ChecklistGuro

Pharmaceutical Recall Readiness Checklist

Recall Team & Responsibilities

Defines roles, contact information, and responsibilities within the recall team.

Recall Team Leader Name

Write something...

Recall Team Leader Contact Number

Write something...

Primary Communication Method

- [ ] Phone
- [ ] Email
- [ ] Pager

Team Leader Responsibilities

Write something...

Quality Assurance Representative Name

Write something...

Last Team Training Date

Enter date...

Team Member Roles

- [ ] Quality Assurance
- [ ] Manufacturing
- [ ] Regulatory Affairs
- [ ] Supply Chain

Recall Team Leader Signature

Product Identification & Traceability

Ensures accurate product identification, lot numbering, and traceability throughout the supply chain.

Batch Number(s) Affected

Enter a number...

Manufacturing Site

- [ ] Site A
- [ ] Site B
- [ ] Site C

Manufacturing Date Range

Enter date...

Quantity Manufactured (per lot)

Enter a number...

Description of Product Identifier (e.g., Serial Number format)

Write something...

Distribution Channels Involved

- [ ] Wholesale
- [ ] Retail Pharmacy
- [ ] Hospital Pharmacy
- [ ] Direct to Patient

Sample Label/Packaging (for reference)

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Affected Product Assessment

Evaluates the scope of the recall, including affected lots, distribution channels, and potential patient impact.

Affected Lot Numbers

Enter a number...

Reason for Recall

- [ ] Defect
- [ ] Adverse Event
- [ ] Regulatory Issue
- [ ] Incorrect Labeling
- [ ] Other

Detailed Description of Defect/Issue

Write something...

Estimated Quantity of Affected Product

Enter a number...

Distribution Channels Affected

- [ ] Wholesale
- [ ] Pharmacies
- [ ] Hospitals
- [ ] Direct to Patient
- [ ] Other

Date Product First Distributed

Enter date...

Potential Patient Impact Assessment

Write something...

Communication & Notification

Outlines procedures for notifying relevant parties, including regulatory agencies, distributors, healthcare professionals, and patients.

Regulatory Agency Notification Required?

- [ ] Yes
- [ ] No

Which Regulatory Agency?

- [ ] FDA
- [ ] EMA
- [ ] Other

Notification Draft (Agency)

Write something...

Distribution Channel Notification Required?

- [ ] Yes
- [ ] No

Notification Draft (Distributors)

Write something...

Distribution Channels Notified

- [ ] Wholesale Distributors
- [ ] Pharmacies
- [ ] Hospitals
- [ ] Retailers

Patient Communication Plan Summary

Write something...

Date of Agency Notification

Enter date...

Time of Agency Notification

Retrieval & Disposition

Details steps for retrieving affected product from the field and handling its proper disposal or return.

