Customer Advisory

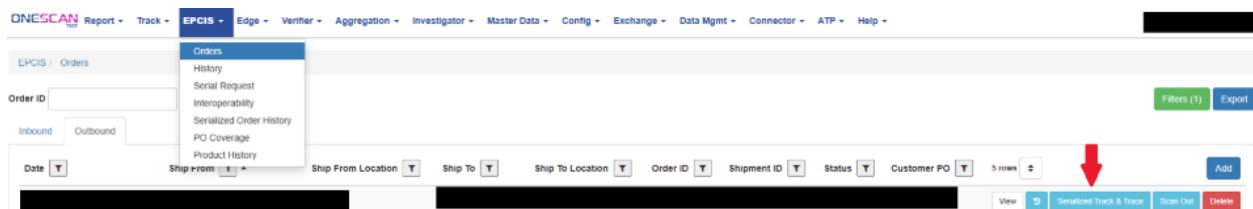# DSCSA PRODUCT TRACEABILITY – T2 VS T3 REPORTING

September 2025

As part of ongoing DSCSA compliance, trading partners have fully transitioned from Transaction History (T3) to EPCIS-based Transaction Information (T2) for product traceability. Prior to November 27, 2023, T3 data—which includes Transaction Information, Transaction Statement, and Transaction History—was required for non-serialized product. After this date, all Manufacturers and Wholesalers are expected to use T2 data to meet the Enhanced Drug Distribution Security requirements under DSCSA.
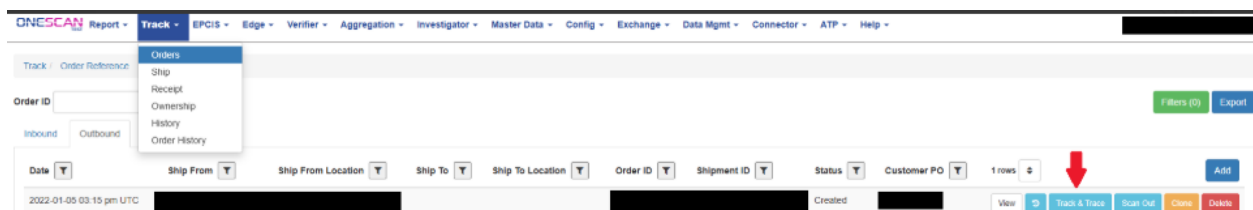
During the hybrid period between November 27, 2023, and the expiration of regulatory extensions (August 27, 2025), some trading partners continued to submit T3 for business purposes. Now, T2 is the official compliance standard, while T3 is no longer required, though it may still be present in some historical shipments.

How to Generate Traceability Reports

Primary report: Use the Serialized Track & Trace report located in EPCIS Module > Orders > Serialized Track & Trace. This report now reflects 100% of T2 data, including Transaction Information, Transaction Statement, and associated serials.

Secondary report: If the Serialized Track & Trace report is unavailable, or the shipment predates the end of trading partner exceptions, you may use lot-level Track & Trace in Track Module > Orders > Track & Trace. Note that this may show incomplete results if the product is T2-enabled.

Key Guidance for Interactions with Regulators

Always provide T2-based traceability first. Explain that T3 has been sunset as a compliance requirement by trading partners gradually after November 27, 2023.

The legal basis for transaction information and transaction statements is in *Section 582(g)(1) of the FD&C Act: secure electronic exchange of transaction info, package-level identifiers, and the ability to respond promptly to regulators in recalls or investigations.*

Summary

We recognize that regulatory interactions can be complex. We have prepared the following to assist you for audit and daily operations:

1. A suggest letter to Inspector in Appendix A.
2. A handout to employees in Appendix B.

These documents will prepare you and your team to demonstrate DSCSA compliance confidently while explaining T2 reporting processes clearly to inspectors.

