

SCM

Using Product Recall Management

24C

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Author: L V K Pratap Paleti

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1 Overview

Overview of Product Recall Management

Product Recall Management is an end-to-end integrated solution that enables you to capture product recalls from different sources.

Product Recalls

A product recall is a request from a manufacturer or regulatory authority to return a product that may be unsafe or defective. These safety issues or product defects may put the consumer at risk or put the manufacturer or seller at risk of legal action.

With ever increasing and changing regulatory compliance, you have to adopt effective recall management strategies and practices.

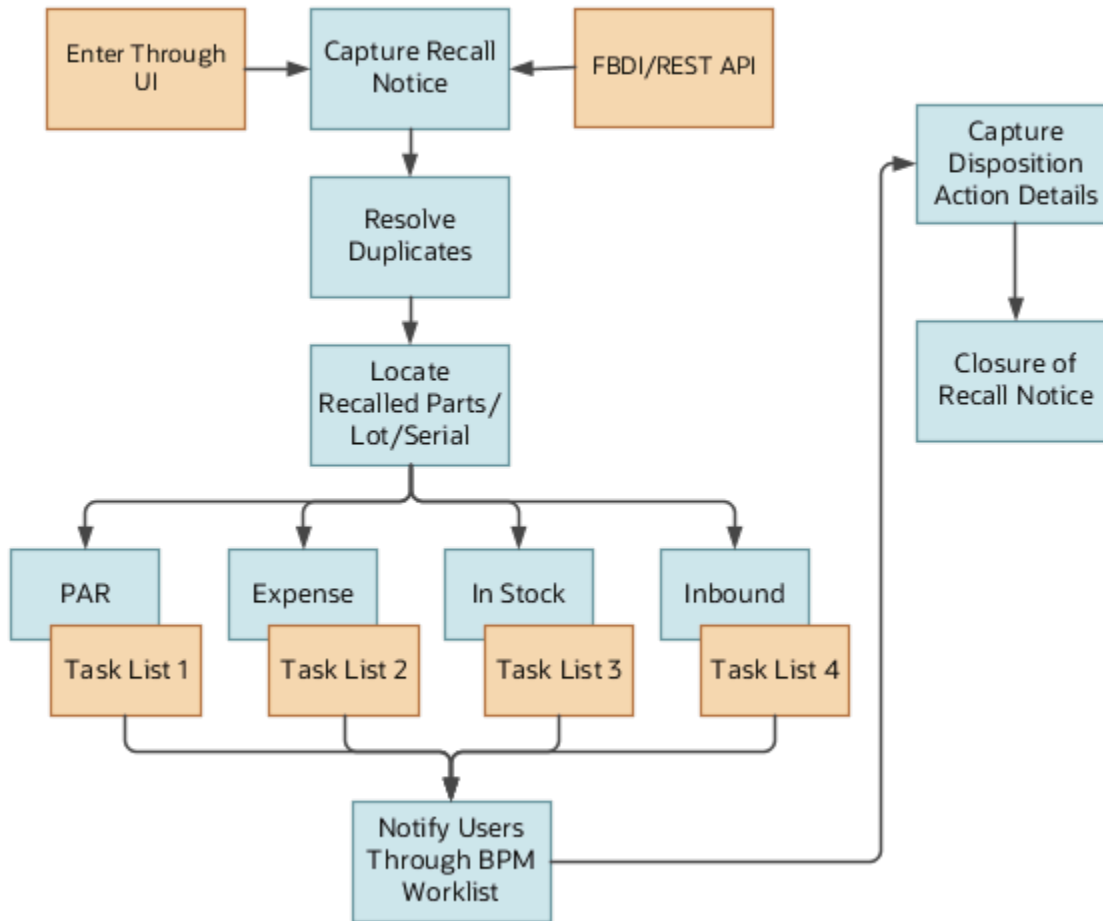
When there's a product recall, it's important that you quickly communicate to all the affected stakeholders about the recall and ensure that they complete the recall tasks assigned to them.

Product Recall Management

Use the Product Recall Management application to capture product recalls from different sources.

