version	Effective Date	Author	Approval
1.0	[Effective Date]	[Name/Title]	[Approver/Signature]