

Supply Chain Work Management, version 8.0

Release Summary | Revision 03

tracelink
NETWORK FOR GREATER GOOD

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Release Summary

What's new in the user interface

Explore upcoming changes in the Supply Chain Work Management, solution version 8.0 solution release. To learn more about the app that powers the solution, see [What's new in the APIs](#).

Release information

This document describes the TraceLink capabilities included in the Supply Chain Work Management, solution version 8.0 solution release, which is available on Validation on 28 September 2023 and Production on 13 Oct 2023.

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

- Supply Chain Work Management, solution version 8.0

Apps that support this solution version:

- Agile Process Teams, version 2023.5

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
14 Sep 2023	01	Initial version.
28 Sep 2023	02	<p>The following updates have been made since the previous revision was distributed:</p> <ul style="list-style-type: none"> • The Communicate Recall Responses to TraceLink system feature is added.

Date	Revision	Description
		<ul style="list-style-type: none"> • 4 issues are added to Resolved issues. • 0 issues are added to Known issues.
Oct 13 2023	03	<p>The following updates have been made since the previous revision was distributed:</p> <ul style="list-style-type: none"> • The Production date is updated to 13 Oct 2023 in the Release Information section.

UI Features

The Supply Chain Work Management, version 8.0 solution introduces the Recalls process for Agile Process Teams Owners and their internal locations to manage and respond to recalls issued by the FDA. Companies that own or link to APT can monitor, respond to, and review and approve recall responses through a secure, shared workspace that provides improved visibility and streamlined communication between stakeholders and trade partners.

The new Recalls process in the Supply Chain Work Management solution allows:

- Recall coordinators and pharmacy technicians to:
 - Receive notifications when the FDA publishes a new recall that may impact any of their company's locations.
 - Opt out of recalls that do not impact a location they have access to.
 - Send recall acknowledgment, impact, quantity, and completion responses to TraceLink on behalf of a location.
 - View the details of a location's recall response.
 - Review and approve a location's recall response if their company is configured to require recall response approval.
 - View updates to a recall made by the FDA or the recalling company.
 - Download all recall responses for a specific location or all locations they have access to for FDA effectiveness reporting.
 - Track a recall's progress across the entire company.

- Send followup messages to potentially impacted locations reminding them to respond to a recall.
- Monitor that status of all ongoing recalls for a specific location or across all locations they have access to.



For more information about which roles have access to which actions, see the [Roles](#) for the new Recalls process.

In this release, all recall responses are submitted only to TraceLink. Companies can use TraceLink to access those responses and download them to use for FDA effectiveness reporting. In a future release, responses submitted to TraceLink can be communicated back to the Pharmaceutical Manufacturer responsible for the recall.

This release also includes enhancements to existing Supply Chain Work Management processes.

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

Submit a Location's Recall Responses to TraceLink

Companies that own Supply Chain Work Management can use the new Recalls process to view the details of a recall issued by the FDA and submit a [acknowledgment](#), [impact](#), [quantity](#), and [completion](#) responses for each of their locations to TraceLink. Additionally, locations that are not impacted by a recall can [opt-out](#) of it. Enabling locations to submit recall responses allows them to quickly and effectively determine how a recall impacts them and communicate that impact to the rest of their company, reducing the time and effort required to respond to and manage recalls.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Review and Approve Recall Responses Submitted by Locations

Recall coordinators for companies that own Supply Chain Work Management can use the new Recalls process to view and [approve or reject](#) a location's responses to a recall if their company is configured to require recall response approval. Approving or rejecting a location's recall responses enables companies and recall coordinators to ensure their locations' responses are accurate and all product is accounted for by checking the responses for inconsistencies and discrepancies.