Appendix A – Letter to Inspectors

10/02/2025

Subject: Request to Update Inspection Guidelines to Reflect T2 as DSCSA Compliance Standard

To whom it may concern,

On behalf of our LSPedia Pharmaceutical customers under the requirement of DSCSA, we wish to clarify DSCSA product traceability expectations. Since August 27, 2025, all Manufacturers and Wholesalers are required to provide serialized EPCIS-based data (T2) as the DSCSA compliance document. Transaction History (T3) has been sunset, though some partners may retain it for internal business purposes.

We respectfully request that inspection protocols recognize T2-based Serialized Track & Trace reports as the official traceability documentation. These reports include all required Transaction Information, Transaction Statements, and associated serials, fully meeting DSCSA obligations. Lot-based T3 reporting should only be referenced for transactions that predate T2 adoption.

Updating inspection guidance to reflect T2 aligns regulatory expectations with current industry practice, reduces confusion, and streamlines compliance interactions. We are available to provide a demonstration of the T2 report and answer any questions you may have.

Thank you for your attention and collaboration in supporting modern DSCSA traceability practices.

Sincerely,
Riya Cao
CEO, LSPedia

Appendix B – Employee Handout
DSCSA PRODUCT TRACEABILITY

September 2025

Overview

- Trading partners have transitioned from Transaction History (T3) to EPCIS-based Transaction Information (T2) for product traceability.

- Prior to November 27, 2023, T3 was required for non-serialized products (Transaction Information, Transaction Statement, Transaction History).

- Post November 27, 2023, trading partners have gradually migrated from T3 to T2 to meet EDDS (Enhanced Drug Distribution Security) requirements under DSCSA.

- The transition period and the exemption period from November 27, 2023, through August 27, 2025, allowed some partners to continue using T3 before they were fully cut over to T2.

- T2 is now the official DSCSA compliance standard. T3 may still exist in historical shipments but is not required for compliance for shipment post 8/27/2025.

How to Generate Traceability Reports?

Primary report

- Serialized Track & Trace report

- Location: EPCIS Module > Orders > Serialized Track & Trace

- Includes 100% of T2 data: Transaction Information, Transaction Statement, associated serials

Secondary report (if T2 unavailable)

- Lot-level Track & Trace report

- Location: Track Module > Orders > Track & Trace

- Use only for shipments predating trading partner T2 adoption

- May show incomplete results for T2-enabled products

Regulator Interaction Guidance

- Always provide T2-based traceability first.

- Explain T3 has been sunset as a compliance requirement.

- Legal reference: Section 582(g)(1) of the FD&C Act.

  o Requires secure, electronic exchange of transaction information

    ○   Must include package-level identifiers for each package

    ○   Must allow prompt response to regulators in case of recalls or investigations

Best Practice

- Always generate the Serialized Track & Trace report first.

- Use lot-level Track & Trace only if T2 is not available.

- Keep a checklist to confirm T2 data is included with each shipment.

T3 to T2 Transition Timeline

Date	Requirement	Notes
Before 11/27/2023	T3 mandatory	Non-serialized product traceability
11/27/2023 – 8/27/2025	Hybrid period	Some partners still submitted T3; T2 adoption begins
5/27/2025 (Manufacturers)	T2 required	Post manufacturer exception deadline, T2 is official compliance document for manufacturers
8/27/2025 (Wholesalers)	T2 required	Post wholesaler deadline, T2 is official compliance document for wholesalers
After 8/27/2025	T2 standard	T2 is the official compliance document for all trading partners. T3 retained only for historical data retention purposes

Summary

- T2 is the current DSCSA compliance standard for all serialized transactions.

- T3 is no longer required but may appear in historical records.

- Serialized Track & Trace report should be your primary source for traceability.

- Lot-level reporting is secondary, for shipments predating T2 adoption.

- This guidance ensures clarity for regulator interactions, compliance demonstrations, and streamlined operations.

Contact for Assistance

- For support on generating T2 reports: support@lspedia.com

- Access OneScan: onescan.lspedia.com

- Need live DSCSA answers. Get DSCSA.AI. Contact am@lspedia.com