US Compliance, version 2023.1.2

Release Summary | Revision 02

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Release Summary

What's new in the system

Explore what's new in the US Compliance, version 2023.1.2 release. To learn more about what's new in the US Compliance, version 1.2.0 solution that provides the user interface for this app, see What's new in the user interface.

> 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?

Release information

This document describes the TraceLink capabilities included in the US Compliance, version 2023.1.2 app release, which is available on Validation on 13 Jul 2023 and Production on 27 Jul 2023.

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

- US Compliance, version 2023.1.2

  Solutions supported by this app version:

  - US Compliance, version 1.2.0

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	The following updates have been made since the previous revision was distributed: • The release version is updated from US Compliance, version 2023.1.0 to US Compliance, version 2023.1.2. • 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. • 0 issues are added to Known issues.

API features

There is no new or updated API functionality included in this release.

System features

Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers use US Compliance to meet the interoperable, electronic tracing requirements for serialized products established by the US Drug Supply Chain Security Act (DSCSA). For outbound shipments, US Compliance receives the shipment details from Serialized Operations Manager, parses the NDCs and lot numbers of the products that require traceability, and generates the transaction information and transaction statement documents (often referred to as the T2 documents) for each NDC and lot number combination. US Compliance then sends the shipment details on to the company

purchasing the product. For inbound receipts, US Compliance receives the receipt details from the company selling the product, parses the NDCs and lot numbers of the products that require traceability, generates the T2 documents for each NDC and lot number combination, and creates a corresponding receipt in Serialized Operations Manager. For more information about how the deliveries and T2 documents are visible in the web UI, see What's new in the user interface.

The following new or updated system functionality is included in this release. These features are changes to the app to support another feature and do not have any impacts on their own.

Filter and View Serialized Deliveries

US Compliance provides the original delivery details for the US target market to Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers who own or link to US Compliance. These delivery details are sourced from the Owner's instance of Serialized Operations Manager or a US Product Track GS1 US Healthcare Transaction History (EPCIS v1.2) message sent by an upstream trade partner in case companies need to retrieve the original delivery details during an audit or troubleshoot problems with the delivery. US Compliance also uses these deliveries to generate T2 documents. See Filter and View T2 Documents below for more information.

By linking to their trade partners in US Compliance, Owners can send or receive deliveries created in Serialized Operations Manager while maintaining the data integrity and security of their serialized system of record.

> Your company's current US Product Track Links from Track & Trace Services are available in US Compliance on the Opus Platform.

Impacts analysis

- Interface options:
  - There are no UI or API impacts. Only processing logic is impacted.

- 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

US Compliance generates T2 documents based on the deliveries sent or received by Pharmaceutical Manufacturers, Repackagers, Wholesale Distributors, and Dispensers who own or link to US Compliance. These T2 documents are required by the DSCSA to document the transfer of ownership, which supports product traceability, and provide attestations that the company transferring ownership complied with the DSCSA product sourcing requirements. Within each delivery, US Compliance determines which product and lot combinations require traceability and generates a T2 document for each of these combinations. If a product on the delivery does *not* require traceability (as designated in Master Data Exchange for the US target market), then US Compliance does *not* create a T2 document.

Impact analysis

- Interface options:
    - There are no UI or API impacts. Only processing logic is impacted.
- 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 T2 Documents for Deliveries from Indirect Trade Partners

This release supports sending receipt details to Product Information Manager so that indirect trade partners can access them. For more information about the corresponding solution feature, see the US Compliance, version 1.2.0 release.

Impact analysis

The impacts for this feature are the same as the Access T2 Documents for Deliveries from Indirect Trade Partners feature in the US Compliance, version 1.2.0 solution release.

Access Shipment Notices for Deliveries from Indirect Trade Partners

This release supports sending shipment notices to Product Information Manager so indirect trade partners can access them. For more information about the corresponding solution feature, see the US Compliance, version 1.0 release.

Impact analysis

The impacts for this feature are the same as the Access Shipment Notices for Deliveries from Indirect Trade Partners feature in the US Compliance, version 1.2.0 solution release.

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

This release supports sending shipment notices for deliveries to Product Information Manager so that direct trade partners that are *not* linked to the Owner's US Compliance network can access them. For more information about the corresponding solution feature, see the US Compliance, version 1.2.0 release.

Impact analysis

The impacts for this feature are the same as the Send Shipment Notices for Deliveries to Direct Trade Partners Not Linked to US Compliance feature in the US Compliance, version 1.2.0 solution release.

Resolved issues

There are no resolved issues in this release.

Known issues

There are no known issues in this release.