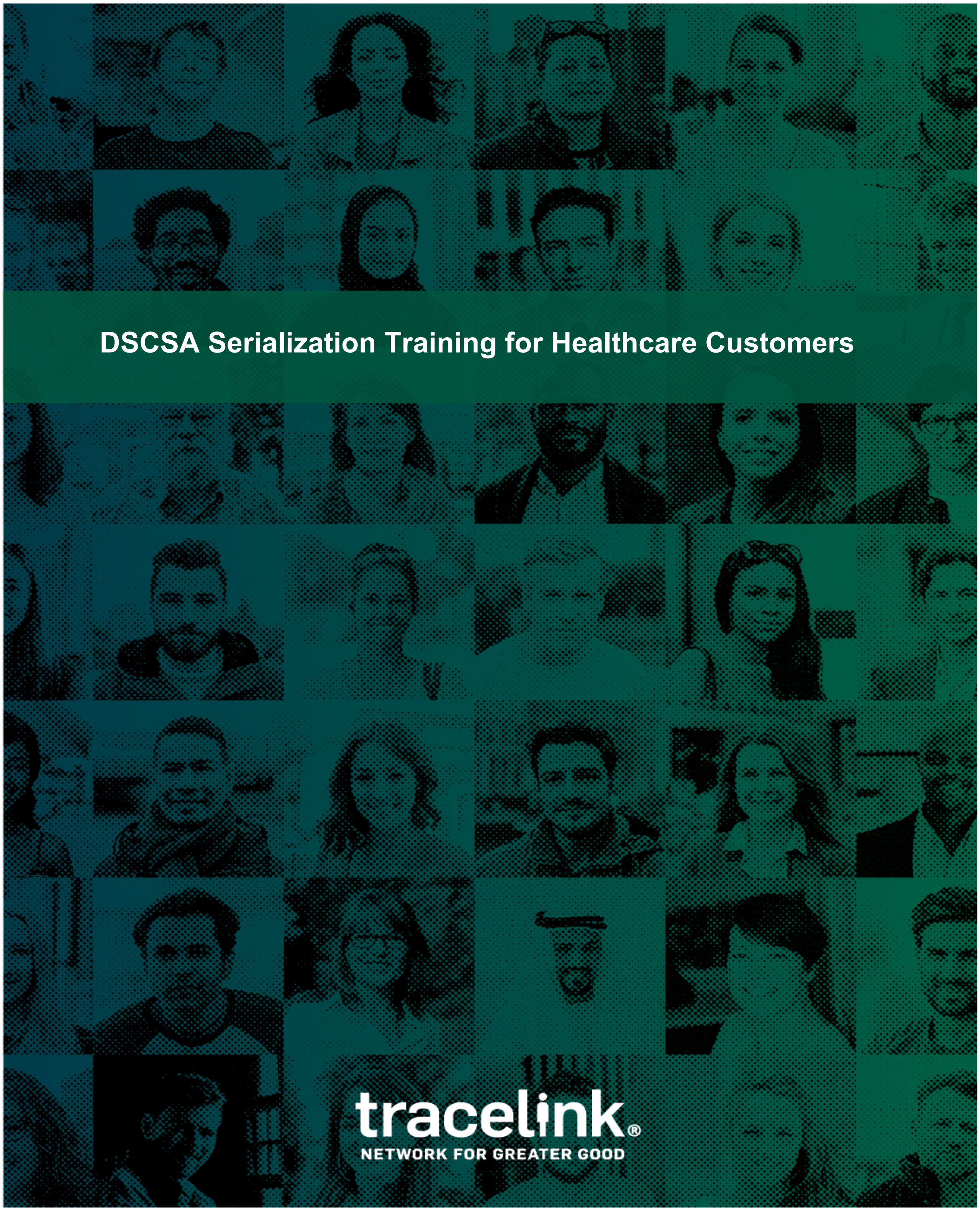
DSCSA Serialization Training for Healthcare Customers



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DSCSA Serialization for Healthcare Customers

In order to comply with the final DSCSA regulations, you need to receive serialized data from your suppliers and prove you are dispensing serialized product if you are audited by the FDA. This student guide accompanies the training session with your HOST team. Please find details of what was presented in the training session including links to related videos.

This Student Guide Includes:

Healthcare Operations Services Team (HOST)

Host manages your DSCSA solutions by administering users, connecting trade partners, handling exceptions, and assisting with daily activities to meet your compliance needs.

DSCSA Overview

The intent of the DSCSA is to ensure patient safety by tracking and tracing pharmaceutical products through the supply chain. So as a product moves from manufacturers to wholesalers to pharmacies, serialized data is passed to each supply chain entity with each change of ownership. This prevents tainted or counterfeit product from slipping into the supply chain, and gives us a full supply chain traceability system.

What is Serialization?

Serialization: Original manufacturers and repackagers are responsible for providing a **unique identifier** for each salable package of product that can be accessed via barcode.

Prior to the serialization regulations, DSCSA covered lot level traceability via Advance Shipment Notices (ASNs) with a Transaction History (T3).

When the data is passed electronically through Product Track, TraceLink saves the product identifier to TraceLink's serialization repository – Serialized Operations Manager. It associates the product identifier with the ASN within the system. Note that once the final regulations are in effect, ASN exchange will no longer be required. However, TraceLink will continue to support ASNs for historical purposes.

How is electronic data exchange accomplished?

You use these TraceLink applications to accomplish this.

- **Serialized Operations Manager** to store and look up serial number information.
- **US Product Track** to exchange serialization data and track your ASNs and their relationship with the serial numbers.
- **Product Information Exchange** to verify serial numbers with the manufacturers.

Note: In this document, the term "serial number" refers to the full product identifier (lot, expiration date, GTIN, and serial number).

Partner Onboarding

There are two main steps you must complete in order to onboard partners to Product Track: Add your partners to Master Data and create ServiceLinks to those partners.

TraceLink's network architecture is built to enable scalability. Therefore, if you already have a link to a partner through Product Track, you do not need to create a new link in order to send EPCIS data.

However, if you are not already linked to your partners through Product Track you must do so.

