



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 salable 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 Product Track.

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 Products (includes searching and voiding)
- How to Update the Status of Serialized Products
- How to Query Serialized Products


Searching for Receipts

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

Search for Receipts

To search for receipts:

1. In Serialized Operations Manager, 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 you're receiving.
3. 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
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	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.

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. In Serialized Operations Manager, click **Queries** and click the [Get Serial Number Status](#) link.
2. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you're managing.
3. Enter the **Serial Number**.
4. 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. In Serialized Operations Manager, click **Queries** and click the [Get Serial Number History](#) link.
2. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you're managing.
3. Click **Request Serial Number History**.
4. Enter the serial number in the pop-up box.
5. Click **Submit**.
6. Click **Search**.
7. Click the **File Name** of the Serial Number History you wish to view.
8. 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. In Serialized Operations Manager, click **Queries** and click the [Get Serial Number History](#) link.
2. Set **Show Data From** to the manufacturing site that provisioned the serial number of the products you're managing.
3. Enter search criteria in the **Search Criteria** section.
4. Click **Search**.
5. Click the **File Name** of the Serial Number History you wish to view.
6. To download a CSV file containing a row for each event, click [Export Events to CSV](#).

Serialization Data in Product Track

While ASNs are still being exchanged, the serialized data is associated with the Product Track delivery. You can search for the serialized data in Product Track.

Watch the video: How to Search for Serialization Data in Product Track

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


To locate serialization data for a delivery, you search using the View Transaction Exchanges page (**Go To > View Transaction Exchanges**). You can filter by transaction exchanges between your company and your trade partners and specify search criteria to find the delivery.



Search for Serialization Data

Transaction exchanges show the transactions between suppliers and customers at the shipment or delivery level. Once you find a shipment or receipt for a delivery, you can view the corresponding serialization data.




To search for serialization data in a delivery:

1. Select **Compliance > US Product Track** in the **Modules** menu.
2. In the **Go To** menu on the top right, click **View Transaction Exchanges**.
3. Ensure that the **Search Criteria** section of the page is expanded. Click the expand icon  if necessary.
4. For **Service Publisher**, select your company.


The **Service Publisher** list contains each Product Track application (service) you have access to; if your company has not purchased TraceLink, select the company whose serialized event data you want to view.


5. Using the **Date On or After** and **Date On or Before** fields, set the date range or keep the default range.
6. Select the type of serialized exchanges **All** from the **Serialization Confirmation Type** drop-down list.
 - **All** - Displays all transaction exchanges, even those with no associated serialization data.
 - **Confirmed - ASN** - Displays transaction exchanges created through an ASN that corresponds to a submitted Serialized Operations Manager (SOM) receipt with associated serial numbers.
 - **Serialized - EPCIS** - Displays serialized transaction exchanges created through EPCIS data exchange.
 - **Unconfirmed - ASN** - Displays transactions exchanges created through an ASN that corresponds to an unsubmitted SOM receipt.
7. Optionally choose other criteria to narrow your search.
8. Click **Search**.

The matching deliveries display.

In the results list, a lot level compliance entry, as well as confirmed and unconfirmed ASNs are denoted with a details icon , and a Transaction History icon . An EPCIS serialization data entry shows only the details icon .

If both lot level compliance data and EPCIS serialization data are transmitted with a delivery, two entries appear in the results list, one for each message.

9. Click  on the serialized data entry.

Note: If you are unsure if the entry is EPCIS serialized data, hover over . The type of transaction displays.

10. Click **Download Serial Numbers** to download the serial numbers to a CSV file.
11. Click **View Serial Numbers** to view the serial numbers for the highest packaging level. A list of serial numbers and additional information displays.

For Serialized - EPCIS entries:

- Click the link in the **Serial Number/Actual Barcode Content** column to see serial number details for the next packaging level.
- You can continue to drill down in the data to the saleable unit level.

For Confirmed - ASN entries:

- Click the [Export Contents to CSV](#) link to download the information from the list, including packaging hierarchy information.

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 **Product Information Exchange** in the **Modules** menu.
2. Click **Verify Product**.
3. Select the **Verification Reason**.
 - **Saleable Return - Check** (default value)
 - **Status Check**
 - **Verify Product Exception**
 - **Illegitimate Product Suspicion**
4. 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 one of the following two options.

- No, I am not in possession of this product. (default value)
- Yes, I am in possession of this product.

6. **Product Source**, displays if you act as a downstream partner. As a downstream partner, select **Another Company Produced this Product** to verify with VRS. If you are both a manufacturer and a downstream partner (wholesaler, for example), you can verify against your own Product Directory. To do so, select **My Company Produced this Product**.

7. Click **Submit**.

Product Information Manager processes the request.

Possible Results

A product is considered "verified" if all four elements (packaging code, serial number, lot, and expiration date) are matched in a VRS. However, manufacturers can customize the responses they return during verification. Therefore, these responses may vary depending on manufacturer customizations. See *Customizing Verification Responses*.

If provided in the response, the contact information (**Email** and **Phone**) of the Producer will display.

