

SOP: Product Labeling and Traceability Management

This SOP details **product labeling and traceability management** processes, encompassing accurate labeling requirements, batch and lot number assignment, barcode implementation, record-keeping protocols, compliance with regulatory standards, and procedures for tracking products through the supply chain. The objective is to ensure product integrity, facilitate efficient recalls, enhance quality control, and maintain transparent and reliable traceability from production to end consumer.

1. Purpose

To define the standardized procedures for labeling products and managing traceability to guarantee product identification, facilitate recall processes, and ensure compliance with applicable regulations.

2. Scope

This SOP applies to all products manufactured, packaged, stored, and distributed by [Company Name]. It covers personnel responsible for labeling, recording, and tracking product movement from production to delivery.

3. Responsibilities

- **Production Staff:** Apply accurate labels and record batch/lot numbers during manufacturing and packaging processes.
- **Quality Assurance:** Ensure compliance with labeling standards, verify information accuracy, and audit traceability records.
- **Warehouse/Logistics:** Maintain traceability when products are moved, stored, or shipped.
- **Regulatory Affairs:** Monitor and update regulatory labeling and traceability requirements.

4. Procedure

4.1 Labeling Requirements

- All product labels must include:
 - Product name and code
 - Batch/lot number
 - Manufacture/expiry date
 - Barcode (if applicable)
 - Compliance symbols (as required by relevant standards)
- Labels must be clear, indelible, and securely affixed to the product/package.

4.2 Batch & Lot Number Assignment

- Assign unique batch/lot numbers according to the Batch Numbering System SOP.
- Document batch/lot details in the production record.

4.3 Barcode Implementation

- Generate barcodes corresponding to each batch/lot number using approved software.
- Integrate barcode printing into the labeling process.
- Verify barcode readability and accuracy at each labeling stage.

4.4 Record-Keeping

- Accurately document all product movement, labeling, batch/lot numbers, and barcode details in electronic or paper-based traceability logs.
- Retain records as per the Record Retention Policy (minimum period defined by regulatory requirements).

4.5 Regulatory Compliance

- Ensure all labels comply with relevant industry standards and government regulations.
- Update labeling templates and traceability practices as regulations change.

4.6 Traceability Procedure

- Track each product from raw material receipt to final distribution, maintaining a continuous traceability trail.
- Respond promptly to traceability inquiries and recall events using recorded data.

5. Documentation & Records

Record Name	Responsible	Retention Period
Batch Production Records	Production / QA	5 Years
Labeling Logs	Production / QA	5 Years
Distribution Records	Logistics	5 Years

6. Revision History

Version	Date	Description	Approved by
1.0	[Insert Date]	Initial release	[Name/Title]