User Guide | INTERNAL
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User Guide for SAP Cell and Gene Therapy Orchestration

THE BEST RUN SAP

Content

1 Solution Overview

Today's cell and gene therapies are revolutionizing the pharmaceutical sector and treating diseases by changing our bodies on a microscopic level. Organizations manufacturing such therapies face logistic, regulatory, and process orchestration challenges.

SAP Cell and Gene Therapy Orchestration is a treatment management platform and exception management system created to control the supply of cell and gene therapy treatments. It supports a make-to-order process from the apheresis center to the pharmaceutical company and back to the hospital for drug infusion to patients.

With **SAP Cell and Gene Therapy Orchestration** you can record and track the chain-of-identity (COI) and chain-of-custody (COC) of custom medicinal products and orchestrate their supply chain to deliver personalized therapies using late stage customization and management of individualized products.

Key Features

- Workflow management and process visibility, alerts, and notifications
- Business rules and master data management
- Task and exception management
- Audit trail, supply chain visualization, e-signatures, and secure patient data storage
- Chain-of-custody (COC) and chain-of-identity (COI) tracking for end-to-end audit reports and other regulatory purposes
- Event-driven data exchange for connected systems and third-party providers
- Label printing with patient data for identified patient delivery
- Manufacturing integration for in-house production as well as for contract manufacturing organizations (CMOs)
- CMO collaboration and courier integration for supply-chain partners
- Notification management to trigger multiple notifications to users for communicating important information and initiate necessary action

Integration

To read, store, and print protected health information (PHI) securely, **SAP Cell and Gene Therapy Orchestration** must be integrated with the Data and Document Integration for SAP Cell and Gene Therapy Orchestration add-on. For more information, see the Setup and Administration Guide for Data and Document Integration for SAP Cell and Gene Therapy Orchestration.

→ Remember

You must always make sure that you use the latest version of the Data and Document Integration for SAP Cell and Gene Therapy Orchestration add-on with SAP Cell and Gene Therapy Orchestration.

2 Getting Started

Check out the following topics to get started with the solution.

- About this User Guide [page 9]
- Working with In-App Help [page 13]

2.1 About this User Guide

This guide provides you with detailed instructions on how to use **SAP Cell and Gene Therapy Orchestration** to track and monitor patient-supplied materials from collection, through processing, to the delivery and administration of a finished product.

- To find information specific to your role, see User Personas [page 15].
- For an overview of the treatment order and manufacturing processes, see Processing a Treatment Order [page 16].

> ⓘ Note
>
> More detailed information is available in the in-app help. To open the help, choose the question mark ⓘ *(Open Help)* in the upper right corner of any app.

Related Information

Working with In-App Help [page 13]

2.2 Common UI Elements

All you need to know about different fields, field types, and other common UI elements in SAP Cell and Gene Therapy Orchestration.

Fields and Their Types in SAP Cell and Gene Therapy Orchestration Apps

Here you find examples of fields, field types, and the characters that you can use for entering values in them.

> **Note**
>
> The following applies only to the configuration apps and master data apps in SAP Cell and Gene Therapy Orchestration.

Field	Purpose	Sample Apps	Field Type	Allowed Characters	Example
ID	Used for specifying the unique identifier of an entity, for example: • Sales Organization ID • Plant ID • Business Partner Role ID	• *Configure Sales Organizations* • *Configure Plants* • *Configure Business Partner Roles*	`ID`	• a to z • A to Z • 0 to 9 • Hyphen -	• ORG1 • AUS7 • CARRIER
User ID	Used to register a new user via the *User Registry Open* API.	NA	`USER_ID`	• a to z • A to Z • 0 to 9 • Hyphen - • Underscore _ • Period . • At sign @ • Plus + • Comma ,	

Field	Purpose	Sample Apps	Field Type	Allowed Characters	Example
• *First Name* • *Last Name* • *Organization Name*	Used for specifying a name, for example: • Contact Person Name • Recipient Name • Organization Name	• *Manage Contact Persons* • *Manage Organizations*	NAME	In addition to English, SAP Cell and Gene Therapy Orchestration supports input in the *Name* fields in the following languages: • European languages such as French, German, Spanish, and Portuguese including the special letter characters that are commonly used in these languages, for example: ß, ç, é, ñ, Ä and so on. • Asian languages such as Korean, Chinese, and Japanese. • Semitic languages such as Arabic and Hebrew. Digits 0 to 9 are supported. The following punctuation marks are supported in the *Name* fields: • Hyphen - • Underscore _ • Colon : • Period . • Comma , • Open Square Bracket [• Close Square Bracket] • Open Parenthesis (• Close Parenthesis)	• François • Müller • 周升巧 • Dräger