You can review inventory and expense purchases to get real-time information about the recalled parts. This helps you to efficiently align resources to quarantine the recalled products and take appropriate action.

This graphic illustrates the Product Recall Management process flow:



Here's what you can do in the application:

- Capture recall notices from different sources, like the regulatory authorities and manufacturers
- Resolve duplicates notices
- Locate recalled parts based on the on-hand inventory balance and historical purchases
- Assign tasks and align resources to quarantine and take action on the affected goods by notifying the respective stakeholders
- Monitor the status of the tasks and close the recall notice

2 Overview of Recall Notices

Overview of Recall Notices

You can capture recall notices for a business unit where you perform materials management functions like receiving, inventory transfers, and so on.

Prerequisites

Here are the prerequisites to capture recall notices:

1. Complete all setup tasks. See the Oracle Fusion Cloud SCM: Implementing Manufacturing and Supply Chain Materials Management guide for more information.
2. A Product Data Steward is responsible for managing the item data. The Product Data Steward must do the following for the recalled items:
 - o Define manufacturer and manufacturer part number (MPN). In Oracle Product Information Management, create trading partner items of type: Manufacturer, and define trading partner item relationship. See the Oracle Fusion Cloud SCM: Using Product Master Data Management guide for more information.
 - o While creating items, mark items as purchasable, and assign a purchasing category. See the Oracle Fusion Cloud SCM: Using Product Master Data Management guide for more information.
 - o For description-based items (description-based items are the items that aren't defined in Product Information Management), create a blanket purchase agreement with reference to the manufacturer and manufacturer part number. See the Oracle Fusion Cloud Procurement: Using Procurement guide for more information.

Create a Recall Notice

Specify the recall notice details on the Create Recall Notice page, under the General, Risk Profile, Contact, and Recall Instructions sections.

Only after you save the information under these sections does the Part Details section become editable, where you can enter the Manufacturer Part Number, and Lot and Serial information. After you have entered all the required information, save and publish the notice.

To create a recall notice:

1. Click Navigator > **Supply Chain Execution** > **Recall Notices**.
2. On the Recall Notices page, select the business unit, and click **Create Notice**.
3. On the Create Recall Notice page, specify the recall details under the General, Risk Profile, Contact, and Recall Instructions sections.
4. Click **Save**. The Part Details section becomes editable.
5. Enter part details like the Part Number, Device Identifier, GTIN, Model, Brand, Part Description and do a search. This automatically derives the manufacturer part number, supplier part number, or master item number. You can then add the manufacturer lot and serial details.

- Click **Publish** to publish the recall notice. You can also choose to click the Publish and Review Duplicates. The Review Duplicates page opens where you can resolve the duplicate recall notices, if any.

Import Recall Notices using FBDI

You can import recall notices from different external sources using the file-based data import (FBDI), which is a macro-enabled excel template.

You must run the Import Recall Notices process to import the recall notices to the Product Recall Management solution. See the Oracle Fusion Cloud Supply Chain Management: File-Based Data Import for SCM guide for more information.

Recall Notice Statuses and Actions

On the Recall Notices page, you can view all the notices, their statuses, and the actions you can take on them.

Here are the statuses and the actions that you can take on recall notices:

Status	Action	Meaning
New	Review	When you capture a new notice, it's in the New status. In this status, you can review, edit, or delete the notice.
Open	Review Duplicate	When you publish the notice, the status changes to Open. In this status, you can't edit or delete the notice. You can review potential duplicates and mark them as duplicate, so the duplicate recall notices aren't processed further.
Open	Locate	This action enables you to identify the recalled parts in different locations with different traceability statuses.
Open	View Progress	After you locate the items, you can view the progress of the assigned recall tasks and the trace details.
Duplicate	No Action	Recall notice is marked as duplicate. No other actions can be performed.
Withdrawn	Review	Recall notice is withdrawn. You can view the change history of the recall notice.

Status	Action	Meaning
Closed	Review	Recall notice is closed. You can view the change history of the recall notice.

