

FOR DISTRIBUTORS, MANUFACTURERS, AND PROCESSORS

FSMA 204 Traceability Solution Provider Evaluation Checklist

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

Supplier Network Activation <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Provide supplier education around FSMA 204 regulations and requirement	☐	☐	☐
Support onboarding of your supplier network	☐	☐	☐
Offer flexible options for suppliers to share traceability data	☐	☐	☐
Support suppliers of varying technical capabilities	☐	☐	☐
Provide supplier activation and enrollment support	☐	☐	☐
Offer tools and resources to accelerate supplier adoption	☐	☐	☐

Visibility & Readiness <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Track traceability readiness across your supplier network	☐	☐	☐
Provide visibility into supplier engagement and completeness of their traceability data	☐	☐	☐
Identify missing or incomplete traceability data	☐	☐	☐

Data Collection & Management <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Collect required CTEs and KDEs from suppliers	☐	☐	☐
Capture and maintain your organization's own traceability records, including applicable receiving, shipping, and transformation events	☐	☐	☐
Securely store master product, location, and event data	☐	☐	☐
Support multiple methods of data exchange (API, ASN, flat file, partner integrations)	☐	☐	☐
Integrate with existing receiving, ERP, WMS, and traceability workflows	☐	☐	☐

Meet Trading Partner Requirements <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Share traceability data with multiple customers from a single platform	☐	☐	☐
Support data sharing with both network-connected and non-network customers	☐	☐	☐
Meet customer-specific traceability requirements without creating separate processes	☐	☐	☐
Scale data sharing across your trading partner network without per-customer limitations or additional fees	☐	☐	☐

Validation & Testing <i>Can the solution:</i>	FULLY	PARTIALLY	NOT AT ALL
Support testing of supplier connections and data-sharing workflows	☐	☐	☐
Support traceback and traceforward test exercises	☐	☐	☐
Help identify readiness gaps before an FDA request	☐	☐	☐

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