Field	Purpose	Sample Apps	Field Type	Allowed Characters	Example
				• At sign `@` • Ampersand `&` • Single Quote Variant `'` • Single Quote Variant `´` • Single Quote Variant `’` • Space ` ` • Blank **Note** Punctuation marks that are not explicitly mentioned here cannot be used in the *Name* fields.	
E-Mail Address	Used for specifying the e-mail ID of a contact person.	• *Manage Contact Persons*	`EMAIL`	User name (before `@`) • `a` to `z` • `A` to `Z` • `0` to `9` • Hyphen `-` • Underscore `_` • Period `.` • Plus `+` Mail server (after `@`): • `a` to `z` • `A` to `Z` • `0` to `9` • Hyphen `-` Domain: • Period `.` • `a` to `z` • `A` to `Z` • `0` to `9` • Hyphen `-`	john.doe@eg-it.com john-doe@eg.com john+doe@eg.co.uk john+doe@eg-site.co.uk

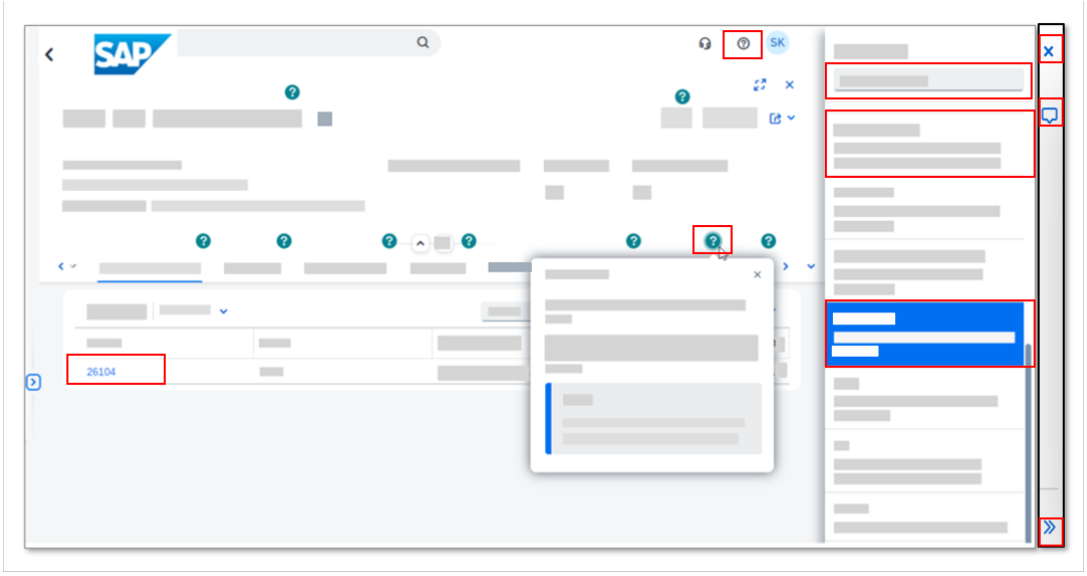
Field	Purpose	Sample Apps	Field Type	Allowed Characters	Example
Telephone *Mobile Phone*	Used for specifying land line or mobile numbers.	*Manage Contact Persons*	PHONE	• 0 to 9 • Hyphen - • Plus + • Parentheses (and)	• +110-9999999 • +86-17722221111 • +49(0)7524-60978

2.3 Working with In-App Help

Get the information you need, when and where you need it.

You can find more information about each app along with detailed field descriptions in the in-app help. To open the help, choose the question mark ⓘ *(Open Help)* in the upper right corner of any app.

This image is interactive. Hover over the boxes to see all the ways you can use in-app help.



- Working with In-App Help [page 13]
- Working with In-App Help [page 13]
- Working with In-App Help [page 13]
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- Working with In-App Help [page 13]
- Working with In-App Help [page 13]
- Working with In-App Help [page 13]

2.4 Available Languages

The solution is available in the following languages:

- Chinese (Simplified)
- English
- French
- German
- Japanese
- Portuguese
- Spanish

3 High-Level Overview

Check out the following topics for a high-level overview of the solution.