You also do this every time you add a new partner. For existing partners, you should ensure that you have both a GLN and SGLN for any partner with whom you are exchanging data. For more information, see *Global Location Numbers (GLNs)* and *SGLNs*.

Adding a Partner to Your Network

In order to exchange data with your partners, their identifiers must be added to your network using the Manage Partners page.

To Add Partner Identifiers to Your Network

To add a partner and its locations to the Manage Partners page:

1. Select **Company Administration > Partners** in the user menu on the top right of the TraceLink window.
2. Check whether the company has already been added to your Manage Partners page before you try to add it:
   a. Under **Search Criteria**, filter the **Company Name**, **Location Name**, and **Identifier** fields to search for the partner.
   b. Click **Search**.

3. If the partner company is not yet on the Manage Partners page, click **Add Partner**.
4. In the **Company Name** field, enter the name of the partner.
5. Click **Search**.
6. Locate the partner's entry in the search results and click the corresponding Add Partner link.
7. Add company and location identifiers as needed:
   a. Under **Identifiers**, select the **Entity Being Identified**.
   b. Select an **Identifier Type**.
   c. Enter the **State / Province** where the site is located.
   d. In the **Identifier Value** field, enter the corresponding value for the identifier type you chose.

      For example, if you chose DUNS, enter the company's DUNS number.
   e. You can add additional identifiers by clicking the Add Another Identifier link.

      Important: You must enter an identifier for the company. You cannot enter location identifiers without entering a company identifier; the **Submit** button appears on the page only after you enter a company identifier.
   f. Click **Submit**.

Once you have added partners and locations, you need to add them to the TraceLink applications.

Checking Partner Readiness

Checking your partner's readiness to exchange data is a multi-step process.

1. Check to see if your partner is linked.
2. Check the weekly Email Report.
3. What to do if your partner is not linked.
4. What to do if your partner is not sending data.

Step 1 - Is Your Partner Linked?

Ensure the Service Link exists

To check if your partner is linked, first see if the ServiceLink exists. If it exists, ensure the Status is **Linked**.

To check the Service Link.

1. Sign into OPUS.
2. From the Main menu, select **Administration**.
3. From the Side menu, select **Company Administration (Classic)**.
4. Click the **ServiceLinks** tile.
5. Enter your Search criteria and click **Search**.
6. The ServiceLink Status should be **Linked**.

If the ServiceLink does NOT exist, please open a case with TraceLink to create it.

Step 2 - Check the weekly Email Report

The Weekly DSCSA Connection Status Report

You will receive a weekly DSCSA Connection Status Report, so that you can get the latest vendor connection status or DSCSA data exchange. Here is an example Email (output to CSV):

PTSOM Onboarding Readiness Report - Healthcare_Edited.csv

	Your_Company_Name	Your_Company_Network_Name	Vendor_Company_Name	DSCSA_Connection_Status	last_outreach_date	Vendor_GLN	rolling_tx_count	lifetime_tx_count	most_recent_file
1	Co Name	Co Network Name	Vendor A	In Progress with TraceLink	3/28/2025	GLN 0813337010xyz	0	0	
2	Co Name	Co Network Name	Vendor B	In Progress with Vendor	3/28/2025	GLN 1100007425xyz	0	0	
3	Co Name	Co Network Name	Vendor C	In Progress with TraceLink	3/28/2025	GLN 0368817000xyz	0	0	
4	Co Name	Co Network Name	Vendor D	In Progress with TraceLink		GLN 0316729000xyz	0	0	
5	Co Name	Co Network Name	Vendor E	In Progress with TraceLink	3/28/2025	GLN 1100008547xyz	0	0	
6	Co Name	Co Network Name	Vendor F	In Progress with Vendor	3/28/2025	GLN 0366215000xyz	0	0	
7	Co Name	Co Network Name	Vendor G	Will Not Send	3/28/2025	GLN 0794816000xyz	0	0	
8	Co Name	Co Network Name	Vendor G	In Progress with Vendor	3/28/2025	GLN 0300650000xyz	0	0	
9	Co Name	Co Network Name	Vendor H	In Progress with TraceLink	3/28/2025	GLN 5391527740xyz	0	0	
10	Co Name	Co Network Name	Vendor I	In Progress with TraceLink	3/28/2025	GLN 8051499760xyz	0	0	
11	Co Name	Co Network Name	Vendor j	Outreach Opt Out	3/5/2024	GLN 0300230000xyz	0	0	
12	Co Name	Co Network Name	Vendor K	In Progress with TraceLink	3/28/2025	GLN 0355513000xyz	0	0	
13	Co Name	Co Network Name	Vendor L	In Progress with Vendor	3/28/2025	GLN 0305480000xyz	0	0	
14	Co Name	Co Network Name	Vendor N	Not Started		GLN	0	0	
15	Co Name	Co Network Name	Vendor O	Live	7/1/2024	GLN 0679716000xyz	264	264	3/26/2025

The report contains the following details:

- The name of your company.
- The TraceLink Network ID of your company.
- The name of the vendor you connect with.
- When TraceLink last sent an outreach to your partner.
- The primary company GLN.

Each connection will have one of the following Statuses:

- **Not Started** - TraceLink is missing information for the partner and is following up (e.g. GLN or email address) or the partner is not yet ready to move forward.
- **In Progress with TraceLink** - TraceLink is gathering information for the partner and is following up (e.g. GLN or email address).
- **In Progress with Vendor** – TraceLink's work is complete, and the partner has been contacted with the relevant information to begin sending you the data.
- **Ongoing TL Project** - There is an active TraceLink Implementation with this vendor and will be completed when this vendor is ready.
- **Live** - Partner is finished and actively sending data.
- **Cancelled** - This company has stated that you do not have a direct relationship, and that this connection should not be established. Please contact the vendor if you think this information is incorrect.
- **Will Not Send** - This company has stated that they won't or can't send EPCIS compliance data. Please contact the vendor if you think this information is incorrect.
- **Outreach Opt Out** - This company has asked not to be contacted by TraceLink's outreach process. Please contact the vendor directly to determine the next steps.