For example, if a location submits a recall response saying they have no stock of the product being recalled, but the recall coordinator notices that their inventory management software indicates they have 50 bottles in stock, the recall coordinator can reject the recall response and ask for clarification as to why the location indicated they did not have any quantity on hand in the response.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

View All Recall Responses Submitted by Locations

Companies that own Supply Chain Work Management can use the new Recalls process to [view](#) whether a company or location has submitted the acknowledgment, impact, quantity, and completion responses to a recall. Viewing all of the responses to a recall across companies and locations enables users to quickly determine which responses are outstanding and which have been submitted based on the response type (e.g. impact) and product in the recall.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

View the Details of Recall Responses Submitted by Locations

Companies that own Supply Chain Work Management can use the new Recalls process to [view the details](#) of each response type submitted by a location for a recall. Viewing the details of a response allows users to view previously submitted responses for record keeping or when investigating any issues with the response.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Export Recall Responses in CSV Format

Companies that own Supply Chain Work Management can use the new Recalls process to [export](#) all responses to a recall in CSV format for the entire company or a specific location. Exporting the responses to a recall enables companies to quickly retrieve those records

and submit them to the recalling company to comply with FDA effectiveness reporting requirements or to retain them for record keeping purposes.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Track a Recall's Progress Across All Locations

Recall coordinators for companies that own Supply Chain Work Management can use the new Recalls process to view high-level information about the recall and [track](#) the overall response status for all of their locations. Viewing high-level information about the recall and which locations are in which state of the recall (e.g. not acknowledged) enables recall coordinators to quickly understand the overall progress made by their company towards completing the recall without having to dig into the locations individually to view the status of each response.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Send Follow-Up Messages to Locations Based on Their Response Status

Recall coordinators for companies that own Supply Chain Work Management can use the new Recalls process to [send follow up messages](#) to locations with the same response status for a given recall. Sending custom follow-up messages for a recall to locations with the same response status enables recall coordinators to communicate with or quickly remind locations with the same response status of deadlines that have past or are approaching.

For example, a recall coordinator who wants to see which of their locations hasn't acknowledged the recall can quickly view all the locations whose **Response Status** for the recall is **Not Acknowledged** and send a custom message to those locations reminding them to acknowledge the recall.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

View the Response Activity for a Recall

Companies that own Supply Chain Work Management can use the new Recalls process to [view](#) the actions taken and modifications made to a location's recall response. Viewing the updates made to a recall in chronological order helps recall coordinators and pharmacy technicians investigate any irregularities or discrepancies related to a location's response activity for a recall.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

View Recall Updates Made by the FDA or the Recalling Company

Companies that own Supply Chain Work Management can use the new Recalls process to [view](#) a public recall's version history and compare two versions of the recall to see the actions taken and modifications made by the FDA or the recalling company from one version to another. Comparing two versions of the recall allows recall coordinators to quickly view only the attributes that have been updated from one version to the next instead of having to switch between the older and newer version of the recall to find what is changed. Additionally, viewing the differences between recall versions enables users to clearly see what updates were made and when they were made and help investigate any irregularities or discrepancies related to a recall's timeline.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Monitor Ongoing Recalls for a Company or Location

Companies that own Supply Chain Work Management can use the new Recalls process to [monitor](#) recalls with an FDA status of ongoing that they are potentially impacted by at the company or location level. Using the dashboard to monitor recalls enables users to visualize key metrics about their recalls such as the number of recalls in each response status (e.g completed), the number of recalls due in the coming weeks, and the number of recalls by product type (e.g biologics). With this information, companies can quickly make informed decisions about which recalls require immediate attention and the state of all recalls for their company or location.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)


Receive Emails and Notifications for Recalls

Companies that own Supply Chain Work Management can use the new Recalls process to receive emails and notifications in the Supply Chain Work Management solution when any of the following occur:

- A new recall noticed is published by the FDA or the recalling company.
- An existing recall is updated by the FDA or the recalling company.
- A recall is assigned a user.
- A recall response is past due.
- A recall response is due withing a specified number of days.

- A location submits a recall response for review.
- A recall response submitted for review is rejected.
- A follow-up message about a recall is received.
- Another user follows a recall you are following or assigned to you.

Receiving emails and notifications about relevant recalls improves overall communication about a recall and ensures key pieces of information and deadlines are not easily missed.

 In this release, users receive notifications for all of the scenarios listed above by default. Contact TraceLink support to modify your notification settings.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Receive Recall Data for Public Recalls Initiated in the Last Year

Companies that own Supply Chain Work Management can have the new Recalls process configured to display the last 12 months of recalls issued by the FDA populated in their instance of Supply Chain Work Management. Configuring Supply Chain Work Management to display the last 12 months of recalls allows Owners to respond to recent recalls using TraceLink. Supply Chain Work Management Owners can also choose to configure the Recalls process to only display recalls added or updated by the FDA after the initial configuration of their Recalls process.