When can you select the Replacement Type as Correction?

Here's when you can select the Replacement Type as Correction for a recalled product:

- If you can make a device correction and then use the product. For example, for a defective device, you can address the notice by calibrating the device.
- When there's a label correction.

In these scenarios, you don't have to return or destroy the product.

Can you capture a description-based item and a master item from the same manufacturer in one recall notice?

No, you can't capture a description-based item and a master item in the same recall notice even though they belong to the same manufacturer.

Note: Master item is the item defined in Product Information Management. You must create different recall notices with the same source document reference to process the recall. The reason is, the manufacturer is treated as two different parties when it's referenced from the Blanket Purchase Agreements and the Trading Partner Item Relationships.

How can I filter results on different pages?

You can filter results in the Recall Notices work area based on their statuses and date range in which they were created.

You can also use the predefined filters displayed in the work area for each status and date range. This helps you to quickly find records, review them, and take further action, if required. On the results returned based on the filters, you can do additional search to further narrow down the results.

You can also filter results in the Notice Progress page and Item Progress page to easily review the trace details and recall task progress in each location. You can search by any attribute that's part of Notice Progress or Item Progress. For example, let's say you want to monitor the progress of recall count task in a particular facility or location, you would

select the task and enter the inventory organization or location or subinventory in the Search field to filter out the results for that facility.

3 Duplicate Notices

Resolve Duplicate Notices

There's always a possibility of receiving the same recall notices from different sources or entities.

For example, you may receive a notice to recall a medication from the manufacturer, regulatory authority, and distributor. This could result in duplicate efforts in tracking and handling the recalled item. To avoid this, for a published recall notice, you can do a validation check for duplicates.

When you review for duplicate notices, an indicator is displayed suggesting which notices may be duplicates. You can ignore the duplicate suggestion and retain the notices for further processing.

Note: If you have already started locating items for a notice, you can't mark that notice as a duplicate.

To resolve duplicate notices:

1. On the Recall Notices page, click **Review Duplicates**.
2. On the Review and Select Duplicates page, review the potential duplicate recall notices. Deselect the notices to be processed further.

Note: Click on a suggested duplicate recall notice to view its details. The Review Notice page of that notice opens where you can view and analyze if the notice is a duplicate.

3. Click **Confirm**.

How are the potential duplicates automatically suggested?

When you click Review Duplicates on the Recall Notices page, the application compares all the notices with the same document reference number and manufacturer. It identifies and retains one recall notice and marks all other matching notices as potential duplicates.

Here's how that recall notice to be retained is identified:

- Recall notice that has the earliest initiation date is retained.
- If there is more than one recall notice with the same initiation date, then the recall notice initiated by the regulatory authority is retained.
- If you have already started locating items for a notice, and the locate process is either in progress or completed, then that recall notice is retained.

4 Locate Recalled Parts

Locate Recalled Parts

You can locate the recalled parts in the supply chain with different traceability statuses.

- For quantity-tracked locations, you can locate parts by the on-hand inventory balance.
- For non-quantity tracked locations, you can locate parts based on the historical transactions.

When an item is lot or serial controlled in Oracle Inventory Management, the recalled parts are traced based on the lot or serial information captured in the recall notice. However, if an item is modeled as a plain item in inventory, the recalled parts are traced by the recall period in which you received.

Recall period is the period between the track start and track end date, which you can specify either when creating a notice or while locating the recalled items.

If you specified the recall period when you create the recall notice, you can change that date range when you start locating the recalled items.

Note: You can locate the recalled parts using the supplier part number in addition to the manufacturer part number and master item number.

Here's what you can't locate:

- Recalled parts residing in a project inventory-enabled organization
- Recalled parts transferred across business units
- Items defined with lot, serial, or revision control in inventory that are delivered to the expense destination against purchase orders
- Items sold to external customers against sales orders
- Items residing as maintenance assets or customer assets
- Any recalled parts that are transferred across business units during the recall period. For example, let's say an item was initially received in an inventory organization in BU1. You perform an internal material transfer to move the item to an inventory organization in BU2. Once the item is received in BU2, when you locate recalled parts for the recall notice entered in BU2, the item is found in the that business unit along with estimated recall quantity. The estimated recall quantity considers the internal material transfer from BU1, regardless of whether the identified location is quantity tracked or not.