Step 3 - When Your Partner is not Linked

Ensure your partner has been added

Check to see if your partner has been added to:

1. Master Data.
2. The Manage Partners page.

Step 4 - When Your Partner is Linked, but Not Sending Data

You might not be receiving their data

Check each of the following:

1. The Error messages (in Info Exchange).
2. Contact your partner and check if they have your company correctly in their system, including your identifiers.

Serialization Data in US Compliance

While ASNs are still being exchanged, the serialized data is associated with US Compliance where you can search for the serialized data.

Watch the video: How to Search for a Serialized Item

Visual Reconciliation

Once you find the serialized data, you can visually reconcile the quantities of the physical products with what you see in the electronic delivery.

Searching for Serialization Data in a Delivery

Use US Compliance to search for Deliveries.

Search for Serialization Data

To Search for Serialization Data

1. Select **My Networks** from the **Main Menu** .
2. Select the US Compliance network from the **Network** drop-down.
3. In the side menu, select **Deliveries > Search**.
4. Enter additional search criteria as necessary to locate the delivery.
5. Click the **View Delivery** (eyeball) icon.
   The **Delivery Information** and **Product Details** display.
6. Click the **View Aggregation Hierarchy** link to view the serial numbers.

Troubleshooting DSCSA Compliance Exceptions for Dispensers

It's likely that during day-to-day operations, something could go wrong. What happens when the physical doesn't match the digital?

In February of 2023, the Partnership for DSCSA Governance (PDG), the Healthcare Distribution Alliance (HDA), and GS1 US jointly hosted a two-day workshop for industry stakeholders. They identified 3 main areas of possible exceptions:

- **Product, No Data**: A trading partner receives product but does not have complete or accurate data.
- **Data, No Product**: A trading partner receives data but does not receive all or some portion of the associated product.
- **Data Issue**: Data misalignment comes from other challenges, such as incomplete/inaccurate master data or barcoding issues.
- **Packaging and Labeling**: A trading partner scans a product at receiving or when preparing it for shipment that shows a mismatch between product label and the transaction data that the manufacturer determines is a labeling issue.
- **Unavailable for Distribution: Product is Recalled, Suspect or Illegitimate**: A trading partner discovers a serial number or lot number is unavailable for distribution due to being recalled, suspect or illegitimate.

Source: https://dscsagovernance.org/wp-content/uploads/2023/03/Exception-Handling-Workshop-Report-.pdf

We'll take a look at one scenario from each of these categories and how to use correction tools in TraceLink.

Scenario 1: Product, No Data

You received 20 packages, but the data only shows Transaction Information (TI) for 10 packages.

How do you fix it? Your partner can either manually create a shipment for the second 10 packages with a new delivery number. Or, you can void the receipt in Serialized

Operations Manager and ask your partner to void their shipment, correct the error, and resend the shipment. Collaborate with your partner to make sure you are both in agreement. See *Voiding Receipts on page 36*.

Watch the video: How to Receive Serialized Products (includes voiding receipts)

Scenario 2: Data, No Product

You purchase 20 packages, your partner sent 20 packages, but the transaction information reflects 22 packages.

How do you fix it? In this case, you have a couple of options. The most important part of this is coordinating with your partner so you are both clear on how you will fix the data.

- **Option 1**: Void the receipt. Ask your partner to void their shipment, correct the data, and resend the shipment.
- **Option 2**: Your partner informs you of the two serial numbers that are in error. They update the serial number status of the serial numbers in question to “Commissioned – Available” instead of “Commissioned – Shipped” in their system. You update the serial number status of those two serial numbers to "Decommissioned." See *Updating the Status of a Serial Number on page 37*.

  Watch the video: How to Update the Status of Serialized Products

Scenario 3: Data Issue

The bar code on the product is incomplete, preventing you from scanning the product.

How do you fix the data? Inform your partner of the problem. Send the shipment back to your partner. Your partner must print new barcodes and resend the shipment.

Scenario 4: Packaging and Labeling

Several unit packages in the shipment have blurred or smudged barcodes due to a printing issue on the manufacturer’s packaging line.

How do you fix the data? Contact the sender to confirm labeling defect. Your partner sends replacement product is sent or issues new EPCIS data (if applicable). Your partner updates their system and clears the exception.

Scenario 5: Unavailable for Distribution: Product is Recalled, Suspect or Illegitimate

During the verification process, one of the scanned serial numbers matches a batch that was recalled by the manufacturer due to contamination risks.

How do you fix the data? Contact your partner to confirm the recall status. The supplier issues an official recall notice and instructions. The receiver removes the product from inventory and logs the exception, the remaining units in the same batch are flagged across the supply chain.

Product Information Exchange

In order to verify products with the Verification Router Service (VRS), you need to add a verification contact first.

Details on how to add a verification contact, manually verifying serial numbers and searching verification history follow.

- *Adding a Verification Contact on the next page*
- *Verifying Products Manually on the next page*
- *Viewing Verification History on page 19*

Watch the related videos:

- How to Add a Verification Contact
- How to Manually Verify Serial Numbers
- How to Search Verification History

Adding a Verification Contact

In the case of suspected illegitimate product, a manufacturer has 24 hours to begin an investigation. In order to ensure that all parties involved can contact one another in a timely manner, a verification contact is required. You must add an email address or a phone number. You can add both if you have them but at least one is required. If adding an email address, it is best practice to use an email address that goes to your verification team's shared email address rather than an individual's email address in case the individual's responsibilities change in the future.

To add a verification contact:

1. Select **Administration** from the **Main Menu** ⠿.
   In the side menu, select **Company Administration (Classic)**.
2. Select the **Services** tile. For **Service Type**, select Product Information Exchange.
3. Click **Search**.
4. Click Configure Published Service.
5. Scroll to the tabs at the bottom.
6. Click the **Verification Contact** tab.
   - Click Add Requester.
   - Enter the **Phone Number** or **Email** of the contact.
   - **Important**: If you choose to add a **Phone Number**, do not add blank spaces to the field. Blank spaces are not allowed in the phone number format for GS1 messages.
7. Click **Submit**.

