

US Compliance, version 1.2.0

Release Summary | Revision 02

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Release Summary

What's new in the user interface

Explore what's new in the US Compliance, version 1.2.0 solution release. To learn more about the US Compliance, version 2023.1.2 app that powers the solution, see [What's new in the system](#).

Release information


This document describes the TraceLink capabilities included in the US Compliance, version 1.2.0 solution release, which is available on Validation on 13 Jul 2023 and Production on 27 Jul 2023.

The following solutions are impacted by this release and will be updated to the version listed:

- US Compliance, version 1.2.0

Apps that support this solution version:

- US Compliance, version 2023.1.2

 This release introduces US Compliance on the Opus Platform, which includes functionality currently available through US Product Track on Track & Trace Services. Future releases will include usability improvements that leverage the new platform's capabilities. At this time, there are no changes to the asynchronous messages and SOAP APIs related to this functionality, and users can still log in to Track & Trace Services to continue using the UI there as well. For more information, see [What's the difference between US Compliance and US Product Track?](#)

The features below are in order of functional relevance (i.e. the typical order in which a user executes a function or task).

Revisions

Date	Revision	Description
19 Jun 2023	01	Initial version.
13 Jul 2023	02	<p>The following updates have been made since the previous revision was distributed:</p> <ul style="list-style-type: none"> • The release version is updated from US Compliance, version 1.0 to US Compliance, version 1.2.0. • Added the Access Shipment Notices for Deliveries from Indirect Trade Partners feature. • Added the Send Shipment Notices for Deliveries to Direct Trade Partners Not Linked to US Compliance feature. • 0 issues are added to Resolved issues. • 11 issues are added to Known issues.

Features

Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers use the US Compliance solution (powered by the US Product Track app) to meet the interoperable, electronic tracing requirements for serialized products established by the [US Drug Supply Chain Security Act](#) (DSCSA). US Compliance allows Owners and Partners to view delivery details and the transaction information and transaction statement (T2) documents for the product and lot combinations on those deliveries. For more information about the business logic that generates deliveries and T2 documents in US Compliance, see [What's new in the system](#).

The following new or updated functionality is included in this release.

Filter and View Serialized Deliveries

Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers who own or link to US Product Track can [filter and view shipments and receipts](#) for the US target market. For more information about the app feature that generates these serialized deliveries, see the [Filter and View Serialized Delivery](#) feature in the US Compliance, version 2023.1.2 release.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Pharmaceutical Manufacturer (both Owners and Partners)
 - Repackager (both Owners and Partners)
 - Wholesale Distributor (both Owners and Partners)
 - Dispenser (both Owners and Partners)

Filter and View T2 Documents

Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers who own or link to US Compliance can [filter and view the T2 documents](#) that TraceLink generates based on the deliveries they send or receive. For more information about the app feature that generates these T2 documents, see the [Filter and View T2 Documents](#) feature in the US Compliance, version 2023.1.2 release.

A regulatory or quality compliance manager can filter to view or download specific T2 documents for internal audits or audits by the US Food and Drug Administration.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Pharmaceutical Manufacturer (both Owners and Partners)
 - Repackager (both Owners and Partners)
 - Wholesale Distributor (both Owners and Partners)
 - Dispenser (both Owners and Partners)


Access Shipment Notices for Deliveries from Indirect Trade Partners

Pharmaceutical Manufacturers, Repackagers, and Wholesale Distributors who link to Product Information Manager and own both Serialized Operations Manager and US Compliance can mark outbound shipments in Serialized Operations Manager as drop shipments. US Compliance then sends the shipment notices for these deliveries to Product Information Manager so that indirect trade partners (e.g. Dispensers) who link to Product Information Manager can [access these shipment notices](#) without linking to the sender's US Compliance network, which allows all members of the supply chain to be in compliance with the DSCSA even if they do not have a direct business relationship with each other.

For example, a Wholesale Distributor might purchase product from a Pharmaceutical Manufacturer and then sell it to a Dispenser before receiving the physical delivery. The Wholesale Distributor can then ask the Pharmaceutical Manufacturer to send the physical delivery straight to the Dispenser. The Dispenser does not have a direct relationship with the Pharmaceutical Manufacturer, so they are not linked to the Pharmaceutical Manufacturer's US Compliance network, but the Pharmaceutical Manufacturer can mark the delivery as a drop shipment, provide a portal access code, and send the shipment notice to Product Information Manager. Then the Dispenser can go to Product Information Manager and use the portal access code to find the shipment notice, where they can download the original EPCIS message to provide an auditor if necessary.

