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Brochure

Why Data Integrity Issues Continue to Trigger FDA Warnings

Data integrity issues often occur when data is spread across multiple systems.

Regulatory inspections repeatedly uncover the same problem across life sciences organizations: incomplete, inconsistent, or unreliable operational data. From missing audit trails to incomplete batch records, these findings reflect deeper weaknesses in how data is captured, managed, and connected across operations.

What Inspectors Are Actually Finding

- Incomplete batch records
- Missing or unreliable audit trails
- Inconsistent laboratory data
- Gaps in inspection-ready documentation
- Manual processes prone to errors

These findings directly impact your ability to demonstrate control over GxP-critical processes.

The Root Cause:
Fragmented Systems

In most environments, critical data lives across disconnected systems.

- Manufacturing data in ERP
- Laboratory data in LIMS
- Quality events in QMS
- Supporting records in spreadsheets or shared drives

When these systems don't work together

- Data must be manually reconciled
- Records become harder to verify
- Audit trails lose reliability

As a result, teams are forced to reconstruct evidence during inspections, slowing response times and increasing the risk of incomplete or inconsistent records.

Why This Creates Ongoing Risk

- ⚠ Audit preparation becomes reactive
- ⚠ Documentation gaps persist
- ⚠ Inspection outcomes become unpredictable

Even small inconsistencies can lead to repeat findings, delayed approvals, and increased regulatory scrutiny.

Business Impact

- Delays in batch release and product approvals
- Increased remediation and validation costs
- Longer audit preparation cycles
- Repeat findings and heightened oversight

What Inspection-Ready Organizations Do Differently

Organizations that consistently meet regulatory expectations change the way data is managed:

Connected data environments
Quality, manufacturing, and laboratory data are aligned across systems

Built-in data integrity controls
Audit trails, e-signatures, and approvals are part of standard workflows

Real-time record capture
Batch data and supporting information are recorded as processes occur

On-demand traceability
Complete, inspection-ready records can be generated instantly

FDA Warning Risk Is Not Just a Data Integrity Problem

The same pattern shows up across operations:

Supply chain traceability | **Process monitoring** | **Regulatory documentation**

Organizations with connected systems can provide complete, inspection-ready data on demand.

See the Full Picture of FDA Warning Letter Risk

The Playbook—Why Life Sciences Companies Receive Warning Letters—gives a complete view of where compliance gaps occur, how they connect, and how to address them across operations, helping you identify risk earlier and avoid repeat findings and delays.

Understand Why Life Sciences Companies Receive Warning Letters

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

Download the playbook

If you're dealing with audit findings or data integrity gaps, you can speak with a life sciences expert to review your current approach to inspection readiness.

Schedule a conversation