Verifying Products Manually

You use the Verify Product function in Product Information Exchange to manually verify products.

Submit a Verification Request Manually

1. Select **My Networks** from the **Main Menu** ⁝⁝⁝.
2. Select the Product Information Exchange network from the **Network** drop-down.
3. Click GO.
4. Click **Product Information Exchange (Classic)** from the side menu.
5. Click **Verify Product**.
6. Select the **Verification Reason**.
   - **Saleable Return - Check** (default value)
   - **Status Check**
   - **Verify Product Exception**
   - **Illegitimate Product Suspicion**
7. For **Verification Source** select one of the following options.
   - **Enter Product Information** to type the information manually:

     Enter the **Packaging Code (GTIN)**, **Lot Number**, **Serial Number**, and **Expiration Date** of the item as listed on the package.
   - **Scan Product Information** to scan the barcode:

     The serial numbers display in the Serial Numbers field.

5. For **Confirmation of Possession**, select:
   - Yes, I am in possession of this product.
6. For **Product Source**, select **Another Company Produced this Product** to verify with VRS.
7. Click Submit.

   Product Information Manager processes the request.

Viewing Verification History

As a downstream partner, you can view the history of verifications requests you initiated.

You request a Verification History report for up to a seven day period. The date range can be within the past twelve years.

To Request a Verification History Report

Note that all fields are required.

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Product Information Exchange** from the **Network** drop-down.
4. Click **Product Information Exchange (Classic)** from the side menu.
5. Click **Verification History**.
6. Click ⊕ Verification History.
7. Select a **Date Range**.

   Note: The maximum range is seven days.
8. Select a **Verification Response**.

   Possible values are **All**, **Valid**, or **Invalid**.
9. Click **Submit**.

   The system completes the operation in the background (asynchronously) so the results may not be ready immediately. When the results are ready they display in the list.

To View and Download a Verification History Report

You can download the Verification History reports for the last seven days.

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Product Information Exchange** from the **Network** drop-down.
4. Click **Product Information Exchange (Classic)** from the side menu.
5. Click **Verification History**.
6. Locate the report in the list.
7. Click the link in the **File** column to download the report.

   For downstream partners, the csv file displays information about:

   - The request, including the packaging code, serial number, and lot.
   - The response, including the response result and details.

Staying Compliant: Special Situations

As a pharmacy or healthcare provider there are a couple of special situations in which you may need to send serialization data:

- In a 340B situation, the physical product is shipped to you (as the covered entity) and you must ship the product and data to the contract pharmacy.

You must track this exchange of serial numbers through Serialized Operations Manager. If there are any problems, you may need to void a shipment. (The procedure is included at the end.)

340B Situations

Currently, in order to stay compliant in these situations, you must follow these steps.

1. In **Serialized Operations Manager > Queries**, retrieve the inbound **Delivery Number** for the serial numbers you are loaning.
2. In **Serialized Operations Manager > Inbound Movement**, search for the unsubmitted receipt with the **Delivery Number**. Receive the whole receipt.
3. In **Serialized Operations Manager > Outbound Movement**, create a delivery for the serial numbers you are loaning.

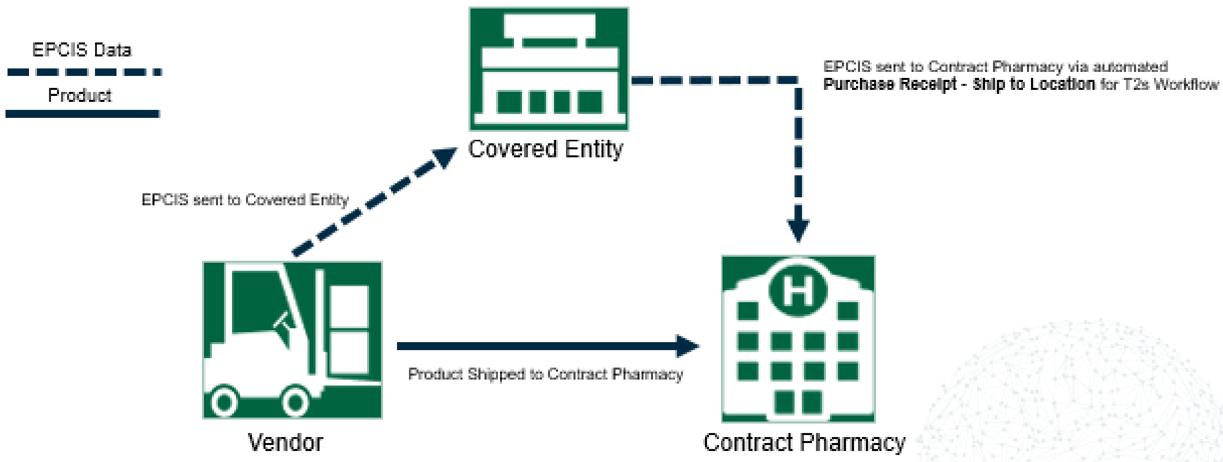
Using the Standard Distribution Model

First ensure the prerequisites have been completed:

- The Contract Pharmacy is added to the TraceLink Network.
- The Contract Pharmacy is added to Partner Master Data.
- The Covered Entity and Contract Pharmacy are ServiceLinked in Product Track.

The **Purchase Receipt – Ship to Location** workflow allows US Product Track to send a copy of the EPCIS data (T2) to the Contracted Pharmacy.

340B – Standard Distribution Model



This is the Standard Distribution Model, a typical 340B situation. This model is sometimes also referred to as the 'Bill-to / Ship-to' model. In this model the physical product is sent to the Contract Pharmacy, but the data goes to the Covered Entity initially. The Covered Entity then must send the data to the Contract Pharmacy where the physical product is located via the Purchase Receipt - Ship to Location for T2s Workflow. If the perquisites are met and the workflow is enabled there is no action required for the covered entity to get the data to the Contract Pharmacy.

Once the EPCIS data is received, the workflow triggers and sends a copy of the Contract Pharmacy.

