DSCSA FAQs for Dispensers

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1. DSCSA COMPLIANCE BASICS

1. What are the key DSCSA requirements for dispensers?
The Drug Supply Chain Security Act (DSCSA) ensures the traceability and safety of prescription drugs in the U.S. supply chain. Here are the key DSCSA requirements for dispensers:

- **Serialized data exchange** requires each drug package to have a unique serial number that can be shared electronically among trading partners.
- **Credentialing and trade partner authentication** confirm that all participants are authorized and verified before exchanging data.
- **Suspect and illegitimate verification** involves quickly investigating and confirming the authenticity of any potentially counterfeit or illegitimate products.

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2. Which pharmaceutical products are covered by DSCSA?
Prescription human drugs in finished dosage form intended for U.S. distribution. Over-the-counter (OTC), veterinary, and certain medical products are excluded.

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3. When do dispensers need to be fully compliant with DSCSA?
By November 27, 2025, dispensers must be able to receive serialized products and interoperable electronic TI/TS data, unless the dispenser has received a waiver or exemption from the FDA or qualifies for the small dispenser exemption. Continued compliance will be required beyond 2025.

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4. What is the small dispenser exemption?
A dispenser qualifies as “small”, if the corporate entity that owns the dispenser has 25 or fewer full-time employees who are either licensed pharmacists or qualified pharmacy technicians. Small dispensers are exempt from the Enhanced Drug Distribution Security

Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act until November 27, 2026

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5. How can I check if my organization is DSCSA-compliant?
Review your ability to receive EPCIS data, verify products, manage exceptions, and retain compliant TI/TS records. In TraceLink, you can view the delivery details in US Compliance to confirm that you are receiving EPCIS data to ensure that you are DSCSA-compliant

You can view serialized transactions within US Compliance in TraceLink

- Log in to https://opus.tracelink.com
- Access US Compliance from My Networks and Click Go
- Click Deliveries from the side menu panel
- Search Deliveries by delivery number, transaction ID, lot number or entity
- Click on view details to view the delivery details

See 'How to Review Deliveries' for more details

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6. How long do dispensers need to keep DSCSA records?
All TI and TS records must be stored for at least six years after each transaction.

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7. What are Waivers, Exemptions, and Exceptions (WEE)?
FDA has the authority to grant waivers, exceptions and exemptions from certain requirements in section 582 of the Food, Drug and Cosmetic Act (FD&C Act). If your supplier has received a WEE approval, then they will be exempt from sending you DSCSA EPCIS data during the duration of the exemption approval period.

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8. How can I find out if my supplier has a WEE?
Check directly with your trading partner as there is currently no central repository for WEE

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2. T2 and T3 DOCUMENTS

9. What are T2 and T3 documents, and how do they differ?

- T3 documents include Transaction Information (TI), Transaction Statement (TS), and Transaction History (TH). T3s will no longer be required after the November 27, 2025 deadline

- T2 documents include only TI and TS, as DSCSA no longer requires TH after the November 27, 2025 deadline

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10. What details are included in Transaction Information (TI)?
The TI contains the Product name, NDC, lot number, dosage form, container size, transaction date, shipment date, quantity, and the names/addresses of trading partners.

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11. What does the Transaction Statement (TS) confirm?
The TS is an affirmation that indicates that your supplier is an authorized trading partner and that the products were received, handled, and transferred in compliance with DSCSA requirements

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12. Do I still need to receive T3s or ASNs after November 27, 2025?
No. After the November 27, 2025 deadline, you should receive EPCIS-formatted electronic data (T2) instead of ASN-based T3 files. Suppliers may still continue sending ASNs as a business document but T2 is the required compliance document after the November 27, 2025 deadline

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13. How can I view or download a T2 document in TraceLink?
You can view or download T2 document within US Compliance in TraceLink

- Log in to https://opus.tracelink.com
- Access US Compliance from My Networks and Click Go
- Click T2 Documents from the side menu panel
- Search Deliveries by delivery number, transaction ID, lot number or entity
- You can choose to View T2 Document or Export Document

See 'How to View T2 Information' for more details

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3. SERIALIZED DATA AND EPCIS

14. How can I view serialized transactions in TraceLink?
You can view serialized transactions within US Compliance in TraceLink

- Log in to https://opus.tracelink.com
- Access US Compliance from My Networks and Click Go
- Click Deliveries side menu panel
- Search Deliveries by delivery number, transaction ID, lot number or entity
- Click on view details to view the delivery details

See ‘How to Review Deliveries’ for more details

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15. What are EPCIS files, and how do they relate to DSCSA?
EPCIS (Electronic Product Code Information Services) files are standardized electronic data formats that record and communicate product serialization commissioning, aggregation and shipment events for DSCSA traceability.