Prerequisites

You can locate recalled items using lot or serial only in one of these scenarios:

- Items with lot or serial control in inventory use the same lot or serial numbers as that of the manufacturer
- Manufacturer lot or serial is defined as supplier lot or serial and is mapped with the internal lot or serial number

Product Traceability Statuses

Here are the product traceability statuses and their meaning:

Product Traceability Status	Meaning
In Stock	Parts lying in the quantity tracked subinventories. These parts are available in the perpetual inventory and are identified based on the stock availability.
PAR	Parts issued to the subinventories where quantity isn't tracked. These parts issued to PAR locations are identified based on the transaction history and are shown as PAR with an estimated quantity.
Expense	Parts received in the expense locations.
Inbound	Parts in-transit, parts in the scheduled supply, and parts received in the receiving dock.

Assignment of Tasks

After the recalled items are traced, a sequence of tasks is assigned to them.

The task assignment is determined based on the product traceability status and replacement type captured in the recall notice.

Here is the sequence of tasks assigned for traced items based on their traceability status and replacement type:

Traceability Status	Replacement Type	Sequence of the Tasks Assignment
In-Stock or PAR or Expense	Credit with or without product return	<ol style="list-style-type: none"> 1. Perform Physical Count and Quarantine Recalled Parts 2. Perform Scrap or Return to Supplier for Recalled Parts 3. Raise Debit Memo Against Disposition for Recalled Parts
In-Stock or PAR or Expense	Make Correction to a Product	<ol style="list-style-type: none"> 1. Perform Physical Count and Quarantine Recalled Parts 2. Follow Recall Instructions
Inbound	Credit with or without product return	<ol style="list-style-type: none"> 1. Deliver Recalled Parts to Quarantine Location

Traceability Status	Replacement Type	Sequence of the Tasks Assignment
		<ol style="list-style-type: none"> 2. Perform Scrap or Return to Supplier for Recalled Parts 3. Raise Debit Memo Against Disposition for Recalled Parts
Inbound	Make Correction to a Product	<ol style="list-style-type: none"> 1. Deliver Recalled Parts to Quarantine Location 2. Follow Recall Instructions

Note: Once the Locate Recalled Parts process is executed for a recall notice, recall count tasks are generated for each location. Also, an FYI notification is sent to the stakeholders as per the rules configured in BPM work list. You can then download the VBCS Excel template either from the Recall Count task notification or the Notice Details page.

Notifications

Based on the business rules setup, notifications are sent to the impacted stakeholders to perform the recall tasks:

- When a task status changes from Not Started to In Progress, a notification is sent to the user as defined in the business rules.
- When recalled parts are identified in expense locations, a notification is sent to the requesters, by default.

See the Oracle Fusion Cloud SCM: Implementing Manufacturing and Supply Chain Materials Management guide for more information about configuring business rules.

Notifications have details about the assigned tasks. For example, here are the details shown in the notification for different tasks:

- Manufacturer lot and serial details for a count task.
- Purchase order or shipment information for a deliver task.
- Recall instructions for an instructions task.

Manage Inbound Shipments and PO Schedules

Whenever you either do a put away transaction or do a positive correction of the quantity while receiving the items, if the received items, lot, or serial has an open recall notice, a count task is automatically created and the status of such items changes to Count Task Generated.

Also, a trace detail record gets created with location details of where the items are put away. Based on these trace details, user completes the counting task. The recalled parts are quarantined and disposed.

