

## **2025 DSCSA Readiness Checklist**

# Ensure your pharmaceutical supply chain is compliant, interoperable, and audit-ready

A compliance prep guide for manufacturers, repackagers, wholesalers, and dispensers

#### What Is the DSCSA?

The Drug Supply Chain Security Act (DSCSA) requires all pharmaceutical supply chain stakeholders to implement electronic track-and-trace systems for prescription drugs.

As of November 27, 2024, all trading partners must exchange and verify T3 data (Transaction Information, Transaction History, and Transaction Statement) electronically—completing full supply chain visibility and traceability.

Stakeholder Group	Enforcement Discretion Deadline	Status
Manufacturers & Repackagers	May 27, 2025	Ended
Wholesalers	August 27, 2025	Ended
Dispensers (26+ full-time employees)	November 27, 2025	Upcoming
Dispensers (25 or fewer full-time employees)	November 27, 2026	Upcoming



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READINESS CATEGORY	YES	NO
TRADING PARTNER VERIFICATION		
I have automated ATP checks built into your procurement and fulfillment systems.		
I can verify authorized trading partner (ATP) status of manufacturers, wholesalers, and dispensers.		
I am retaining ATP documentation for a minimum of 6 years.		
My system can generate and send T3 documentation (TI, TH, TS) for each product sold or transferred.		
T3 DATA EXCHANGE		
I can receive and store T3 data from upstream suppliers.		
I store T3 data in an electronic, interoperable format (e.g., EPCIS).		
My system links T3 data to product serial numbers.		
PRODUCT SERIALIZATION & TRACEABILITY		
My products are serialized at the package level with unique identifiers (SNI).		
I have a repository that tracks serialized units across events (ship, receive, dispense).		
I can initiate, manage, and track recalls or product verifications in real time.		
I am integrated with a Verification Router Service (VRS) for suspect product checks.		
SYSTEM INTEGRATION & AUTOMATION		
My ERP, WMS, and 3PL systems are integrated to maintain end-to-end data continuity.		
My data exchange process is automated, not reliant on manual uploads.		
I am using a GS1 EPCIS-compliant solution for serialization and T3 exchange.		
AUDIT & COMPLIANCE READINESS		
I can produce DSCSA compliance reports for any shipment within 48 hours.		
My SOPs are updated to reflect 2024 DSCSA traceability requirements.		
My staff has received recent training on DSCSA workflows and exceptions handling.		
Listore T3 data for at least six years, with secure backups and controlled access		



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#### If You Checked "No" to 3 or More Items...

Your organization may be at risk of non-compliance under the 2024 DSCSA requirements, which could result in supply chain interruptions or regulatory penalties.

#### **Get DSCSA-Ready with Confidence**

We help pharmaceutical companies implement solutions that:

- Automate T3 data generation and storage
- Support full product serialization workflows
- Integrate with ATP, VRS, EPCIS, and 3PL providers
- Make audits painless and compliance seamless

### **Bonus: Free DSCSA Systems Audit**

Need help assessing where you stand?

Schedule your complimentary 30-minute DSCSA Systems Audit <u>HERE</u> We'll review your current processes and provide a custom action plan.

**NOTES**