Enable the Purchase Receipt - Ship to Location Workflow

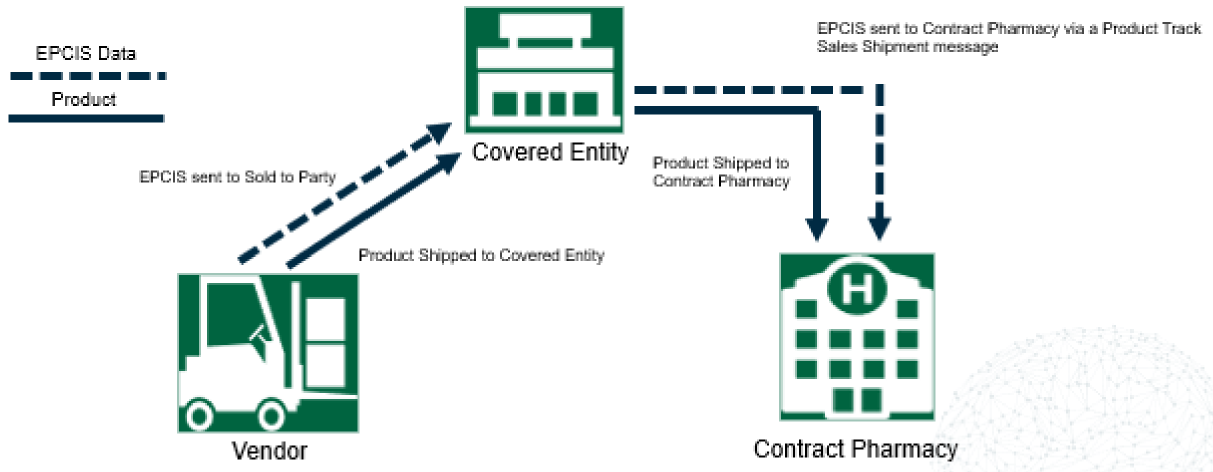
1. Select **My Networks** from the **Main Menu** ⁝⁝⁝ .
2. Select the Administration network from the **Network** drop-down.
3. Click **Company Administration (Classic)** from the side menu.
4. Click the **Workflow Events** tile.
5. In the Event Source (Application) drop-down, select the **US Compliance - Product Track** application.
6. Find the **Purchase Receipt - Ship to Location** workflow (for T2s) and select the check box to enable it.
7. Click **Save**.

Using the Alternative Distribution Model

First ensure the prerequisites have been completed:

- The Contract Pharmacy is added to the TraceLink Network.
- The Contract Pharmacy is added to Partner Master Data.
- The Covered Entity and Contract Pharmacy are ServiceLinked in Product Track.

340B - Alternative Distribution Model



In the Alternative Model, the physical product and the data go to the Covered Entity. Then the Covered Entity must send the data and physical product to the Contract Pharmacy. Here, the Covered Entity performs a SOM receipt to receive the product and data together and then sends both the product and data by creating a Product Track SOM Sales Shipment message.

Step 1: Retrieve the Inbound Delivery Number for the Serial Number

1. Select **My Networks** from the **Main Menu** .
2. Select the Serialized Operations Management network from the **Network** drop-down.
3. Click GO.
4. Click **Serialized Items** then **Search** from the side menu.
5. Enter the **Serial Number**.
6. Click Search.
7. Note the **Last Delivery Number**.

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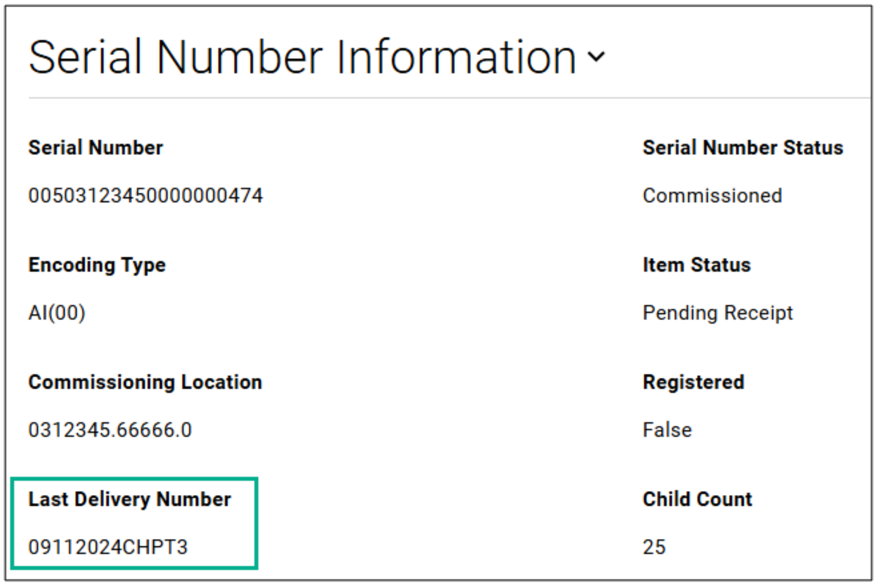

8. Repeat this process for each serial number you wish to send.

Step 2: Find and Receive the Inbound Receipt

1. Select **My Networks** from the **Main Menu** .
2. Select the Serialized Operations Management network from the **Network** drop-down.
3. Click GO.
4. Click **Receipts** then **Search** from the side menu.
5. In the **Delivery Number** field, enter the **Delivery Number**.
6. In the **Search Criteria** section enter the **Delivery Number**.
7. Ensure the **Status** is **In Progress**.
8. Clear all Additional Filters, if any.
9. Click Apply.

10. Click the Delivery Number link in the **Delivery Number** column.

11. Expand the Receive Serial Numbers section and select either **Receive All** or **Receive Specific Serial Numbers**.

12. If you selected the **Receive Specific Serial Numbers** radio button, enter the specific serial numbers.

13. Choose any of the desired options.

14. Click **Receive**.

    All the serial numbers in the receipt are now in an **Available** state which means they are ready to ship.

15. Repeat this step for any additional inbound receipts if other serial numbers you are sending are on a different inbound receipt.

