The FSMA 204 "24-Hour Traceability" Audit Checklist

Self-Assessment: Is Your Facility Ready for an Electronic Record Request?

Under FSMA 204, if you handle foods on the Food Traceability List (FTL), you must provide a sortable electronic spreadsheet containing specific Key Data Elements (KDEs) to the FDA within 24 hours of a request.

- **Phase 1: The "Digital Spine" Audit (Technical Requirements)** — Failure in any of these points means your current system is likely non-compliant.

Phase 1: The "Digital Spine" Audit

Verify your technical readiness across these four critical requirements:

☐ Electronic Export

Can your system export all traceability data into a single, sortable spreadsheet (CSV or Excel) without manual data entry?

☐ The 24-Hour Rule

Have you successfully completed a mock traceability pull from "Finished Good to Raw Ingredient Source" in under 24 hours?

☐ 2-Year Archive

Can you instantly access and export records for any batch produced in the last 24 months?

☐ ALCOA+ Alignment

Are your digital records **A**ttributable (who did it?), **L**egible, **C**ontemporaneous (done in real-time?), **O**riginal, and **A**ccurate?

Phase 2: Critical Tracking Event (CTE) Mapping — Verify that your records capture these specific data points for every FTL item in your facility.

CTE #1: Receiving (Incoming Materials)

Verify that your records capture all required data points at the point of receipt for every FTL item.

☐ Traceability Lot Code (TLC)

Is the incoming lot code from the supplier logged and linked to the internal record?

☐ TLC Source

Do you have the physical location description (Name, Address, Phone) of where that lot code was originally assigned?

☐ Previous Source

Is the "Immediate Previous Source" (the vendor you bought it from) recorded for every receipt?

☐ Product Identity

Are the Product Description, Quantity, and Unit of Measure (UOM) all logged in the same row?

CTE #2 & #3: Transformation & Shipping

2. Transformation (Manufacturing/Processing)

This is where most manual systems fail.

- **Input/Output Linkage:** Does your batch record explicitly link every Input TLC (ingredients) to the new Output TLC (finished good)?
- **Transformation Date:** Is the exact date the transformation was completed logged (not just the start date)?
- **New TLC Source:** Is your facility correctly logged as the "TLC Source" for the new finished good lot?

3. Shipping (Finished Goods)

- **TLC Sharing:** Is the Traceability Lot Code sent to your customer (via ASN, portal, or invoice) for every shipment?
- **Recipient Data:** Do you have the Name, Address, and Phone for every "Immediate Subsequent Recipient"?
- **Reference Documents:** Are the Bill of Lading (BOL) or Invoice numbers linked directly to the lot number in your digital export?

Phase 3: The "Stress Test" (Mock Audit) — Pick one random lot of finished product from last month and answer these three questions.

Phase 3: Stress Test & Scoring

1

Ingredient Lot Identification

Can you identify every ingredient lot used in this batch within 15 minutes? ☐ Yes ☐ No

2

Supplier Address Lookup

Can you find the original physical address of the supplier who assigned the lot code for the most expensive ingredient? ☐ Yes ☐ No

3

Single Spreadsheet Export

Can you export a single spreadsheet that shows the entire "Transformation" history of this lot without opening multiple files? ☐ Yes ☐ No

Score Your Facility

✅ 0–2 "No" Answers

Audit-Ready. You likely have a digital system that supports FSMA 204 requirements.

⚠️ 3–5 "No" Answers

Audit-Risky. You are at high risk of failing a 24-hour data request.

🚨 6+ "No" Answers

Audit-Failure. Your current manual or fragmented system cannot meet the legal requirements of FSMA 204.

> **How BatchBuddy Solves This:** BatchBuddy's Traceability Engine automatically captures these KDEs during the production process. When the FDA calls, you don't panic—you click "Export FSMA Report" and deliver a compliant, sortable spreadsheet in seconds. Stop the 24-hour scramble. Get BatchBuddy Audit-Ready today.

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Standard Operating Procedure: FSMA 204 Traceability Readiness

Department: Quality Assurance / Operations | **Subject:** Maintenance and Retrieval of Traceability Records

1. PURPOSE

To ensure the facility maintains compliance with the FSMA 204 Traceability Rule, specifically the ability to provide a sortable electronic spreadsheet of Key Data Elements (KDEs) for all items on the Food Traceability List (FTL) within 24 hours of an FDA request.

2. SCOPE

This SOP applies to all Critical Tracking Events (CTEs) including Receiving, Transformation, and Shipping of regulated products.

3. RESPONSIBILITIES

- **Quality Manager:** Responsible for maintaining the digital "Traceability Plan" and conducting quarterly mock traceability drills.
- **Warehouse Lead:** Responsible for capturing incoming Traceability Lot Codes (TLC) and TLC Source data at the point of receipt.
- **Production Lead:** Responsible for linking ingredient TLCs to finished product TLCs during the transformation process.

4. Data Integrity Standards (ALCOA+)

All traceability data must be recorded within the BatchBuddy system following ALCOA+ principles:

Attributable

Every data entry is linked to a specific user via digital signature.

Contemporaneous

Data must be logged at the time the CTE occurs (e.g., as ingredients are scanned into a batch).

Original

The digital record in BatchBuddy serves as the primary "original" record for regulatory purposes.