- **Verified Product:** The product is a legitimate product.
- **Verified Product - Product Recalled:** The product is a legitimate product but it has been recalled from the market. A warning displays.
- **Verified Product - Product Expired:** The product is a legitimate product but it has been recalled from the market. A warning displays.
- **Invalid Product:** The product is found but cannot be verified as legitimate because some part of the verification request does not match. For example, the expiration date you entered differs from the expiration date that is returned from the verification request. An error displays.
- **Invalid Product - Product Expired:** The product is found and verified but the product is expired and the manufacturer chose to return an invalid response. An error displays.

- **Invalid Product - Product Recalled:** The product is found and verified but the product has been recalled from the market and the manufacturer chose to return an invalid response. An error displays.
- **Invalid Product - Product Suspect:** The product is found and verified but the product has been marked as "suspect." Suspect products always return an invalid response. In this case the manufacturer chose to display that the product is suspect.
- **Invalid Product - Manufacturer Policy:** This result may be returned for the following reasons:
 - The product is found and verified but the product is marked as "suspect." Suspect products always return an invalid response. In this case the manufacturer chose not to indicate that the product is suspect.
 - The product is found and verified but the product is marked as recalled. The manufacturer sends an invalid response but does not indicate the product is recalled.
 - The product is found and verified but the product is expired. The manufacturer sends an invalid response but does not indicate the product is expired.
- **Invalid Product - Contact Manufacturer:** Displays only for downstream partners, such as wholesalers. The product is verified but cannot be verified as legitimate. However, the system returning the information does not provide a reason as to why the product is invalid. An error displays.
- **Unable to Verify:** The product is not found in Product Information Manager or an external VRS. The system could not verify whether or not the product is legitimate. In this case, it is likely the manufacturer is not connected to a VRS.

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:

- You may need to loan some of your medication to another healthcare provider, such as a hospital.
- 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.)

Loaning Medication and 340B

Currently, in order do 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.

Detailed procedures follow.



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

1. Select **Serialized Operations Manager** in the **Modules** menu.
2. Select **Queries > [Get Serial Number Status](#)**.

3. Enter the **Serial Number**.
4. Click **Search**.
5. Note the **Last Delivery Number**.

The screenshot shows a web interface titled "Get Serial Number Status". Below the title is a search criteria section with a dropdown arrow and the text "Search Criteria". Underneath, there is a "SERIAL NUMBER" field with a red asterisk, containing the value "011794119946321721140000043738". To the right of the field are "Search" and "Reset" buttons. Below the search section, there are two columns of information. The left column is titled "Serial Number Information" and lists: SERIAL NUMBER (011794119946321721140000043738), ENCODING TYPE (A(01)+A(21)), and COMMISSIONING LOCATION (487902.870039.0). The right column is titled "SERIAL NUMBER STATUS" and lists: SERIAL NUMBER STATUS (Commissioned), ITEM STATUS (Pending Receipt), REGISTERED (False), and LAST DELIVERY NUMBER (AW-20230523, highlighted in yellow). Below these columns is an "Item Information" section listing: ITEM CODE (GTIN-14 17941199463217) and LOT NUMBER.

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



Step 2: Find and Receive the Inbound Receipt

1. Select **Serialized Operations Manager** in the **Modules** menu.
2. Select **Inbound Movement** > [View Receipts](#).
3. In the **Search Criteria** section enter the **Delivery Number**.
4. Ensure the **Status** is **Unsubmitted**.
5. Click **Search**.
6. Click the [Delivery Number](#) link in the **Delivery Number** column.
7. Click **Next**.
8. Click **Submit**.

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

9. 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 **Serialized Operations Manager** in the **Modules** menu.
2. Select **Outbound Movement** > [Create Delivery](#).
3. Enter a **Delivery Number** of your own choosing.
4. For **Sale Type**, select **Sale - In Country**.
5. For **From Country Code** and **To Country Code**, select **US**.
6. Enter a **From Business**, **To Business**, **Ship From Location** and **Ship To Location**.

Four addresses are required for US EPCIS data exchange.

7. Enter the **Delivery Number** in the **Portal Access Code** field.

Your partner uses this to access the Shipment Notice on the Product Information Manager Shipment Notices page.

8. 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.

9. Click **Next**.

10. Click **Next** again.

11. In the **Serial Numbers** section, select **Scan Serial Numbers**. This option allows you to type in the box.

Enter the serial numbers in the box.

12. Ensure the **Automatically disaggregate serial numbers that are aggregated to another number** check box is selected.
13. Click **Submit**.



Void an Outbound Delivery

1. Select **Serialized Operations Manager** in the **Modules** menu.
2. Select **Outbound Movement** > [View Deliveries](#).
1. Set the **Status** to **Submitted**.
2. Enter additional search criteria as necessary to locate the delivery.
3. Click **Search**.
4. Click the [Delivery Number](#) link for the delivery you wish to void.
5. Click **Void Delivery** at the bottom of the screen.
This brings you to the Void Delivery screen.
6. Enter the Void Information.
 - a. Select a **Reason** for the void.
 - b. For **Order Cancelled**, select **Yes - order was cancelled**.
7. Click **Submit**.

