

DSCSA Readiness Checklist

To ensure compliance with the Drug Supply Chain Security Act (DSCSA), companies in the pharmaceutical supply chain should consider the following:

Master Data Management (MDM)

Ensure your IT organization is responsible for managing DSCSA-related data, including:

- Global Location Numbers (GLNs): Especially important if you have multiple warehouses in different geographic regions.
- Global Company Prefix (GCP): Necessary for consistent serialization and product identification across locations.

3PL Serialization

For third-party logistics providers (3PLs), establish clear serialization processes for inbound, outbound, and end-to-end tracking. These must be configured by the client or business unit to ensure compliance.

Barcode Validation

Verify that barcodes representing the National Drug Code (NDC) are properly linked to their respective Stock Keeping Units (SKUs) to avoid mislabeling and ensure traceability.

Handling "Grandfathered" Inventory

Create a plan for inventory not yet recorded in your level 4 serial number management system. This "grandfathered" stock cannot be audited using serial numbers, so proper segregation is necessary.

Standardize Packaging and Labeling

Ensure product and packaging sizes are standardized to accommodate the correct 2D Data Matrix or 1D UPC-A barcode labels for compliance.

Serial Shipping Container Code (SSCC) Management

Define the structure, check digits, and volume of SSCCs to ensure proper tracking through your supply chain.

Eligibility Marking

Flag products that are eligible for DSCSA compliance in your product profile tables for easier identification and management.

DSCSA Readiness Checklist

Pilot Testing with Vendors

Conduct pilot tests with a few trusted vendors to validate the system's accuracy. Identify any errors encountered during shipments and adjust accordingly.

Optimize Performance

Collaborate with your level 4 Serial Management Track and Trace provider to ensure fast and reliable communication between your systems. This is critical for avoiding delays, especially during inbound and outbound audits.

Ensure that RF devices used in automated settings have fast and stable connectivity to prevent timeouts during scanning.

EPCIS Compliance

Confirm that the version of Electronic Product Code Information Services (EPCIS) you're using aligns with industry standards, such as GS1 EPCIS 1.2, for seamless messaging and data transfer.

Schema Compatibility and Error Management

Work closely with your serial management provider to ensure schema compatibility when shipping to other parties. Identify and address common errors during the pilot phase to ensure smooth DSCSA implementation.

LIMIT
LESS
DELIV
ERED