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16. How can I view EPCIS files from my suppliers?

- Log in to https://opus.tracelink.com
- Access US Compliance from My Networks and Click Go
- Click Deliveries side menu panel
- Search Deliveries by delivery number, transaction ID, lot number or entity
- Click on view details to view the delivery details
- You can click on Message Information>Input File to view and download the EPCIS file

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17. How can I check for EPCIS file transmission errors?
You can view for EPCIS file transmission issues by going to Info Exchange

- Log in to https://opus.tracelink.com
- Access Administration from Main Menu
- Click TTS Administration>Administration
- Click Info Exchange
- You can filter for Processing Status ‘Failed-All’ and Business Process - Transaction Type ‘Product Track US - Received SOM Serialized Sales Shipment’ and add additional filtering by a partner to check for EPCIS file transmission errors from a specific partner

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4. TRADE PARTNER READINESS

18. What are Authorized Trading Partner (ATP) requirements for DSCSA?
All DSCSA trading partners must hold valid state or federal licensure depending on their role within the supply chain in order to transaction with DSCSA data

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19. How can I check the DSCSA readiness status of my suppliers?
Use the weekly PTSOM Onboarding Readiness Report from TraceLink which provides the latest status of all your linked trading partners for serialized DSCSA transactions

Sample report:

PTSOM Onboarding Readiness Report.csv

	Your_Company_Name	Your_Company_Network_ID	Partner_Name	Date_ProductTrack_Link_Created	DSCSA_Serialized_Status	Your_Next_Action
1	Co. Name	COMPNAME	Partner A	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
2	Co. Name	COMPNAME	Partner B	4/12/2024	Pending Confirmation	3PL Sending on Behalf of Trade Partner
3	Co. Name	COMPNAME	Partner C	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
4	Co. Name	COMPNAME	Partner D	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
5	Co. Name	COMPNAME	Partner E	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
6	Co. Name	COMPNAME	Partner F	2/26/2016	LIVE	No Action
7	Co. Name	COMPNAME	Partner G	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
8	Co. Name	COMPNAME	Partner H	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
9	Co. Name	COMPNAME	Partner I	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
10	Co. Name	COMPNAME	Partner J	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
11	Co. Name	COMPNAME	Partner K	1/4/2024	Not Live	Contact Trade Partner to Expedite
12	Co. Name	COMPNAME	Partner L	2/26/2016	LIVE	No Action
13	Co. Name	COMPNAME	Partner M	2/26/2016	LIVE	No Action
14	Co. Name	COMPNAME	Partner N	4/8/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation
15	Co. Name	COMPNAME	Partner O	2/26/2016	Inactive	Contact Trade Partner to Expedite or Confirm Cancellation

Below is a brief description of the fields reported:

- Your_Company_Name: Your company name
- Your_Company_Network_ID: Your company network ID (internal use only)
- Partner_Name - Your trade partner company name
- Date_Product_Track_Link_Created: Date the link to your trade partner was initiated
- DSCSA_Serialized_Status
    1. **Configured and Waiting for Live Data** - The link is set up but has never been used.
    2. **Pending Confirmation** - Data might already be flowing, possibly through a 3PL (Third-Party Logistics provider). Please confirm if you are receiving data from this partner in US Compliance.
    3. **LIVE** - The link is active and currently exchanging transaction data.
    4. **Inactive** - The link exists but has never exchanged any data ? no lot-level or serialized transactions recorded.
    5. **Cancelled** - The link is not needed anymore and is no longer in use.
- Your_Next_Action
    1. **Confirm Data from 3PL** - Let TraceLink know if you are receiving data from this vendor through a 3PL by emailing case@tracelink.com.
    2. **Contact Vendor / Confirm Cancellation** - Reach out to your vendor to speed up data exchange, or confirm with TraceLink if the link should be cancelled.
    3. **Contact Vendor Directly** - You must ask your vendor directly to start sending transactions.
    4. **No Action Needed** - Nothing required at this time.

20. How can I subscribe to the weekly PTSOM Onboarding Readiness Report to check the DSCSA readiness status of my suppliers?
Please file a case with TraceLink Support via the Customer Success Portal with a request to subscribe to receive the PTSOM Onboarding Readiness Report.