⚠ If Supply Chain Work Management is configured to initially display the last 12 months of recalls, only the locations initial linked to the Owners instance of Supply Chain Work Management during configuration will display the historical recalls data. Any locations linked after initial configuration will only display recalls added or updated by the FDA after the location is linked.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Enhanced Side Menu Navigation

For all existing processes, users can navigate between the Monitor, Search, and Add screens using the new Search and Add options in the Do menu. These new Do menu options provide a more intuitive experience than the existing Dashboard View and Table View icons in the toolbar and allow users to quickly switch between the Monitor, Search, and Add screens.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Enhancements to Existing Processes

The following enhancements are made to existing processes:

- For all processes, the breadcrumb navigation is enhanced to allow users to quickly navigate to a searched instance and back to the Search screen without losing the applied search filters. This eliminates the need to re-apply search filters every time users search for a process and allows easy navigation across searched instances.
- A new keyword filter is added to the Search screen for Incidents, Compliance Exceptions, Tasks, Sub-tasks, and Document Reviews. Users can use the keyword filter to retrieve search results by specifying a keyword.
- The [compliance exceptions](#) dashboard is updated to include two new tabs:
 - Overview – This tab provides users with a quick glance at the number of compliance exceptions as cards, categorized according to Category, Product, Status, Accountable Entity, Priority, and Recent Updates.
 - Pending Actions – This tab enables users to see the number of pending actions as cards, categorized as per Due Date, Business Unit, Accountable Entity User, and Responsible User. The Pending Actions tab and all cards in the Pending Actions tab, except the By Due Date card, are new and introduced in Supply Chain Work Management, solution version 8.0.
- On the Search Compliance Exceptions screen, users can [access](#) the new View Responses panel using the action menu. The new comments panel saves the time and effort to open each compliance exception, navigate to the comments section, and view responses.
- For the Task process, the new Date Submitted and Date Closed fields are added to the General section of the View Sub-tasks screen. These two fields help users track when a sub-task was submitted and closed.
- For Incidents, Tasks, Sub-tasks, and Document Reviews, the number of notifications received by followers when the process is modified are consolidated into a single notification for all changes made in two minutes of each other.
- For all processes, except Direct Supplier Incidents, the Process ID field in the Linked Processes section will also show the Process Type and Status of the linked process.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Enhancements to Incidents and Document Reviews

On the Add and Edit Screens for [Incidents](#) and [Document Reviews](#), intuitive validation has been added on associated fields to improve the user experience. For example, when adding a new instance for any of these processes, the **Incident Sub-category** field is now disabled if an **Incident Category** is not selected.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

System features

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.

Communicate Subscription Rules for Public Recall Notifications to TraceLink

This feature enables TraceLink to populate Owners Supply Chain Work Management instances of the new Recalls process with new recalls when they are published by the FDA.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - Dispensers (Owners and Partners)

Communicate Recall Responses to TraceLink

This feature enables TraceLink to communicate recall responses submitted in Supply Chain Work Management to other TraceLink applications, such as Product Information Manager.

Impact analysis

- Interface options:
 - There are no UI or API impacts
- Business segment impacts:
 - Dispensers (Owners and Partners)

Resolved issues

ID	Interface	Issue Description
31330: UI - Transaction ID Section Fails to Function Correctly	Web UI	<p>When creating a new Complaint issue, several aspects of the Transaction ID section do not function correctly. An update is required to address these display issues.</p> <p>This issue is resolved.</p>
31533: UI - Additional Content Sections Fail to Display Correctly	Web UI	<p>In the Add Incident screen, the UI fails to display additional arrayed elements correctly after the initial click. An update is required to correct this issue.</p> <p>This issue is resolved.</p>
32595: Digital Recall Data Entered on PIM UI Fails to Display in APT	Web UI	<p>Digital Recall data (containing only mandatory fields) entered via the Product Information Manager (PIM) UI does not display when viewing from the APT UI screens. An update is required to correct this situation.</p> <p>This issue is resolved.</p>
33787: Product Master Data Fails to Display in Impacted Product Field	Web UI	<p>Product Master Data selected from the Impacted Products drop-down field fails to display when viewing a saved incident. This affects all processes. An update is required correct this issue.</p> <p>This issue is resolved.</p>

Known issues

There are no known issues in this release.