Here are the different resolution statuses that the inbound trace records for a recalled item can be in:

Status	Description
Recall Exempted	When you mark an item as exempt from a recall. For example, when there is a recall notice for items, but only some of them were received. For the remaining items that are not shipped yet, if the supplier affirms that only non-defective items will be further shipped, you can then mark them as recall exempt.
Recall Auto Exempted	When you do a put away transaction for a lot or serial that doesn't have an open recall notice, but the item has an open inbound trace detail.
Replaced	When the buyer does mass replacement of item on a PO line that has been identified as inbound in the recall trace details.
Count Task Generated	When a count task is created for a put away transaction done against the ASN or PO line that has been identified as inbound in the recall trace details.
Auto Closed	When a deliver task is manually completed, without taking any action. For example: <ul style="list-style-type: none"> • When the PO line that has been identified as inbound in the recall trace details is manually cancelled or • The in-transit shipment is cancelled.

Once all the inbound trace records generated by the Locate Recalled Parts process get resolved either by doing a put away, or by mass replacement on purchase orders, or by recall exemption, the deliver task to which these inbound trace records are associated will automatically get completed.

Note: Schedule the Generate Recall Count Tasks for Missing Receiving Events schedule process to run soon after the put away is done. This ensures that the count tasks are generated for all the put away transactions performed for the items on recall. See the *Generate Recall Count Tasks for Missing Receiving Events* topic in the Oracle Fusion Cloud SCM Scheduled Processes for SCM guide for more information.

How You Locate a Recalled Part

To locate the recalled part:

1. On the Recall Notices page, click **Locate**.
2. Specify the date range in the **Track Start Date** and **Track End date**.

Note: If you already entered the Track Start Date and Track End Date when creating the recall notice, you see those dates here. If required, you can change this default date range.

3. Click **Locate**. The details of the located parts are displayed under the Lines, Tasks, and Locations tabs.
4. View the item details under the **Lines** tab. Click the link on the Manufacturer Part Number to view the trace details and tasks assigned for that item.

5. Click the **Tasks** tab to filter by a specific task. View the task progress and trace details of all the items in the recall notice. For example, you can filter by count task, and view all departments where the count task is in progress, and the departments where the count task is completed.
6. Click the **Location** tab to filter by the inventory organization or in combination with subinventory to view the trace details of all the items in the recall notice.

On locating parts:

- Tasks are assigned to the item and notifications are concurrently sent to stakeholders to take necessary actions.
- Users can complete the task as instructed in the notification. After they complete the task, the task status is changed to Completed.
- After the first task in the sequence is completed, the next task is initiated, and a notification is sent to the stakeholder. After all the tasks in the sequence are completed, the recall notice line is closed.
- After all the lines are closed, the recall notice is Closed.

How does the task groupings and relevant stakeholder notifications happen?

You define the traceability grouping parameters as part of the implementation. That implies that you define traceability grouping either by inventory organization, location, or subinventory.

Based on these grouping parameters, tasks are grouped, and notifications are sent.

For example, if you define each department as a location, and the traceability grouping parameter is set as location, then:

- recalled parts traced in different subinventories of that location are grouped together
- a common count task is assigned for that location
- a notification for count task is sent to the user responsible for that location

Similarly, if you define each department as a subinventory, and the traceability grouping parameter is set as subinventory, then:

- recalled parts traced in different stock locators of that subinventory are grouped together
- a common count task is assigned for that subinventory
- a notification for count task is sent to the user responsible for that subinventory

When will the recall line status change to In Progress?

When all items are located and tasks are assigned to the recall lines, the status of the line changes to In Progress.

When can I withdraw a recall notice or a notice line?

On the Notice Details page:

- You can withdraw a recall notice or line when it's in the Open status and when the duplicates are resolved.
- You can choose to withdraw a line if the locate process doesn't identify the recalled part in your organization. So, tasks aren't assigned for that recall line and the line remains in the Open status.

While withdrawing a line or a notice, you can enter comments, if any.

When can I delete a recall notice or a notice line?

You can delete a recall notice or a line only when it's in the New status.

5 Disposal of Recalled Parts

Disposal of Recalled Parts

When you locate parts for a recall notice, tasks are assigned for items, and notifications are sent to the relevant stakeholders to dispose of the recalled parts.

