

Mock Recall Simulation Checklist

Supplement · Cosmetics · Food & CPG Manufacturing

| | | | | |
|---------------------|------------------|-----------|-----------------------|---------------|
| FDA 21 CFR Part 111 | FSMA 204-Aligned | ISO 22716 | NSF / SQF / BRC Ready | GMP Compliant |
|---------------------|------------------|-----------|-----------------------|---------------|

Use this checklist to conduct a compliant mock recall simulation in Batch Buddy or manually from paper records. Complete every section using your actual production records. Archive the completed checklist alongside your batch records as part of your audit readiness package. **Recommended frequency: at least once annually, or 30–60 days before a scheduled GMP audit.**

Section 1 — Simulation Information

Simulation date: _____ Simulation time started: _____

Conducted by (name & title): _____

Reviewed by (QA manager): _____

Simulation type: _____ Triggered by: _____

Simulation type: Routine annual drill / Pre-audit preparation / Post-OOS investigation / New supplier onboarding / Software system change
Triggered by: Scheduled calendar event / OOS result / Supplier notification / Consumer complaint / Auditor request / Other

Section 2 — Scenario Definition

- Suspect lot or batch clearly identified and documented

Record the lot number, ingredient name, supplier, and reason for selection below.

- Simulated notification date and time recorded

This is the moment your organization "received" the recall trigger. Document it precisely.

- Recall trigger type defined

Options: Ingredient contamination / Potency OOS / Supplier COA failure / Consumer complaint / Routine drill

- Scope of simulation defined

Record whether this is a full recall simulation (all affected products and customers) or a targeted trace.

Suspect lot number: _____

Ingredient / product name: _____

Supplier name: _____

Reason for selection: _____

Notes / findings: _____

Section 3 — Raw Material Traceability (Upstream)

In Batch Buddy: navigate to Recall Simulation → New Drill → enter the suspect lot number to trigger automatic upstream and downstream tracing.

- Receiving record located for suspect lot

Confirm: lot number, receiving date, quantity received, receiving operator, and storage location.

- Supplier COA located and on file

Confirm COA includes: potency/assay result, identity testing, heavy metals, microbial, and product-specific tests.

- Lot split or sub-lot records documented

If the lot was split across multiple storage locations or production runs, all sub-lots are identified.

- Quarantine or hold records checked

Confirm whether any portion of this lot was previously quarantined, placed on hold, or rejected.

- Any related supplier notifications or deviations documented

Check CAPA records and supplier correspondence for this lot.

| Lot number | Receiving date | Qty received | Qty used | Qty remaining | Status |
|------------|----------------|--------------|----------|---------------|--------|
| | | | | | |
| | | | | | |
| | | | | | |

Notes / findings:

Section 4 — Production Batch Traceability

In Batch Buddy: the Forward Trace chain shows all production runs that consumed the suspect lot, with batch numbers, quantities used, and QC disposition — automatically.

- All production batches using suspect lot identified

Cross-reference the suspect lot against all batch records. Confirm no batches are missing.

- Batch records located for each affected production run

Each record should include: batch number, production date, formula version, operator, yield, and QC disposition.

- Electronic Batch Records (EBR) verified as complete and unaltered

Confirm audit trail integrity — no retroactive edits, no missing signatures.

- QC disposition for each batch documented

Record whether each batch was: Released / Quarantined / Rejected / Pending / Shipped

- Yield anomalies or deviations in affected batches noted

Flag any batches where yield fell outside normal range. Link to CAPA records if applicable.

| Batch # | Production date | Formula / SKU | Qty produced | Yield % | QC disposition |
|---------|-----------------|---------------|--------------|---------|----------------|
| | | | | | |
| | | | | | |
| | | | | | |

Notes / findings:

Section 5 — Finished Goods & Inventory Disposition

In Batch Buddy: the drill report's "Units at Risk" KPI summarises on-hand vs. shipped disposition for every affected finished goods lot automatically from your inventory and shipment records.

- All affected finished goods SKUs and lot numbers identified

Map each affected production batch to its finished goods lot numbers and SKUs.