Step 3: Create an Outbound Delivery

1. Select **My Networks** from the **Main Menu** .

2. Select the Serialized Operations Management network from the **Network** drop-down.

3. Click **GO**.

4. Click **Serialized Operations Management (Classic)** from the side menu.

5. Select **Outbound Movement** > Create Delivery.

6. Enter a **Delivery Number** of your own choosing.

7. For **Sale Type**, select **Sale - In Country**.

8. For **From Country Code** and **To Country Code**, select **US**.

9. Enter a **From Business**, **To Business**, **Ship From Location** and **Ship To Location**.

    Four addresses are required for US EPCIS data exchange.

10. Add a **Transaction ID** of your own choosing.

- For example, for **Identifier Type** select **Other**.
- Enter the **Delivery Number** you just entered in the **Identifier Value** field.
- Leave **Document Date** blank.

11. Click **Next**.
12. Click **Next** again.
13. In the **Serial Numbers** section, select **Scan Serial Numbers**. This option allows you to type in the box.

    Scan the serial numbers or paste/enter them in the Serial Numbers box.
14. Ensure the **Automatically disaggregate serial numbers that are aggregated to another number** check box is selected.
15. Click **Submit**.

Void an Outbound Delivery

1. Select **My Networks** from the **Main Menu** .
2. Select the Serialized Operations Management network from the **Network** drop-down.
3. Click **GO**.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Select **Outbound Movement** > View Deliveries.
6. Set the **Status** to **Submitted**.
7. Enter additional search criteria as necessary to locate the delivery.
8. Click **Search**.
9. Click the Delivery Number link for the delivery you wish to void.
10. Click **Void Delivery** at the bottom of the screen.

    This brings you to the Void Delivery screen.

11. Enter the Void Information.

    a. Select a **Reason** for the void.

    b. For **Order Cancelled**, select **Yes - order was cancelled**.

12. Click **Submit**.

Serialized Operations Manager

Serialized Operations Manager manages serialized inventory operations, such as, receiving, returns, and destruction. Once products are serialized, their data resides in the TraceLink repository. Serialized Operations Manager communicates with other TraceLink applications like US Compliance.

You basically use Serialized Operations Manager to verify the serialized information in the system and to troubleshoot issues. You can view the deliveries that you received and you can query the status of the serial numbers. You use this information to prove that you are transacting on serialized product.

Watch related videos:

- How to Receive Serialized Product using Serialized Operations Manager
- How to Update the Status of a Serialized Item
- How to Search for a Serialized Item

Searching for Receipts

This procedure shows how to search for submitted or unsubmitted receipts.

Search for Receipts

To search for receipts:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Inbound Movement** and click the View Receipts link.
6. Set **Show Data From** to the manufacturing site that provisioned the serial numbers of the products you're receiving.
7. Enter **Search Criteria** to filter the list of deliveries needing to be received. Click the **Search Criteria** expand icon if necessary. The following table shows search criteria you can set.

Field	Description
Delivery Number	Search for serial numbers in a specified delivery. **Note:** Since it is possible to have the same **Delivery Number** for deliveries from different partners or locations, the uniqueness of the delivery is determined by the combination of **Delivery Number**, the **Ship From Location**, and the **From Business**.
Receipt Type	Filter serial numbers by the type of receipt transaction: ▪ **Purchase – Import** ▪ **Purchase – In Country** ▪ **Return – Import** ▪ **Return – In Country** ▪ **Transfer – Import** ▪ **Transfer – In Country**

Field	Description
Status	▪ **Submitted** - Shows submitted receipts. ▪ **Unsubmitted** - Shows unsubmitted receipts. ▪ **Voided - All** - Shows receipts with any of the voided statuses listed below. ▪ **Voided - Cancelled** - Receipt is voided, the order is cancelled and cannot be corrected. ▪ **Voided - Corrected** - Receipt is voided and subsequently corrected. ▪ **Voided - Not Corrected** - Receipt is voided, the order is not cancelled and therefore can be corrected but has not yet been corrected.
Date On or After / Date On or Before	Enter the first and last date of a range to filter the receipts. You can enter the dates in the **Date On or After** and **Date On or Before** fields or select date using the calendar icons (9).
Keywords	Enter a value such as the business identifier or transaction identifier. SOM matches the value against serialized number data. If you enter multiple keywords, serial numbers must match all keywords to be returned.

The search lists up to 10,000 results. Further refine the search criteria if necessary.

You can search for any delivery number to find the receipt through the Serialized Operations Manager's Search Receipt screen.

For matching receipts, the results table displays the delivery number, the type of shipment (for example, **Purchase – Import**), the date of the shipment, the status (**Submitted** or **Unsubmitted**), the business that shipped the products in the delivery, the location the products shipped from, and the transaction identifier.

The list is ordered by date. You can click a column header to sort the list by a different value.

4. Click a Delivery Number link to:

- View the receipt details for deliveries that were **Submitted**. Click Download Serial Numbers to download the serial number hierarchy of the delivery items to a CSV file. See *Downloading the Serial Number Hierarchy for a Delivery* for more details.
- Update the receipt details for deliveries that are **Unsubmitted**. You can update the delivery information, click **Next** to add order item information, and click **Next** to add serial numbers. Click **Submit**. See *Updating Receipts on the next page* for more details.
- View the receipt details for deliveries that were **Voided**. For receipts with the status **Voided - Not Corrected**, you can correct the receipt from the page by clicking **Correct Receipt**.

Downloading the Serial Number Hierarchy for a Receipt

You can download a CSV that contains the serial numbers of all containers and products in a delivery. The file contains one row for each serial number with the following columns:

- SerialNumber
- ParentSerialNumber
- InternalMaterialNumber
- CountryDrugCodeType
- CountryDrugCode
- PackagingCodeType
- PackagingCode
- PackagingLevel (Each, Innerpack/Bundle, Case/Shipper, Pallet)
- LotNumber
- ExpirationDate
- ManufacturingDate

The file is named [ShipmentType]-[DeliveryNumber]-[ShipmentDate in DDMonYYYY format].csv, where ShipmentType is ReturnShipment, SaleShipment or TransferShipment.