Disposal tasks include:

- Performing the recall count and quarantining the affected parts
- Returning or scrapping the quarantined parts

How you Perform a Recall Count and Quarantine Parts

Based on the notifications, the warehouse operator, par counter, or requester can start the recall count in all locations that include quantity tracked, par and expense locations.

You can report the recall count quantity in Oracle Inventory Management using one of these:

- Recall Count Responsive Application
- Partner solutions like RF smart
- Oracle Visual Builder Plug-in for Microsoft Excel
- Any third-party application by leveraging the Inventory Count rest API
See the Inventory Rest API documentation for more information.

You can even report count quantity for parts physically identified in locations that weren't traced when locating.

Reporting the count quantity automatically transfers the stock of counted parts to a quarantine location, which is a non-reservable recall subinventory. Here's how the counted parts are quarantined:

- When count quantity is reported in a quantity-tracked subinventory, the application initiates the subinventory transfer transaction to move the stock to the recall subinventory.
- When count quantity is reported in a non-quantity tracked location like a par subinventory or expense location, the application initiates the recall receipt transaction to receive the parts in recall subinventory.
- When count is recorded for description-based items and for items that can't be stocked, the application doesn't create any transfer or recall receipt. You must ensure that they're physically quarantined and disposed of at the earliest.

The count task is closed after the counted quantity from all the identified locations is moved to the recall subinventory.

Perform Recall Counts Using the Recall Count Responsive Application

Count your recalled parts using the Recall Counts responsive application on your mobile device or desktop. Scan items and locations on your mobile device and quarantine the parts that are affected due to the recall.

To initiate the Recall Counts responsive application, from the Supply Chain Execution tab, click Inventory Management (New).

You can scan the perpetual and PAR locations, items, lot numbers, and serial numbers using an external barcode device. Use the camera on your mobile device to scan or enter these attributes manually from a list of values. You can record the counts by selecting the tasks specific to your locations.

You can enter the counted quantity for the recalled items or against the recalled lots. The count quantity can be entered in stocking unit of measure if it is defined for the item subinventory combination or for the item org combination. If the stocking unit of measure is not defined, you can enter the count quantity in primary unit of measure.

You can also record the counts by simply scanning the recalled serial numbers.

Once you record and confirm the counts for the selected count tasks, the application automatically initiates a transaction to move the counted quantity to a default quarantine location configured for the inventory organization in the recall parameters.

You also have an option to load the defective parts that are counted and pulled from the respective locations into a pick subinventory and drop them in the default quarantine location. You can perform this pick and drop by simply scanning the pick subinventory and recall subinventory which aligns with the physical material movement. The drop action initiates a transaction to move the counted quantity into the quarantine location.

You can configure the recall parameters for an inventory organization to decide whether or not the intermediate step of pick and drop is required while recording the recall counts.

You can record recall counts using the mobile device in real-time, as well as in an offline mode.

Note: Use the offline mode capability to seamlessly perform recall counts for locations that don't have internet connectivity. You must be connected to Oracle Cloud at the time of choosing the organization before you begin to record your recall counts in an offline mode. This caches the data for all the locations in the chosen organization allowing you to work offline. You can record your recall counts the same way as you do in the online mode while you work offline. The recorded recall counts are synced with Oracle Cloud as soon as your mobile device is connected to the internet.

How you Return or Scrap Quarantined Parts

After performing the recall count and quarantining the affected parts, here's how you can dispose of them as instructed in the recall notice:

- If the replacement type in the recall notice is Request a Product Return with Credit, you can return the affected parts to supplier in one of these two ways:
 - For items that can't be stocked, return them with a reference to the original receipt.
 - When the recalled items exist in the recall subinventory, return them without referencing the original receipt or purchase order.
- If the replacement type in the recall notice is Request a Credit without Product Return, you can scrap the item without referencing the original receipt or purchase order in one of these two ways
 - For items that can't be stocked, return them with a reference to the original receipt.
 - For items that can be stocked, you can only physically quarantine the recalled parts, and close the disposal task manually.

