

Brochure

Why Process Monitoring and Traceability Gaps Continue to Trigger FDA Warnings



For supply chain and operations leaders, these findings often point to gaps in how materials, suppliers, and processes are tracked across systems.

Traceability and process-related findings often occur when supply chain and operational data are not consistently captured or connected. Regulatory inspections repeatedly uncover gaps in the monitoring of materials, suppliers, and processes. These issues reflect limited visibility across the operational environment.



What Inspectors Are Finding

- ✓ Supplier verification failures
- ✓ HACCP or preventive control deficiencies
- ✓ Incomplete traceability records
- ✓ Inconsistent supply chain documentation
- ✓ Process monitoring irregularities

The Root Cause:

Siloed Operational Systems

In many organizations, supply chain, warehouse, and quality systems operate independently:

Supplier and procurement data
in one system

Inventory and warehouse
data in another

Process and production data in
separate environments

Quality records managed
independently

When these systems are not aligned

Material traceability
becomes incomplete

Supplier compliance
is difficult to verify

Process monitoring
data is inconsistent

As a result, teams cannot generate a reliable, end-to-end view of materials and processes during inspections.

Why This Creates Ongoing Risk

- ⚠️ Gaps in traceability are difficult to detect early
- ⚠️ Supplier-related risks remain hidden
- ⚠️ Process deviations are harder to investigate

Even small gaps can lead to inspection findings, product quality concerns, and increased regulatory scrutiny.

Business Impact

- 🔍 Delays in product release and approvals
- 🔍 Increased risk of recalls or investigations
- 🔍 Supply chain disruptions and inefficiencies
- 🔍 Higher remediation and compliance costs

These impacts affect operational continuity, cost structures, and product availability.

What Inspection-Ready Organizations Do Differently

Organizations that maintain control across the supply chain and operations focus on visibility and traceability:

End-to-end traceability

Materials can be tracked across suppliers, production, and distribution

Integrated operational data

Supply chain, warehouse, and quality data are aligned

Consistent process monitoring

Data is captured and linked to materials and processes in real time

Faster issue resolution

Complete information is available for investigation and response

Warning Letter Risk Doesn't Occur in Isolation

The same pattern extends across operations:

Data integrity
and recordkeeping

Process monitoring

Regulatory
documentation

Gaps in traceability are often linked to broader issues in how operational data is managed.

The Complete View of Warning Letter Risk

The playbook—Why Life Sciences Companies Receive Warning Letters—shows where these gaps occur, how they connect across operations, and what it takes to address them, so you can identify issues earlier and reduce operational and compliance exposure.

Understand What's Driving Warning Letters in Life Sciences

Explore the most common sources of compliance risk and how organizations reduce exposure.

[Download the playbook](#)

If traceability or process gaps are limiting visibility across your supply chain, you can speak with a life sciences expert to assess your current approach.

[Schedule a conversation](#)