Download the Serial Number Hierarchy

To download the serial number hierarchy for a delivery:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Then do one of the following:
   - For a shipment, click **Outbound Movement** and click the View Deliveries link.
   - For a receipt, click **Inbound Movement** and click the View Receipts link.
2. Set **Show Data From** to the manufacturing site that provisioned the serial numbers of the products.
3. Set the **Status** to **Submitted**. Or, for shipments, you can choose any voided option.
4. Enter other **Search Criteria** as necessary to locate the delivery.
5. Click **Search**.
6. Click the link for the delivery in the **Delivery Number** column.
7. Click the Download Serial Numbers link to download the serial number hierarchy of the delivery items to a CSV file.

Updating Receipts

You can update receipt details for **Unsubmitted** receipts.

Update Receipts

To update receipts:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Inbound Movement** and click the View Receipts link.
6. Set the **Status** to **Unsubmitted**.
7. Enter additional search criteria as necessary to locate the receipt.
8. Click the Delivery Number link for the receipt.
9. Update fields as required.

   For descriptions of the fields, see *Creating Receipts for Serialized Products*.

10. If no serial numbers have been specified, do one of the following:

    - Select **Scan Serial Numbers** and type or scan an item's barcode (up to 30,000 characters).
    - Select **Upload Serial Numbers from File** and click **Choose File**. Each serial number in the file must be on its own row. Files can be as large as 50 MB.

    If serial numbers have been specified, a file name containing the previously specified serial numbers is displayed.

    You can do the following:

    - Click the filename to download and view the specified serial numbers.
    - Click **Add More**, then select **Scan Serial Numbers** or **Upload Serial Numbers from File** to add additional serial numbers to the previously specified serial numbers.
    - Click **Remove** to remove previously specified serial numbers. The status of the serial numbers will change from Picked to Available.

7. If you wish to void the receipt, select the **Void Receipt** option. Click **Confirm** to void the receipt.

8. If the delivery is complete, select the **Delivery complete** box.

   If **Delivery complete** is selected, all included serial numbers are updated with the item status of Available and the Receipt Status is set to Submitted. If **Delivery complete** is not selected, all included serial numbers are updated with the item status of Available and the Receipt Status remains Pending.

   Note: This option only displays if Serialized Operations Manager is configured to allow partial deliveries. The **Save for Later** button is disabled if this option is selected.

9. If you wish to implicitly register serial numbers during receipt, select the **Register unknown serial numbers** check box.

   You use this to record (register) serial numbers in the system if you are a repackager, wholesaler, or pharmacy and your supplier has not provided you with serialized product information. Once registered in the system, you can perform actions on the serial numbers, such as shipping and destroying.

10. Click **Submit** or click **Save For Later** to complete the receipt later.

Voiding Receipts

Sometimes, problems such as shipping errors or damage to goods can be discovered after you have received a delivery. In this case, you can void a receipt in SOM.

To Void a Receipt

1. Select **My Networks** from the **Main Menu** .
2. Select the Serialized Operations Management network from the **Network** drop-down.
3. Click **GO**.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Inbound Movement** and click the View Receipts link.
6. Set the **Status** to **Submitted**.
7. Enter additional search criteria as necessary to locate the Receipt.
8. Click the Delivery Number link for the delivery you wish to void.
9. Click **Void Receipt** at the bottom of the screen.

   This brings you to the Void Receipt screen.

6. Enter the Void Information:

Field	Description
Reason*	Specify the reason you are voiding the receipt from the drop down list.
Transaction Date	Defaults to the current date.

Field	Description
Description	Optionally enter a description of the void.
Order Cancelled?*	Specify whether or not the order is being cancelled. If you mark the void as **Yes - order was cancelled**, the delivery status will become **Voided - Cancelled** and cannot be corrected. If you mark the void as **No - order was not cancelled**, the delivery status will become **Voided - Not Corrected**. You can correct the shipment.

7. Click **Submit**.

   A confirmation message appears stating that the void action cannot be undone.

8. Click **Confirm** to complete the action.

Updating the Status of a Serial Number

Edge systems, such as TraceLink's Smart Inventory Tracker, update the status of serial numbers automatically during warehouse operations such as shipping, receiving, aggregating, and disaggregating. You can also update the status of serial numbers manually in the Serialized Operations Manager user interface.

Update a Serial Number's Status

Important: In general, you use the Update Serial Number Status page for data repair only. When you update serial number status on this page, Serialized Operations Manager updates the data in the repository but, in most cases, does not trigger compliance reporting. However, there are some events that will trigger certain compliance reports. For example, if you change the status of an item to Under Investigation or Available, certain European Union Compliance reports might be triggered.

The following procedure describes how to update the status of a single item. Enter, scan, or upload multiple serial numbers to update the status of a group of items.

To update a serial number's status:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Status Update** and select the Update Serial Number Status link.
6. On the top right of the SOM window, set **Show Data From** to the manufacturing site that provisioned the serial number you're updating.
7. From the **Serial Number Status** menu, select the status to which you're updating the serial number.
8. If you set the **Serial Number Status** to **Commissioned** or **Registered**, set the **Item Status** to the state of its associated item: Available, Blocked, Pending Receipt, Picked, Received, Shipped, or Under Investigation.
9. If you set the **Serial Number Status** to **Commissioned, Decommissioned**, **Destroyed**, or **Registered**, you may select a **Reason Code** from the drop-down list.

   Note: It is recommended that if a product is stolen, withdrawn, or misplaced, you decommission the serial number rather than destroy the product since there is no confirmation that the product has actually been destroyed.
10. For **Update Type**, select one of the following:
    - Select **Product Status Update** if you're updating the status as a standard operation.
    - Select **Modifying Product Incorrect Status** if you're replacing an incorrect status.

    The **Update Type** and **Reason Description** fields are used in audit reports.

7. Optionally, enter a **Reason Description**.

8. In the **Serial Numbers** section of the page, enter the serial numbers to be updated using one of these methods:

   - Type a serial number in the text box. If typing in multiple serial numbers, place each number in its own row. Please note that you can receive a partial shipment by entering the received child serial numbers and using the **Automatically disaggregate serial numbers** check box.