Note: While performing returns or scrap, ensure that the recall notice number and the line number are specified in the Oracle Receiving. Only then are the disposition transaction details captured against each disposal task.

Complete Disposal Tasks

The disposal task for an inventory organization is completed when:

- the disposal quantity is equal to or greater than the reported count quantity
- all the count and deliver tasks for that inventory organization are complete

Note: When disposal is complete, stakeholders are notified to create a debit memo for the return or scrap of the recalled items. After the stakeholders are notified, the debit memo task is marked as complete.

How You View the Disposition Details

To view the disposition details of a recalled item:

1. On the Recall Notices page, click **View Progress**.
2. View the item details under the **Lines** tab. Click the link on the Manufacturer Part Number to view the disposition details for that item. Disposition details include the disposition method, disposal quantity, transaction date, and Ship To Location details.

Manual Actions for Recall Tasks

Here are the recall tasks and the manual actions that you can take on them:

Task	Manual action allowed for the Task	Details
Deliver Recalled Parts to Quarantine Location	Close	You must always manually close the Deliver task.
Perform Physical Count and Quarantine Recalled Parts	No manual action is allowed	The count task is always automatically closed.
Follow Recall Instructions	Close	You must always manually close the Instructions task. To close the instructions task, the task preceding it should not be in the In Progress status
Perform Scrap or Return to Supplier for Recalled Parts	Close and Withdraw	The Disposal task can be either manually or automatically closed. To manually close or withdraw the disposal task, none of the preceding tasks should be in the In Progress status. The subsequent Debit memo task automatically is closed or withdrawn.
Raise Debit Memo Against Disposition for Recalled Parts	No manual action is allowed	The Debit Memo task is always automatically closed or withdrawn.

Note: When a recalled item is located with inbound trace status, the Deliver Parts to Quarantine Location task is assigned to the recall line.

You can do one of the following:

- Deliver these parts to the quarantine location when they arrive in your organization.
- Cancel the in-transit shipment or purchase order when the supplier hasn't yet shipped those parts.

You must manually close this task after taking the relevant action.

Similarly, when the replacement type is Correction in the recall notice, the Follow Recall Instructions task is assigned to the recall line. You must manually close this task when there is a device or label correction for a product. This is because you will have to manually intervene to complete the recall instructions.

How You Close or Withdraw Tasks

To close or withdraw the tasks:

1. On the Recall Notices page, click **View Progress**.
2. On the Notice Details page, select the **Tasks** tab.
3. From the **Tasks** drop-down list, select the task.

4. For the required line:
 - o To close the tasks, click **Complete Task**.
 - o To withdraw the task, click **Withdraw**.

Note: You can also close or withdraw tasks from the Item Details page by clicking the Manufacturer Part Number under the **Lines** tab. While closing or withdrawing tasks, you can enter comments, if any.

When will the Disposal task status change to In Progress?

Here's when the Disposal task status changes to In Progress:

- For an inventory organization, if the task before the disposal task is a count task and it's marked as completed with some count quantity reported for that organization.
- You perform a return or scrap referring the recall notice.

Here are the scenarios when the disposal task status remains Not Started:

- If there is no count quantity reported in the identified locations, there is nothing to dispose of. So, the task status doesn't change to In Progress. In this scenario, you can withdraw the disposal task to close the recall notice.
- If the task before the disposal task is Deliver and it's marked as completed because the inbound shipments are canceled, then there is nothing to dispose of. In this scenario, you can withdraw the disposal task to close the recall notice.
- If the task before the disposal task is Deliver, and it's marked as completed because the inbound shipments are delivered to the quarantine location. You can return or scrap the parts referring the recall notice, which automatically changes the disposal status to Completed.

6 Closure of Recall Notice

Closure of Recall Notice

When all the tasks assigned to a recall notice line are marked as Completed either automatically or manually, the recall notice line is closed automatically. This ensures that a recall line is closed only after all affected goods are quarantined and disposed of.

When all the lines in a recall notice are closed, the recall notice is marked as Closed.

Note: You can review the task history and trace details for the closed recall notices at any future point of time.