User Management

Learning Objectives

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

- Add users to TraceLink.
- Add users to Serialized Operations Manager and Product Track.
- Create and assign a custom role.

Overview

For a user to view serialization data, you must first add them to TraceLink. At that point, the user will not have access to any of the applications they need to complete their tasks. Therefore, you assign them permissions by adding them to Serialized Operations Manager and assigning them a custom role. The custom role gives the user access to only those functions in Serialized Operations Manager that they need.

If you want a user to access ASNs and serialization data in Product Track, you must also add them to Product Track.



Add a New User

Note: To add users, you must have the Company Administrator role or another role that allows full access to the Manage Users function.

To add a user:

1. Log in to TraceLink by entering <https://www.tracelink.com> in your browser and clicking **Log in**.

To log in to a test account instead, enter <https://itest.tracelink.com> in your browser.

2. Select **Company Administration > Users** in the user menu on the top right of the TraceLink window.
3. Click **Add New User(s)**.
4. For **Email Addresses of New Users**, enter one or more email addresses.

If you enter more than one address, separate the email addresses with commas.

5. Click **Submit Changes** and click **Confirm**.


TraceLink sends the user an activation email. The user clicks the link to create the account and password.

You must invite the user to an application to provide them with access to the application. See *Adding Users to Applications*.




Add a User as a Manager (formerly Service Administrator)

To add a user as a Manager:

1. Select **Company Administration > Services** in the user menu on the top right of the TraceLink window.
2. Enter **Search Criteria** to locate the application to which you are adding the user.
3. Click **Search**.
4. Find the application and configure it.
 - If your company is the Owner of the application, click the [Configure Published Service](#) link.
 - If your company is linked to the application, click the [Configure Subscription](#) link.
5. In the **Service Administrators** tab at the bottom, click the  [Add Another Service Administrator](#) link on the right.

Note that you do not have to make any updates to the top portion of the page, just in the **Service Administrators** tab.

6. In the **Enter a company member name** field, type the user's email address or click the drop-down icon  and select a user.
7. Click **Submit**.



Create a Role

To create a role:

1. Select **Company Administration > Roles** in the user menu on the top right of the TraceLink window.
2. Click **Create New Role**.
3. For **Role Information**, enter the **Name** and **Description** of the role you're creating.

The **Permissions** tab lists the applications and functions for which you can customize access.

4. Under **Function**, select all functions you want users with this role to access.

You can also click the [Select All](#) and [Deselect All](#) links to set the permissions.

Note: To leave the default permissions for a function, do not select the function.

5. Under **Access Level**, select **Full Access** or **Read Only** for each function you selected.

If you select **Full Access**, users with this role can create or update the data managed by the function. If you select **Read Only**, users can view the data only.

You can also click the [Grant Full Access to selected functions](#) or [Grant Read Only access to selected functions](#) links to set the access level.

Note that for certain functions you cannot assign **Read Only** access. For example, for Serialized Operations Manager, it is not possible for a user to have **Read Only** access to **Create Delivery** since it is an operation.

6. Optionally, you can add users to the role during the create action.

You can do this in either of two ways. In the **Users** tab:

- Click the [Add User to Role](#) link on the top right. Fill in the user information.
- To add a list of users, click the [Upload List of Users](#) link on the top right. Select a CSV file to upload. The following table describes the columns. Each entry must be on its own line.

Column	Description
User Email Address	Email address of the user you would like to add to the role.
Action	Add the user to the role. Valid values (case sensitive): Add.

Refresh the screen to see the results. If the upload is successful, the users appear in the users list. Otherwise, an error message displays indicating the entries with errors.

Note that you do not have to add users when you create a new role. You can either update a role to add users or assign users to roles in **Company Administration > Users**.

7. Click **Submit**.

A success message appears in green at the top of the window. It might take a few minutes for the new role to appear in the Manage Roles list. Refresh your browser to refresh the list.

Assigning a Custom Role


You can assign a role to any user with a TraceLink account—Business Users or Company Administrators.

If you assign a user multiple roles that control access to the same function, the user is assigned the highest access level for the function. So if one of a user's roles provides full access to a function and another of the user's roles provides read-only access to the same function, the user receives full access.

Assign a Custom Role

To assign a custom role:

1. Select **Company Administration > Users** in the user menu on the top right of the TraceLink window.
2. Enter **Search Criteria**. To list all users, set **Account Status** to **All** and set **Role** to **All**.

If the **Search Criteria** fields don't show, click the expand icon .

3. Click **Search**.
4. Find the user in the list and click the [View Details](#) link in the Actions column.
5. In the **Roles** tab, select the custom role you want to assign to the user.

Note: If the **Company Administrator** role is selected, the user has full access to all Company Administration functions. Uncheck the **Company Administrator** role to assign custom roles that include a subset of Company Administration permissions.

6. Click **Submit Changes** and click **Confirm**.

When the user next logs in to TraceLink, the functional permissions take effect.