



FDA Recall Checklist – Step-by-Step Compliance Guide

Life Science Quality and Regulatory Experts

This FDA Recall Checklist will help ensure your company follows a structured, compliant, and efficient recall process in alignment with FDA regulations.

Use this checklist to:

- Ensure compliance with FDA recall procedures
- Minimize legal and financial risks
- Protect consumer safety

Step 1: Identify the Issue & Risk Assessment

- Conduct an internal investigation (complaints, product testing, deviation reports).
- Determine root cause (contamination, labeling errors, safety risks, etc.).
- Classify the recall based on FDA risk categories:
 - - Class I: Severe risk (life-threatening or serious health risks).
 - - Class II: Moderate risk (temporary health issues, labeling errors).
 - - Class III: Low risk (minor violations, unlikely to cause harm).
- Implement immediate corrective actions to stop distribution.

Step 2: Notify the FDA & Key Stakeholders

- Notify the FDA Recall Coordinator in your region.
- Submit the Recall Information Package to the FDA.
- Notify internal teams (Regulatory, Quality, Legal, Supply Chain).
- Notify distributors, retailers, and affected customers.
- Issue public recall notice (if required for Class I & high-risk Class II recalls).

Step 3: Develop & Execute the Recall Strategy

- Cease production & quarantine affected inventory.
- Initiate retrieval procedures with distributors and retailers.
- Implement reverse logistics to track returned products.

- Prepare public notification plan if necessary (press releases, website updates).

Step 4: Corrective & Preventive Actions (CAPA)

- Conduct a root cause analysis (RCA) using Failure Modes and Effects Analysis (FMEA).
- Implement corrective actions (update SOPs, improve supplier oversight).
- Conduct employee retraining on updated compliance procedures.
- Document all actions for FDA compliance review.

Step 5: Recall Effectiveness Check & FDA Audit Preparation

- Verify that all affected products have been removed.
- Conduct recall effectiveness checks (customer follow-ups, distributor audits).
- Submit a final recall status report to the FDA.
- Prepare for a potential FDA recall audit.
- Request official recall closure from the FDA.

Pro Tip: How to Prepare for Future FDA Recalls

- * Develop a recall preparedness plan BEFORE an incident occurs.
- * Train employees on recall procedures annually.
- * Conduct mock recall drills to improve response efficiency.
- * Use digital batch tracking & serialization systems for quick traceability.
- * Work with compliance experts to ensure full FDA recall readiness.

Need Expert Recall Support?

Handling an FDA recall is a complex process requiring quick action, clear communication, and regulatory compliance expertise. If you need expert guidance, contact MLKC Consulting for recall management, FDA response preparation, and compliance support.

Contact us today for a Recall Consultation!

Email: [Your Email] | Website: [Your Website] | Phone: [Your Phone]