Standard Operating Procedure (SOP)
Completed Product Traceability and Recall Process

This SOP details the **completed product traceability and recall process**, covering the steps for tracking finished products from production to distribution, ensuring accurate record-keeping for batch identification, facilitating swift product recalls when necessary, coordinating with relevant departments for effective communication, and implementing corrective actions to maintain product safety and regulatory compliance.

1. Purpose

To describe the process for traceability of completed products and to outline actions required for product recall or withdrawal to ensure consumer safety and regulatory compliance.

2. Scope

This SOP applies to all finished products manufactured, stored, and distributed by the company.

3. Responsibilities

- **Quality Assurance (QA):** Maintains records, conducts traceability and recall drills, oversees recall execution.
- **Production:** Ensures accurate batch coding and record-keeping.
- **Warehouse/Logistics:** Maintains distribution records and supports recall retrieval.
- **Regulatory Affairs:** Communicates recalls to authorities as required.
- **Sales/Customer Service:** Notifies customers and distributors if recall is initiated.

4. Definitions

Term	Definition
Traceability	The ability to track the history, application, or location of a product batch throughout the supply chain.
Recall	The action of removing or correcting products that are in violation of laws or pose safety risks, whether initiated by the company or a regulatory body.
Batch/Lot Number	Unique identifier for a specific production run for traceability.

5. Procedure

1. **Product Identification and Traceability**
    a. Assign a unique batch/lot number during production to each finished product batch.
    b. Record batch numbers in production, packaging, and distribution logs.
2. **Record-Keeping**
    a. Maintain records of ingredients, production, packaging, storage, and distribution for each batch for the specified retention period.
    b. Ensure records are easily accessible for rapid retrieval in case of recall.
3. **Initiation of Product Recall**
    a. Assess potential safety or regulatory issue (via internal report, customer complaint, or regulatory notification).
    b. Convene the Recall Committee to determine recall necessity and scope.
    c. Document decision and rationale for recall initiation.
4. **Execution of Recall**
    a. Identify affected batches and ascertain their distribution status using traceability records.
    b. Notify relevant stakeholders (distributors, customers, regulatory authorities) as per regulatory guidelines.
    c. Arrange collection, segregation, and secure storage of recalled products.
    d. Maintain detailed records of all recalled products (quantity, batch, location).
5. **Internal and External Communication**
    a. Issue statements to staff, customers, and (if required) the public regarding recall actions.

    b. Maintain updated contact lists for rapid distribution of recall notifications.
6. **Corrective and Preventive Actions (CAPA)**
    a. Investigate root causes of the recall event.
    b. Implement measures to prevent recurrence.
    c. Document all CAPA actions and monitor effectiveness.
7. **Recall Completion and Review**
    a. Verify all affected products are removed from distribution and accounted for.
    b. Submit final recall report to management and regulatory authorities if required.
    c. Review recall process and update SOP as necessary.

6. Documentation and Records

- Batch/Lot production records
- Distribution logs
- Recall log and communications
- CAPA reports
- Final Recall Report

7. References

- Applicable national/local regulations on product recall
- Internal Quality Manual and Record Retention Policy

8. Revision History

Revision	Date	Description	Approved by
1.0	2024-06-XX	Initial release	[Name/Title]