



DSCSA Compliance for Pharmacies and Healthcare

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NETWORK FOR GREATER GOOD

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DSCSA Compliance for Pharmacies and Healthcare

Learning Objectives

At the end of this module, you will be able to:

- Describe the DSCSA regulations at a high level.
- Query the system to verify your serialized data exchange.
- Manage users in TraceLink (for administrators only).

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.

This law has been gradually phased in over a period of 10 years. This document focuses on the final requirements for dispensers (pharmacies and healthcare systems).

What is Serialization?

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

Prior to the serialization regulations, DSCSA covered lot level traceability.

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).

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: <ul style="list-style-type: none"> ▪ Purchase – Import ▪ Purchase – In Country ▪ Return – Import ▪ Return – In Country ▪ Transfer – Import ▪ Transfer – In Country

Field	Description
Status	<ul style="list-style-type: none"> ▪ 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 (📅).
Keywords	<p>Enter a value such as the business identifier or transaction identifier. SOM matches the value against serialized number data.</p> <p>If you enter multiple keywords, serial numbers must match all keywords to be returned.</p>

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* 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**.



Querying a Serial Number

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

Serial Number Query Results	
Serial number information	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ 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	<p>The Distribution Type row is included if the Event is Shipped or Received.</p> <p>Shipment distribution types include:</p> <ul style="list-style-type: none"> ▪ Return - Export ▪ Return - In Country ▪ Sale - Export ▪ Sale - In Country ▪ Transfer - Export ▪ Transfer - In Country <p>Receipt distribution types include:</p> <ul style="list-style-type: none"> ▪ 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](#).

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.

Product Information Manager and Exchange

Introduction


Product Information Manager is a TraceLink-owned application to which TraceLink customers link in order to facilitate master data sharing and product verification. When customers link to Product Information Manager, they are provided with the Product Information Exchange application.

The Product Information Exchange application acts as an access point to data in the Product Information Manager repository. Pharmaceutical manufacturers and repackagers use Product Information Exchange to load data and verify products. Wholesalers and the healthcare segment use Product Information Exchange to access data and verify products.

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.