- User Personas [page 15]
- Processing a Treatment Order [page 16]

3.1 User Personas

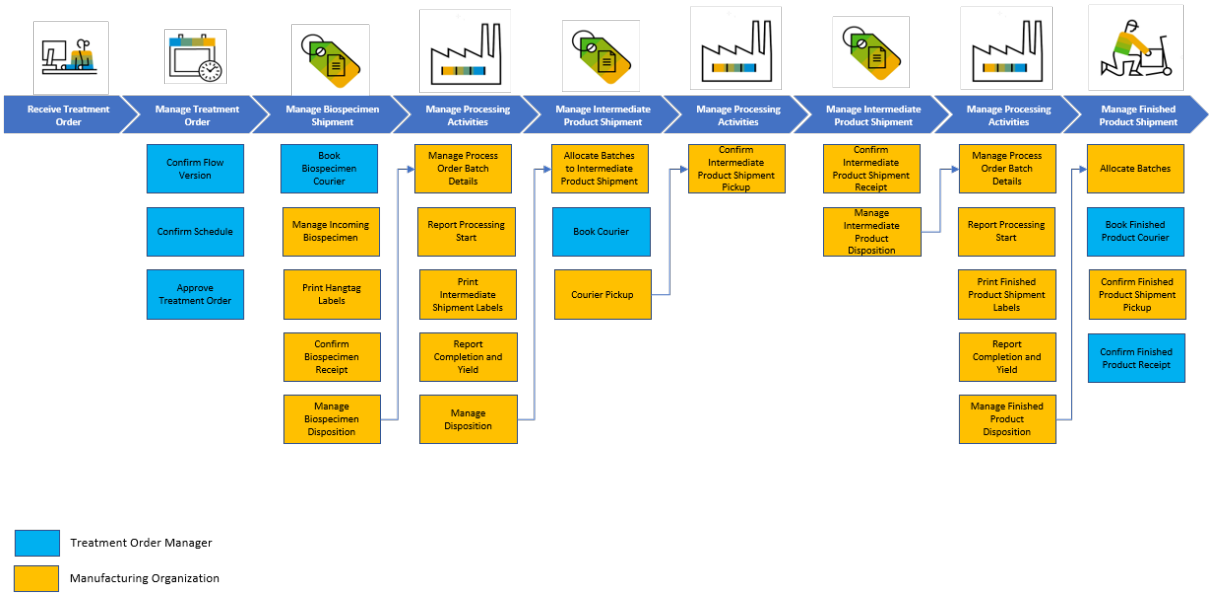
SAP Cell and Gene Therapy Orchestration provides several applications based on your role. To find out more about the features available to you, choose your role below.

- Creating Business Configuration Data [page 17]
- Setting Up Master Data [page 76]
- Managing Treatment Orders [page 95]
- Managing the Manufacture of Finished Products [page 163]
- System Administration [page 229]

3.2 Processing a Treatment Order

Here is an overview of the treatment order process from start to finish.

