

SOP: Recall and Product Withdrawal Procedures

This SOP details **recall and product withdrawal procedures**, covering the identification of affected products, communication protocols, coordination with regulatory authorities, customer notification, product retrieval processes, verification of corrective actions, and documentation requirements. The purpose is to ensure swift and effective removal of compromised products from the market to protect consumer safety and maintain regulatory compliance.

1. Purpose

To establish standardized procedures for the recall and withdrawal of products that may pose a risk to consumer safety or do not comply with regulatory requirements, ensuring prompt action and preventing further distribution or use.

2. Scope

This procedure applies to all products identified as requiring recall or withdrawal, and covers all personnel involved in recall management at any facility, warehouse, or distribution center.

3. Responsibilities

Role	Responsibility
Recall Coordinator	Leads recall team, initiates recall, oversees actions, communicates with authorities and stakeholders.
Quality Assurance Manager	Assesses affected lots, verifies documentation, ensures effectiveness of corrective actions.
Customer Service	Notifies customers, manages communications, answers queries from clients and distributors.
Warehouse/Logistics	Isolates and retrieves recalled products, maintains records of product returns and disposals.
Regulatory Affairs	Liaises with regulatory authorities, submits required notifications and reports.

4. Recall and Withdrawal Procedures

- Identification of Affected Product:**
 - Determine SKU, batch/lot numbers, production dates, and distribution scope.
 - Review traceability records to define the extent of affected stock.
- Communication Protocols:**
 - Notify internal stakeholders and recall team immediately.
 - Prepare and distribute external communications to customers and distributors.
- Coordination with Regulatory Authorities:**
 - Inform relevant authorities within required timelines (as per local regulations).
 - Provide detailed reports as requested.
- Customer Notification:**
 - Issue recall notices in writing, specifying product details, risk, and return procedures.
- Product Retrieval Process:**
 - Arrange return logistics or local disposal where appropriate.
 - Record quantities retrieved/disposed and maintain chain of custody.
- Verification of Corrective Actions:**
 - Ensure all affected product is removed from market.
 - Implement and verify effectiveness of corrective and preventive actions (CAPA).
- Documentation Requirements:**
 - Record all actions, communications, and outcomes in a recall file.
 - Retain documentation per company policy and regulatory requirements.

5. Documentation and Records

- Recall initiation reports
- Internal and external communications
- Return/Disposal forms
- Regulatory notifications
- Corrective and preventive action reports

- Recall effectiveness checks and closure reports

6. References

- Applicable national and international regulations
- Company quality manual
- Previous recall reports (if relevant)

7. Revision History

Version	Date	Description	Approved By
1.0	2024-06-07	Initial SOP issued	QA Manager