

FOR SUPPLIERS

FSMA 204 Traceability Solution Provider Evaluation Checklist

Compare traceability providers against the capabilities needed to support FSMA 204 readiness and customer data-sharing requirements.

Data Capture <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Capture required CTEs and KDEs	☐	☐	☐
Support initial packing, receiving, shipping, transformation, and first land-based receiving	☐	☐	☐
Store master product and location data	☐	☐	☐
Support multiple data-capture methods (API, SFTP, flat file, manual entry, third-party integrations)	☐	☐	☐

Customer Data Sharing <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Capture data once and share it with multiple customers	☐	☐	☐
Support data sharing with both network-connected and non-network customers (customers not using the same platform)	☐	☐	☐
Meet customer-specific requirements without creating separate processes	☐	☐	☐

Readiness & Compliance Support <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Provide a guided FSMA 204 readiness program	☐	☐	☐
Break readiness down into actionable milestones	☐	☐	☐
Identify completion status and outstanding gaps	☐	☐	☐
Help prepare required documentation	☐	☐	☐
Provide training resources, expert guidance, and readiness support	☐	☐	☐

Validation & Testing <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Test customer connections and data-sharing workflows	☐	☐	☐
Provide guidance and tools to help assess traceability labels	☐	☐	☐
Support traceback and traceforward test exercises	☐	☐	☐
Help identify and address traceability gaps before an FDA request	☐	☐	☐

Retrieval & Reporting <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Generate FDA-compliant electronic sortable spreadsheets	☐	☐	☐
Retrieve records within the 24-hour FDA requirement	☐	☐	☐
Support traceback and traceforward investigations	☐	☐	☐
Maintain required records for the required retention period (2+ years)	☐	☐	☐