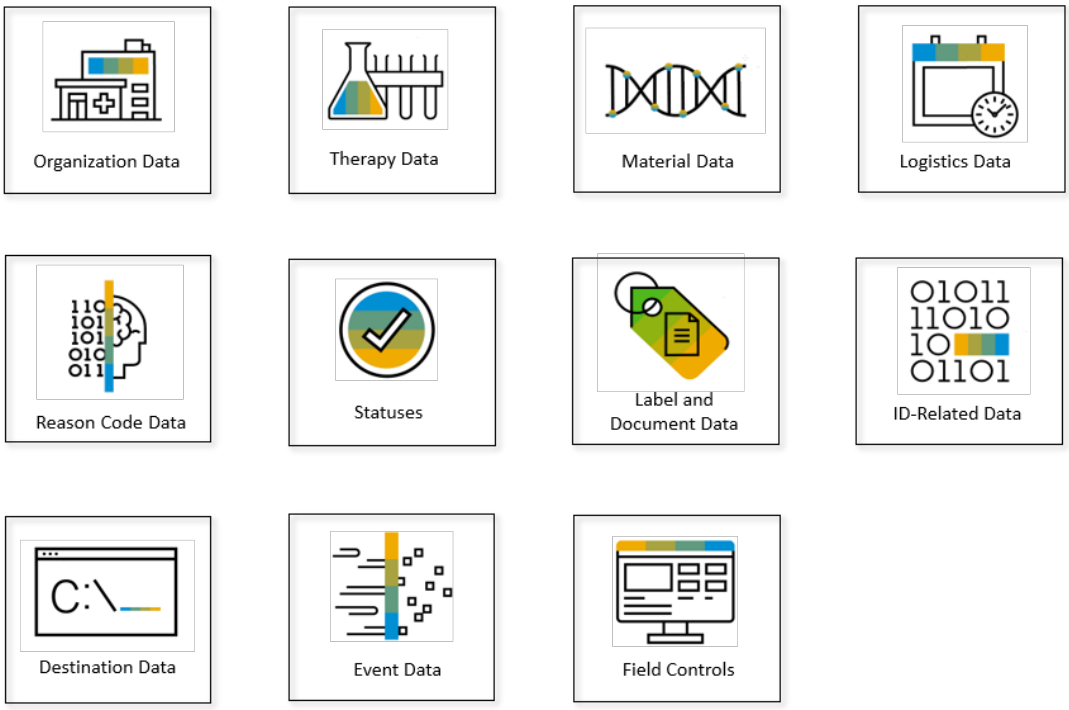
Processing a Treatment Order



4 Creating Business Configuration Data

SAP Cell and Gene Therapy Orchestration provides multiple apps that enable you to configure your business data. While you do not need to follow any strict order when creating business data, some data is used in other configuration apps and therefore must be created first. You can find these dependencies in the Administration Guide under Set Up Configuration Data. Configuration data, once created, cannot be deleted. You can, however, discard drafts before they are saved. You can also activate and deactivate records as required. You can save or modify records that are created by you or another user. Drafts remain in draft mode until they are saved. You can begin editing a draft by another user once the system-defined timeout has elapsed.

> → Remember
>
> You must maintain reason codes for all supported actions that can be performed in the configuration apps while setting up the system. For configuration and master data apps in SAP Cell and Gene Therapy Orchestration, you maintain reason codes in the Configure Change Reasons [page 42] app.
>
> When you create a new record or edit an existing record in any configuration, master data, or transactional app, the system uses the reason codes defined in the respective apps mentioned above to apply the change reason selected by you to the record. If no reason codes are found, the *Save* action will fail and the system will throw an error.



4.1 Organization Data

You can use the following apps to configure organizational data in SAP Cell and Gene Therapy Orchestration.

4.1.1 Configure Sales Organizations

View, create, edit, activate, and deactivate a sales organization for a material.

Context

With this app, you can configure the sales organization for a material.

A sales organization is an organizational unit in logistics that structures the company according to its sales requirements. The sales organization is the highest level in the sales area and is used to create a sales distribution chain in the material master.

You can assign a sales organization to a material under *Sales Distribution Chain* in the *Manage Materials* app.

Procedure

1. In the *Configure Sales Organizations* app, choose *Create*.
2. Enter a unique identifier for the sales organization.

   You can enter up to 4 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The sales organization is created and available for use in your master data.

Related Information

Configure Sales Areas [page 21]

4.1.2 Configure Distribution Channels

View, create, edit, activate, and deactivate a distribution channel for a material.

Context

With this app, you can configure the distribution channel for a material.

The distribution channel is the channel through which a material reaches the customer. For example, this can be a reseller, partner, service center, distributor, and so on.

You can assign one or more distribution channels to a sales organization under *Sales Distribution Chain* in the *Manage Materials* app.

Procedure

1. In the *Configure Distribution Channels* app, choose *Create*.
2. Enter a unique ID for the distribution channel.

   You can enter up to 2 characters.

3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The distribution channel is created and is ready for use in your master data.

Related Information

Configure Sales Areas [page 21]

4.1.3 Configure Divisions

View, create, edit, activate, and deactivate divisions.

Context

With this app, you can configure divisions for use in sales areas.

A division is a logical grouping of goods or services that share common properties or a common line of business, for example Pharmaceuticals or Tissue Diagnostics. A division is created for the purpose of carrying out statistical analyses and marketing and is one of three attributes of a sales area, along with the sales organization and distribution channel.