Shipment notices are sent to Product Information Manager for indirect trade partners to access if the original shipment:

- Is marked as a **Drop Shipment**.
- Includes a **Portal Access Code**.

 Product Information Manager will be released shortly after this US Compliance release.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Pharmaceutical Manufacturer (both Owners and Partners)
 - Repackager (both Owners and Partners)
 - Wholesale Distributor (both Owners and Partners)
 - Dispenser (both Owners and Partners)

Send Shipment Notices for Deliveries to Direct Trade Partners Not Linked to US Compliance


Pharmaceutical Manufacturers, Repackagers, and Wholesale Distributors who link to Product Information Manager and own both Serialized Operations Manager and US Compliance can [automatically make shipment notices available for deliveries that are sold to direct trade partners who are not linked to their US Compliance network](#). When an Owner enters a **To Business** for the shipment in Serialized Operations Manager, but that **To Business** is not actually linked to the Owner's US Compliance network, the shipment notice

is automatically sent to Product Information Manager, which allows the **To Business** to view the shipment notice details and download the original EPCIS message for the shipment notice to provide to an auditor.

For example, a Pharmaceutical Manufacturer might sell a shipment of vaccines directly to a doctor's office, because the doctor's office will be dispensing those vaccines to their patients in the office, rather than sending patients to a pharmacy. However, this doctor's office is not linked to the Pharmaceutical Manufacturer's US Compliance network. When TraceLink attempts to send the shipment notice to the doctor's office, Info Exchange returns a map out error because the doctor's office is *not* linked to the Pharmaceutical Manufacturer's US Compliance network. When this map out error occurs, US Compliance then sends the shipment notice and its details to Product Information Manager, where the doctor's office can access and download the shipment notice details.

Shipment notices are sent to Product Information Manager for direct trade partners to access if the original shipment:

- Specifies a **To Business** that is not linked to the Owner's US Compliance network.
- Is *not* marked as a **Drop Shipment**.
- Includes a **Portal Access Code**.

 Product Information Manager will be released shortly after this US Compliance release.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Pharmaceutical Manufacturer (both Owners and Partners)
 - Repackager (both Owners and Partners)
 - Wholesale Distributor (both Owners and Partners)
 - Dispenser (both Owners and Partners)

Resolved issues

There are no resolved issues in this release.

Known issues

The following known issues are included in this release and will be fixed in a future patch release.

ID	Interface	Issue Description
33220: Unable to Download Serial Number CSV File	Web UI	When one shipment is processed with 200K SNs, the Serial Number CSV file for that specific shipment can be successfully downloaded. However, when multiple shipments, each with 200K SNs are processed, the CSV files for all shipments are unavailable for download.
33232: Search Not Working with Special Character as First Character	Web UI	Search does not provide accurate results if the first character of the search string is a special character, for example, plus sign (+) pound sign (#).
33237: Screen Auto-Refreshes Repeatedly When Switching from Process Drop-down	Web UI	When changing the Process drop-down between Deliveries and T2 Documents, the screen refreshes repeatedly.
33382: Collapsing All Parts on View T2 Document UI Leaves One Section Displayed	Web UI	On the View T2 Document UI, taking the action to collapse detailed information allows Product Identifiers to remain displayed on the screen.
33385: Next Page Arrow Displays When No Further Records Available	Web UI	The next page arrow on the Product Identifiers table of the View T2 Document UI displays despite no additional records available to display.
33690: Partial Text Search Not Supported	Web UI	Searching with partial text using a wildcard character (*) is not supported.
33691: End Date Appears Incorrectly When	Web UI	When navigating using the breadcrumbs back to the Search page, the end date in the Search filter displays an additional day

ID	Interface	Issue Description
Navigating Back to Search Page		compared to the end date set originally in the Search criteria.
33693: Case Insensitive Search Not Supported	Web UI	Search results are based on case sensitive search criteria and do not support case insensitive searches.
33702: Downloading Shipments Without Search Criteria in CSV Not Supported	Web UI	If Search Criteria is not entered, downloading Shipments to a CSV file fails. Search criteria must be entered to successfully download Shipments in a CSV.
33703: Search Not Available on Sender and Receiver Names Containing Spaces	Web UI	Searching on a Sender or Receiver name containing any spaces fails to provide accurate results.
33712: Custom Date Range Month Not Updated When Using Calendar Date Selection	Web UI	In the Review Deliveries screen, when using the Calendar Date Selection popup to search on the Date Shipped field, the selected month is not updated to the Date Shipped field.