Legible

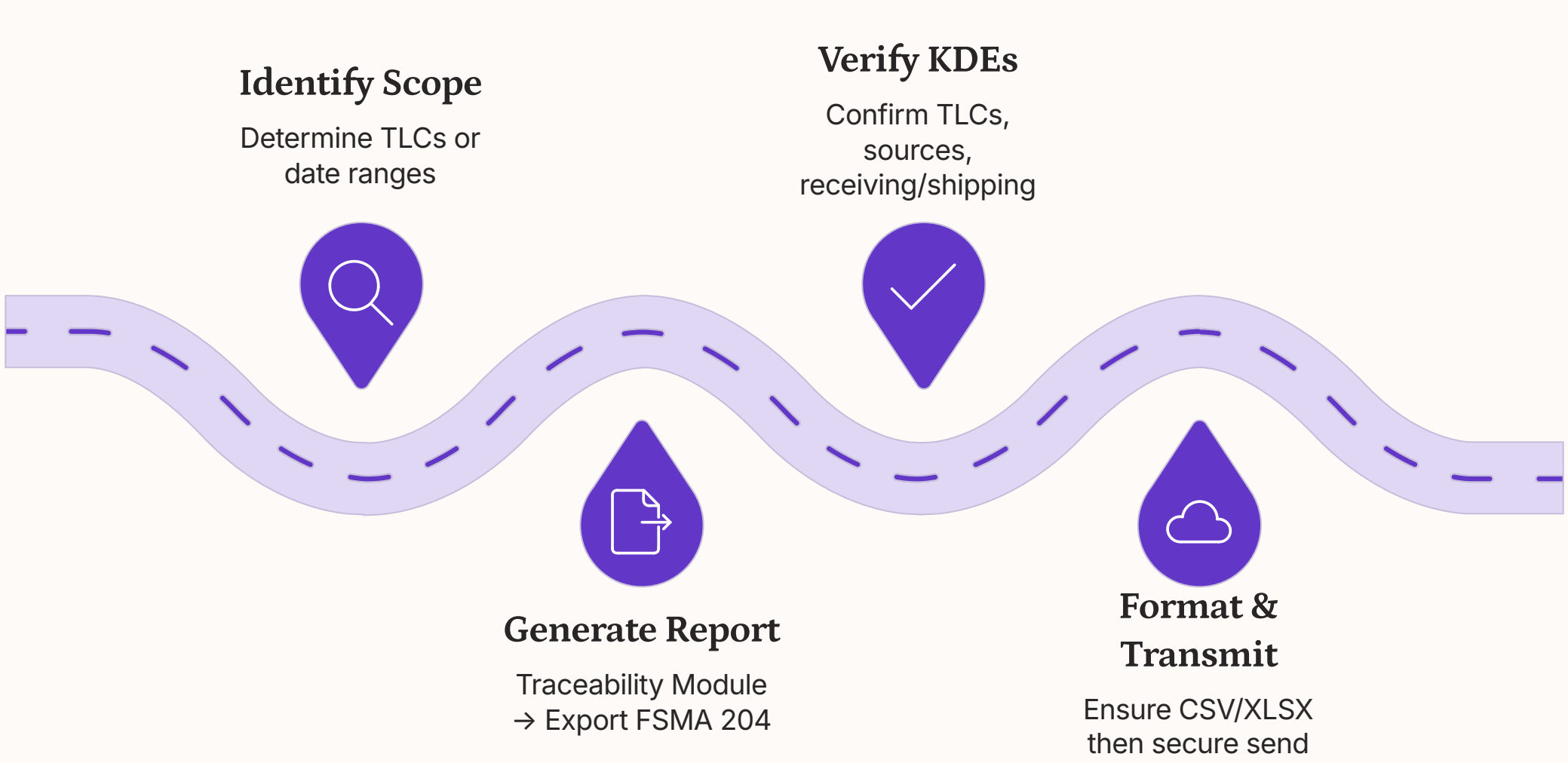
All records must be permanently legible and readable for the full 2-year retention period. No overwriting or illegible entries are permitted.

Accurate

Data must reflect the true values at the time of the CTE. Errors must be corrected with a traceable amendment, not deleted.

5. Procedure: The 24-Hour Data Request

Upon receipt of an official request for traceability records from the FDA:



Following these five steps ensures your facility can respond to any FDA data request within the legally required 24-hour window.

6–7. Mock Drills & Training Requirements

6. Mock Recall & Drill Frequency

Frequency

A mock traceability drill must be performed at least **once every six months.**

Success Metric

Successful retrieval of a full-chain **"Source-to-Customer"** report in under **4 hours.**

7. Training Record

All personnel involved in data entry for traceability must be trained on this SOP and the BatchBuddy Traceability Module.

24hr

FDA Response Window

Maximum time to deliver a compliant KDE spreadsheet upon request.

4hr

Drill Success Target

Full "Source-to-Customer" report retrieval benchmark.

2yr

Archive Requirement

Instant access to records for any batch produced in the last 24 months.

Stop the 24-hour scramble. Get BatchBuddy Audit-Ready today. BatchBuddy's Traceability Engine automatically captures these KDEs during the production process. When the FDA calls, you don't panic—you click "Export FSMA Report" and deliver a compliant, sortable spreadsheet in seconds.

Resource provided by

batch buddy™

The Batch Operations System for Supplement Manufacturers

This checklist and SOP were created by the team at BatchBuddy to help supplement manufacturers achieve FSMA 204 compliance. BatchBuddy replaces manual spreadsheets with electronic batch records, full lot traceability, and real-time production management — so you're always audit-ready.

Visit Our Resource Library →

Explore more guides, checklists, and SOPs to streamline your operations and stay FDA GMP compliant.