You can maintain the division for a material under *Basic Data* in the *Manage Materials* app.

Procedure

1. In the *Configure Divisions* app, choose *Create*.
2. Enter a unique ID for the division.

   You can enter up to 2 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The division is created and is available for use in your master data.

Related Information

Configure Sales Areas [page 21]

4.1.4 Configure Sales Areas

View, create, edit, activate, and deactivate sales areas.

Prerequisites

- One or more sales organizations have been created.
- One or more distribution channels have been created.
- One or more divisions have been created.

Context

With this app, you can configure a sales area for an organization.

A sales area is a specific combination of sales organization, distribution channel, and division. It indicates the basic sales structure of the company and is used for reporting purposes.

You can assign a sales area to an organization under *Location Types* in the *Manage Organizations* app.

Procedure

1. In the *Configure Sales Areas* app, choose *Create*.
2. Enter a unique identifier for the sales area.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Select a sales organization.

   This is the sales organization you are assigning to the sales area.

5. Select a distribution channel.

   This is the distributon channel you are assigning to the sales area.
6. Select a division.

   This is the division you are assigning to the sales area.
7. Choose *Create*.

Results

The sales area is created and ready for use in your master data.

Related Information

Configure Divisions [page 20]
Configure Distribution Channels [page 19]
Configure Sales Organizations [page 18]

4.1.5 Configure Business Partner Roles

View, create, edit, activate, and deactivate business partner roles.

Context

With this app, you can configure business partner roles and change the role category as required.

Business partners can perform different roles at different locations. With this app, you can create business partner roles to identify the different roles business partners can play, for example *Vendor*, *Customer*, *Courier*, and so on.

You can select from a list of standard business partner role categories to create each business partner role. You can assign a business partner role to an organization in the *Manage Organizations* app.

Procedure

1. In the *Configure Business Partner Roles* app, choose *Create*.
2. Enter a unique identifier for the business partner role.

   You can enter up to 40 characters.

3. Enter a description.

   You can enter up to 250 characters.
4. Enter a category.

   These values are pre-defined and delivered with the solution.
5. Choose *Create*.

Results

The business partner role is now available for use when creating master data.

Related Information

Create an Organization [page 78]

4.1.6 Configure Address Types

View, create, edit, activate, and deactivate address types.

Context

With this app, you can configure the different addresses of an organization, such as an office address, base address, and so on. For each organization, ensure that you select a standard address to specify the base location of the organization.

The configured address type can then be used under *Addresses* in the *Manage Organization* app.

Procedure

1. In the *Configure Address Types* app, choose *Create*.
2. Enter a unique code for the address type.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 50 characters.
4. [Optional] Select the *Standard Address* check box if this is the primary address of the organization.

5. Choose *Create*.

Results

The configured address type is available for use in the *Manage Organization* app.

Related Information

Configure Flow Section Types [page 37]
Create an Organization [page 78]

4.1.7 Configure Organization Location Types

View, create, edit, activate, and deactivate organization location types.

Context

With this app, you can configure different location types for an organization.

Organization types are used to model the structure of an organization and identify where different functions in the organization are performed. For example, a location type can be a treatment center, pickup location, collection location, courier, and so on.

> **Note**
>
> If an organization has multiple address types, you can specify a different organization location type for each address.

You can assign location types to an organization as well as maintain information pertinent to the location type in the **Manage Organizations** app.

Procedure

1. In the *Configure Organization Location Types* app, choose *Create*.
2. Enter a unique ID for the for the type of organization location.

   You can enter up to 40 characters.
3. Enter a description.

You can enter up to 250 characters.

4. Select an *Organization Location Category*.

   These categories define the function of the organization which could be a pickup or dropoff location, courier, or a manufacutirng plant. These values are pre-defined and delivered with the solution. Possible values are:

   - Administration Location (ADM)
   - Bill To Location (BIL)
   - Contract Manufacturing Organization (CMO)
   - Collection Location (COL)
   - Courier Organization (COU)
   - Dropoff Organization (DOL)
   - Distribution Center (DSC)
   - Infusion Location (INF)
   - Plant (PLN)
   - Pickup Location (PUL)
   - Ship To Location (SHL)
   - Treatment Center (TMC)

5. Choose *Create*.

Results

The organization location type is available for use when creating master data.