- Current inventory quantities and locations confirmed

For each affected SKU lot: on-hand quantity, warehouse location, and current hold/release status.

- Any affected inventory physically quarantined or flagged

In a real recall, affected inventory would be quarantined. Document the simulated quarantine decision and method.

- Disposition of all affected finished goods recorded

For each lot: On hand / Shipped / Quarantined / Destroyed / Returned. No lots unaccounted for.

- Finished goods COA records located for all affected lots

Confirm COA records are complete, signed, and include all required test parameters.

| FG lot # | SKU / product name | Qty produced | Qty on hand | Qty shipped | Disposition |
|----------|--------------------|--------------|-------------|-------------|-------------|
| | | | | | |
| | | | | | |

Notes / findings: _____

Section 6 — Customer & Shipment Traceability (Downstream)

In Batch Buddy: the Backward Chain maps every customer shipment linked to affected finished goods, with ship date, quantity, and customer contact details — no manual cross-referencing required.

- All customer orders containing affected finished goods identified

Pull every order that included an affected SKU lot number. No orders missing.

- Shipment dates, quantities, and tracking numbers recorded

For each affected order: ship date, carrier, tracking number, quantity shipped.

- Customer contact information confirmed current and accessible

Verify that contact details for all affected customers are on file and up to date.

- Any returns, complaints, or adverse events linked to affected lots documented

Check customer complaint log and return records for the affected lot period.

- Simulated customer notification list prepared

In a real recall, customers would be notified. Confirm you have a complete list with contact details ready.

| Customer name | Order # | Ship date | SKU / lot | Qty shipped | Notified? |
|---------------|---------|-----------|-----------|-------------|-----------|
| | | | | | |
| | | | | | |

Notes / findings: _____

Section 7 — Response Time Documentation

In Batch Buddy: simulation start time and report generation time are recorded automatically and appear in the signed drill report. Your documented response time requires no manual calculation.

Simulation start time: _____

Simulation end time: _____

Total response time (hours:minutes): _____

FSMA 204 requires traceability records producible within 24 hours of an FDA request. **Target response time: under 4 hours for a well-prepared manufacturer.**

- Response time is within acceptable range for your quality policy

Document your internal target response time in your SOP if not already defined.

- Any steps that caused delays are identified and documented

Note which records took longest to locate and why.

- All records retrieved were complete, accurate, and unaltered

Flag any records that were incomplete, missing, or raised data integrity concerns.

Notes / findings: _____

Section 8 — Gaps Identified & Corrective Actions

Document every gap, discrepancy, or documentation weakness identified during this simulation. Each gap should result in a CAPA. *In Batch Buddy, open the CAPA module directly from the drill report page to link corrective actions to this simulation automatically.*

| Gap identified | Section | Severity | CAPA # assigned | Owner | Due date |
|----------------|---------|----------|-----------------|-------|----------|
| | | | | | |
| | | | | | |
| | | | | | |

Severity guide: **Critical** = regulatory finding risk · **Major** = significant documentation gap · **Minor** = process improvement opportunity

Section 9 — Simulation Sign-Off & Archiving

- All sections of this checklist completed in full

No sections left blank. N/A recorded where a section does not apply, with explanation.

- Simulation report compiled and saved to quality records

Archive location documented below. Include this checklist and any supporting evidence.

- All identified gaps have CAPA numbers assigned

No gaps left without an owner and due date.

- Next scheduled simulation date confirmed

Recommended: within 12 months, or before next GMP certification audit.

- Completed checklist reviewed and approved by QA manager

QA manager signature and date required below before archiving.

Archive location / document reference: _____

Next simulation scheduled date: _____

Batch Buddy drill report ID (if applicable): _____

Conducted by _____

QA manager approval

Signature: _____

Signature: _____

Date: _____

Date: _____

Run this simulation in minutes with Batch Buddy's built-in recall simulation — instant lot traceability, affected customer reports, and HMAC-signed drill report generation, all in one click.

Start free at batchbuddy.ai