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5. PRODUCT VERIFICATION

21. What is a Verification Router Service (VRS), and why is it important?
A VRS is a distributed, interoperable system that allows trading partners (wholesalers, dispensers, etc.) to electronically verify a product identifier (2D Data Matrix with NDC, serial number, lot, expiration date). Under DSCSA, dispensers must verify a product's serial number (PI) when:

- handling suspect or illegitimate products
- responding to FDA or trading partner requests

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22. When am I required to verify a product?
Whenever a product appears suspect, upon FDA request, or during standard verification triggered by your trading partner. You can verify a product by going to Product Information Exchange (PIE)

- Log in to https://opus.tracelink.com
- Access My Networks from Main Menu
- Select Product Information Exchange from My Networks and click Go
- Click on Product Information Exchange (Classic)
- Click on Verify Product
- Select the appropriate Verification Reason and Verification Source
- Select 'Another Company Produced this Product'
- Select 'Yes, I am in possession of this product'
- You can either scan in the serial number or manually enter the serial number and submit

See '[How to Verify Product'](#) for more details

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23. How can I search for a verification history?
You can search for a verification history to verify all your verification requests by going to Product Information Exchange (PIE)

- Log in to https://opus.tracelink.com
- Access My Networks from Main Menu
- Select Product Information Exchange from My Networks and click Go

- Click on Product Information Exchange (Classic)
- Click on Verification History
- Select + Verification History and specific one one week date range filter and submit

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6. PRODUCT RECEIVING AND SCANNING

24. Do I need to scan every product under DSCSA?
No, it is not required to scan every product under DSCSA.

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25. Is reporting receipts a required part of the DSCSA requirements?
No, reporting receipts is not required as a part of DSCSA requirements. However, in order to reconcile physical products with EPCIS data, you can choose to report receipts to TraceLink

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26. What receiving options are available in TraceLink?
TraceLink supports receiving using the below options:

- User Interface
- Wedge Scanner
- Smart Inventory Tracker (SIT) application
- Application Programming Interface (API) integration with dispenser systems

See ‘How to Receive Serialized Product using Serialized Operations Manager’ for more details

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27. Which wedge scanners are supported?
TraceLink supports standard GS1-databar ready scanners from manufacturers such as Honeywell.

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7. EXCEPTIONS AND SPECIAL SCENARIOS (340B)

28. What are DSCSA exceptions?
Compliance Exceptions occur when there is a mismatch (or matching cannot occur) between the physical product received and the associated compliance information received in the EPCIS transaction. Trade partners exchanging DSCSA data must communicate and collaborate on exceptions to ensure continuity in the supply chain and ultimately product availability to patients

Healthcare Distribution Alliance (HDA) has published ‘Exceptions Handling Guidelines for the DSCSA version 2.0, October 2023’ to guide and standardize how compliance exceptions are managed in the industry with the below exception categories:

- Data Issues: Incorrectly formatted data, incorrect sGLN
- Product, No Data: Wrong serial number sent, seller sent data to the wrong buyer
- Data, No Product: Seller sends the data but cancels the physical shipment
- Packaging and Labeling: 2D barcode scanning issues, damaged SSCC
- Unavailable for Distribution: Product shows as recalled or suspect during verification

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29. What 340B models does TraceLink support?
TraceLink supports both the Standard and Alternate 340B Distribution Models, enabling compliant EPCIS data sharing between covered entities and contract pharmacies.

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8. USER AND PARTNER MANAGEMENT

30. How can I add a new user in TraceLink?
Here are the steps to add a new user in TraceLink:

- Log in to https://opus.tracelink.com
- Access Administration from Main Menu
- Select ‘Company Users’ from ‘Users’ in the side menu
- Click New to add a new user
- Enter the user’s First Name, Last Name and Email Address
- Click Save to add the new user

The system sends an email invitation to the new user

See ‘ How to Add a User to OPUS’ for more details

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31. How can I assign a role to a new user in TraceLink?
Here are the steps to assign a role to a new user in TraceLink:

- Log in to https://opus.tracelink.com
- Access Administration from Main Menu
- Select ‘Network Members’ from ‘Users’ in the side menu
- Click New to assign role to an existing user

- Select User Type as Internal
- Select User Name (email from dropdown)
- Select the appropriate Application
- Select the role to assign to the user. Click on + button add additional roles
- Click Save to assign role(s) to the user

See 'How to Assign a User to a Network' for more details

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32. How can I add a new trading partner?

Here are the steps to add a new partner in TraceLink:

- Log in to https://opus.tracelink.com
- Access Master Data from Main Menu
- Select 'Partners' from Partner side menu panel
- Click New to add a new partner
- Enter Partner Name and click + on Identifiers to add an identifier type and value and set the Primary ID
- Click Save
- Then, click on the partner name hyperlink in the Search Partners page to enter the address details for the partner where the mandatory fields will be highlighted
- Click Save

See 'How to Add Partners' for more details

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9. TRAINING AND SUPPORT

33. How can I get trained on DSCSA and TraceLink?

Sign Up for TraceLink's live online training sessions, watch tutorials in TraceLink Healthcare and Pharmacies Resource Center,. You can also sign up to attend our US DSCSA Dispenser Innovation Forum

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34. How can I contact TraceLink Support?

Please file a case with TraceLink Support via your Customer Success Portal