   - Select **Scan Serial Numbers** and scan an item's barcode. You can scan up to 30,000 characters.

   - Select **Upload Serial Numbers from File** and click **Choose File**. Each serial number in the file must be on its own row. Files can be as large as 50 MB.

9. Click **Submit**.

Querying a Serial Number

Use SOM to obtain the following data on a serial number:

Serial Number Query Results	
Serial number information	■ Encoding format ■ Status ■ Status of associated item ■ Commissioning Location ■ Registered ■ Last Delivery Number (if the serial number is associated with either an outbound shipment or an inbound receipt) ■ Product Recall Markets (if lot has been recalled) ■ Market Withdrawal Markets (if product has been withdrawn) ■ Crypto Key and Crypto Code (if using Russia Crypto Codes application)
Item information	■ Item's code ■ Lot number ■ Expiration Date ■ Manufacturing Date ■ Packaging level ■ Reason Code ■ Package Size/Spec ■ Product Name ■ Product Description ■ Strength ■ Dosage Form ■ Country Drug Code ■ Country Market Code ■ Internal Material Number
Delivery information	■ Receipt Information ■ Shipment Information
Parent information	Provides a link to the item's parent so that you can access its serial number information.
Child information	Provides a link to the container's child so that you can access its serial number information.

Query a Serial Number

To query a serial number:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Queries** and click the Get Serial Number Status link.
6. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you're managing.
7. Enter the **Serial Number**.
8. Click **Search**.

Querying a Serial Number's History

Use SOM to display a table containing each event in the lifecycle of a serial number. The operation returns general information about the serial number and a list of events.

The Get Serial Number History operation provides the following general information about the serial number:

Serial Number History Results	
Serial Number Information	■ Encoding format ■ Status ■ Status of associated item ■ Product Recall Markets (if lot has been recalled) ■ Delivery Number link (if the serial number is associated with either an outbound shipment or an inbound receipt) ■ Market Withdrawal Markets (if product has been withdrawn) ■ Commissioning Location
Item Information	■ Item's code ■ Lot number ■ Manufacturing Date ■ Expiration Date ■ Packaging level ■ Reason Code ■ Package Size/Spec ■ Product Name ■ Product Description ■ Strength ■ Dosage Form ■ Country Drug Code ■ Country Market Code ■ Internal Material Number

For each event, the Get Serial Number History operation provides the time the event occurred as well as the following information:

Event	Value	Description
Event	Serialization event	Possible values: Status Updated, Received, Shipped, Packed, Unpacked, Commissioned, Provisioned, Registered, and Repackaged.
Business Step	Business process step associated with serialization event	Possible values: destroying, receiving, shipping, packing, unpacking, commissioning, decommissioning, deactivating, reserving, unreserving, encoding, stocking, holding, picking, inspecting, registering, dispensing, disposing, and stock_taking.
Disposition	Serialization number status	Possible values: destroyed, received, in_transit, in_progress, active, inactive, reserved, unreserved, encoded, deactivated, sellable_accessible, blocked, not_started, stocking, holding, inspecting, dispensing, disposing, and stock_taking.
Business Location	Location GLN identifier / Location Name	Location where serialization event occurred.
Delivery Number	Delivery number of the associated shipment or receipt	Links to the corresponding shipment or receipt.
Transactions	Document corresponding to the serialization event	Business transactions include documents such as purchase orders.
Reason Code	List of codes assigned to the serial numbers during status update operations	Possible values: Damaged, Dispensed, Disposed, Expired, Misplaced, Recalled, Repackaged, Stolen, Sampled, Sampled by Authorities, and Withdrawn.
Update Type	Type of serial number update	Possible values: Product Status Update and Modifying Product Incorrect Status
Description	Reason description	The reason for the update, destroy, or decommission operation. If no value was entered, the row does not display.
From	Ship from address	The **From** row is included if the Event is Shipped or Received.
To	Ship to address	The **To** row is included if the Event is Shipped or Received.

Event	Value	Description
Distribution Type	Types of shipments and receipts	The **Distribution Type** row is included if the Event is Shipped or Received. Shipment distribution types include: ▪ Return - Export ▪ Return - In Country ▪ Sale - Export ▪ Sale - In Country ▪ Transfer - Export ▪ Transfer - In Country Receipt distribution types include: ▪ Purchase - Import ▪ Purchase - In Country ▪ Return - Import ▪ Return - In Country ▪ Transfer - Import ▪ Transfer – In Country
Parent Container	Package containing the item corresponding to the serial number. Displays for aggregate and disaggregate operations.	Displays the serial number status of the parent.
Performed By	First and last name and the system ID of the user.	Indicates the user and system that initiated the event. If no value was entered, the row does not display.

Request a Serial Number's History

To view the serial number's history:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Queries** and click the Get Serial Number Status link.
6. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you're managing.
7. Click **Request Serial Number History**.
8. Enter the serial number in the pop-up box.
9. Click **Submit**.
10. Click **Search**.
11. Click the **File Name** of the Serial Number History you wish to view.
12. To download a CSV file containing a row for each event, click Export Events to CSV.

View a Serial Number's History

You can query an item code and lot only if they have associated serialized items.

To view the serial number's history:

1. Click the **Main Menu**.
2. Select **My Networks**.
3. Select **Serialized Operations Management** from the **Network** drop-down.
4. Click **Serialized Operations Management (Classic)** from the side menu.
5. Click **Queries** and click the Get Serial Number Status link.
6. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you’re managing.
7. Enter search criteria in the **Search Criteria** section.
8. Click **Search**.
9. Click the **File Name** of the Serial Number History you wish to view.
10. To download a CSV file containing a row for each event, click Export Events to CSV.

Resources

You can access all the videos from this course, including a recorded session, on this page.

HOST Resource Center

For other administrator functions such as:

- Adding new users
- Connecting to wholesalers
- Troubleshooting

Contact HOST by emailing case@tracelink.com.