Number of Affected Units Retrieved

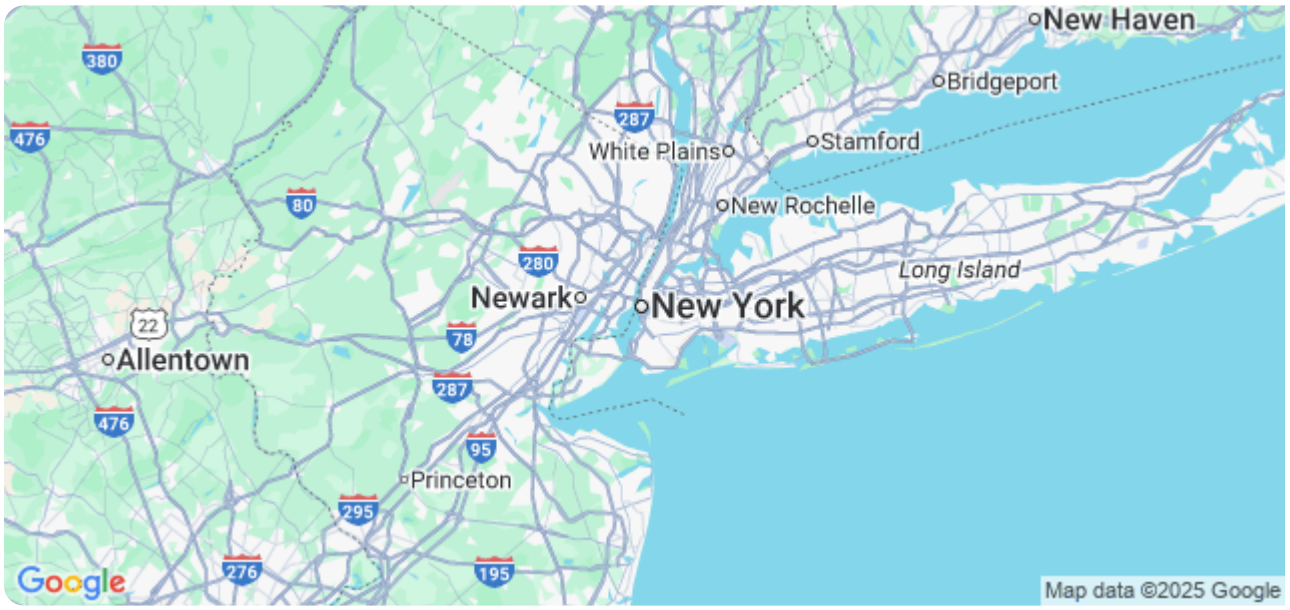
Enter a number...

Number of Units Remaining to Retrieve

Enter a number...

Primary Retrieval Location

Set My Current Location



Date Retrieval Started

Enter date...

Date Retrieval Completed (Target)

Enter date...

Disposition Method

- [ ] Destruction
- [ ] Return to Manufacturer
- [ ] Credit
- [ ] Other

Detailed Description of Disposition Actions

Write something...

Supporting Documentation (e.g., Destruction Certificates)

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Record Keeping & Documentation

Specifies requirements for maintaining accurate records throughout the recall process, including documentation of actions taken and rationale.

Recall Initiation Date

Enter date...

Summary of Recall Event and Findings

Write something...

Number of Lots Affected

Enter a number...

Estimated Number of Units Affected

Enter a number...

Affected Product Batch Records

Upload File

Description of Communication with Regulatory Agencies

Write something...

Regulatory Agency Notification Status

- [ ] Notified
- [ ] Acknowledgement Received
- [ ] Response Submitted

Supporting Documentation (e.g., lab reports, complaints)

Upload File

Recall Team Lead Signature

Corrective & Preventive Actions (CAPA)

Identifies steps to determine root cause of the issue and implement corrective and preventive actions to prevent future recalls.

Describe the Root Cause of the Recall Event

Write something...

Detail the Corrective Actions Taken to Address the Immediate Issue

Write something...

Outline Preventative Actions to Avoid Recurrence

Write something...

Number of Personnel Trained on Corrective/Preventive Actions

Enter a number...

Verification Method of CAPA Effectiveness

- [ ] Process Observation
- [ ] Data Analysis
- [ ] Audit
- [ ] Other

Planned Completion Date for CAPA Implementation

Enter date...

CAPA Review and Approval Signature

Training & Awareness

Verifies training records and confirms awareness of recall procedures across relevant personnel.

Number of Employees Trained

Enter a number...

Last Training Date

Enter date...

Training Method (e.g., Classroom, Online)

- [ ] Classroom
- [ ] Online
- [ ] Hybrid

Summary of Training Content

Write something...

Training Record Verification Status

- [ ] Verified
- [ ] Pending Verification

Upload Training Records (if applicable)

Upload File

Review and Update

Establishes a schedule and process for regularly reviewing and updating the recall plan to ensure its effectiveness.

Last Review Date

Enter date...

Summary of Review Findings and Changes

Write something...

Review Frequency (in months)

Enter a number...

Review Status

- [ ] Completed
- [ ] In Progress
- [ ] Not Started

Reviewer Signature

Next Scheduled Review Date

Enter date...