What's new in the user interface

Explore upcoming changes in the Supply Chain Work Management, solution version 8.0 solution release. To learn more about the app that powers the solution, see [What's new in the APIs](#).

Release information

This document describes the TraceLink capabilities included in the Supply Chain Work Management, solution version 8.0 solution release, which is available on Validation on 22 Feb 2024 and Production on 23 March 2024.

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

- Supply Chain Work Management, solution version 10.0

Apps that support this solution version:

- Agile Process Teams, version 2024.1

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
25 Jan 2024	01	Initial version.

UI Features

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

Download Recalls in CSV Format and Usability Enhancements

This feature contains the following enhancements to the Recalls process:

- On the Search screen, users can now [Download a List of Recalls](#) displayed in the results table in CSV format.
- The following enhancements are made to improve navigation for the recalls process:
 - On the [View Product Details](#) screen for a particular recall, the icons for **Next** and **Previous** are replaced by buttons to increase visibility and allow easier navigation to a recall's list of products.
 - The **Responding Entity** field is now renamed more accurately to **Responding Locations** for clarity.
 - On the [Track Recall Progress](#) screen, in the addition to the **Tracelink Recall ID**, you can now use the **FDA Event ID** to search for specific recalls and track their progress.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

New Attributes to Compare Recall Versions and Minor Usability Enhancements

This feature contains the following enhancements to the Recalls process:

- On the [Compare Versions](#) screen, for updates to a particular recall, the following new comparison attributes are added:
 - NDC
 - Serial Number
 - Lot Number
 - Expiration Date

These attributes will be displayed only if they are updated across the compared versions.

- The following enhancements are added to improve usability:
 - For a recalled product, when no product quantity is provided, the **Product Quantity Recalled** and **Inventory Impacted** fields will display as "--" character.
 - On the [Search](#) screen, for newly created recalls, the **Last Activity** column will display the user name as Tracelink.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Allow External Users to Join a Supply Chain Work Management Network and Team

Application Administrators can now add external users to the Supply Chain Work Management network and teams. This allows a company to outsource its work to external users. For example, a Manufacturer owns Supply Chain Work Management and purchases products from a Contract Manufacturing Organization (CMO), which is also on the same network and team as the Manufacturer. With this feature, the Manufacturer can directly add the 3PL to their network and the team, so they can work on behalf of the Manufacturer.

For more information on how to add external users to a network and a Supply Chain Work Management team, see [Give users access to networks and links](#) in the Administer Help Center.

Impact analysis


- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Send Event-based Notifications to Email Distribution Lists

Owners can now configure email distribution lists to receive specific email notifications that are triggered by Supply Chain Work Management. For example, an Application owner can set up an email distribution list and configure it to receive notifications when External Manufacturing Incidents are created or updated.

The following processes support this feature:

- [Compliance Exceptions](#)
- [Tasks and Sub-tasks](#)
- [External Manufacturing Incidents](#)
- [Incidents](#)
- [Document Reviews](#)

 To add and configure a distribution list in the application, contact support.

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Enhancements to all Existing Processes

The following enhancements have been made to existing processes:

- You can now link [Sub-tasks](#) under the Linked Processes section. Sub-tasks are shared objects and can result from different processes or also lead to different processes. For example, a sub-task to ship a particular lot of products to a Pharmacy can lead to a compliance exception if the Pharmacy receives tampered products. Similarly, a compliance exception can lead to a new sub-task to replace the tampered drugs.
- You can now upload files only of the following types. Uploading any other file type is restricted to prevent malicious files and protect data.

- Document files:
 - .doc, .docx (Microsoft Word)
 - .xls, .xlsx (Microsoft Excel)
 - .ppt, .pptx (Microsoft PowerPoint)
 - .pdf (Adobe PDF)
- Image files:
 - .jpg
 - .jpeg
 - .png
 - .gif
 - .bmp
- Audio and video files:
 - .mp3 (audio)
 - .mp4 (video)
 - .avi (video)
 - .mkv (video)
- Text files:
 - .txt
 - .csv

Impact analysis

- Interface options:
 - Web UI
- Business segment impacts:
 - All business segments for both Owners and Partners

Resolved issues

There are no resolved issues in this release.

Known issues

There are no known issues in this release.