Related Information

Configure Flow Section Types [page 37]
Create an Organization [page 78]

4.1.8 Configure Purchasing Organizations

View, create, edit, activate, and deactivate purchasing organizations.

Context

A purchasing organization is the organization from which materials for an order are procured. With this app, you can configure the vendor information required for creating a purchase order.

Procedure

1. In the *Configure Purchasing Organizations* app, choose *Create*.
2. Enter a unique ID for the for purchasing organization.

   You can enter up to 4 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The purchasing organization is available for use in *Manage Order* app, under *Location Types*.

Related Information

Create an Organization [page 78]

4.1.9 Configure Countries/Regions

View, create, edit, activate, and deactivate countries/regions.

Context

With this app, you can define multiple countries/regions where the business takes place.

Procedure

1. In the *Configure Countries/Regions* app, choose *Create*.
2. Enter a unique identifier for the country/region.

   You can enter up to 20 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The configured countries/regions are available for use in the master data.

Related Information

Create a Contact Person for an Organization [page 77]

4.2 Therapy Data

You can use the following apps to configure therapy data in SAP Cell and Gene Therapy Orchestration.

- Configure Therapy Types [page 28]
- Configure Therapy Categories [page 27]
- Configure Indications [page 29]

4.2.1 Configure Therapy Categories

View, create, edit, activate, and deactivate therapy categories.

Context

A therapy category is used to group therapy types, for example, Radiotherapy, Immunotherapy, or Chemotherapy. With the *Configure Therapy Categories* app, you can create a therapy category which can then be associated with a therapy or therapy type in the *Manage Therapies* app.

A therapy can be mapped to a country/region through the *Manage Therapies* app. Later, the therapy can be associated with an order type.

Procedure

1. In the *Configure Therapy Categories* app, choose *Create*.
2. Enter a unique ID for the therapy category.

   You can enter up to 40 characters.
3. Enter a name.

You can enter up to 50 characters.

4. Enter a description.

   You can enter up to 250 characters.

5. Choose *Create*.

Results

The therapy category can now be assigned to a therapy in the *Manage Therapies* app.

Related Information

Create a Therapy [page 80]
Map Treatment Center to Pickup or Drop Off Location [page 82]

4.2.2 Configure Therapy Types

View, create, edit, activate, and deactivate therapy types.

Context

You can configure a therapy type such as a commercial or clinical therapy, using the *Configure Therapy Types* app. The configured therapy type can then be associated to a therapy in the *Manage Therapies* app.

Procedure

1. In the *Configure Therapy Types* app, choose *Create*.
2. Enter a unique ID for the therapy type.

   You can enter up to 40 characters.

3. Enter a name.

   You can enter up to 50 characters.

4. Enter a description.

   You can enter up to 250 characters.

5. Choose *Create*.

Results

The therapy type can now be assigned to a therapy in the *Manage Therapies* app.

Related Information

Create a Therapy [page 80]

4.2.3 Configure Indications

View, create, edit, activate, and deactivate indications.

Context

An indication is a sign, symptom, or medical condition that leads to the recommendation of a particular treatment. With this app, you can configure different indications that can be used when managing a therapy.

Procedure

1. In the *Configure Indication* app, choose *Create*.
2. Enter a unique ID for indication.

   You can enter up to 40 characters.
3. Enter a name.

   You can enter up to 255 characters.
4. Enter a description.

   You can enter up to 250 characters.

Results

The indication information is available for use in the *Manage Therapies* app under *Indications*.

Related Information

Create a Therapy [page 80]

4.3 Material Data

You can use the following apps to configure material data in SAP Cell and Gene Therapy Orchestration.

- Configure Material Types [page 30]
- Configure Material Groups [page 31]
- Configure Material Type and Material Group Combinations [page 32]
- Manage Outbound Materials [page 86]
- Manage Inbound Materials [page 85]
- Configure Packaging Types [page 33]
- Configure Transportation Groups for Materials [page 34]
- Configure Temperature Condition Codes [page 35]
- Configure EAN Categories [page 36]

4.3.1 Configure Material Types

View, create, edit, activate, and deactivate material types.

Context

You can use this app to configure material types.

A material type groups together materials with the same basic attributes, such as raw materials, semifinished products, finished products, and so on.

Every material must have a material type. You can maintain the material type for a material in the *Manage Materials* app.

Procedure

1. In the *Configure Material Types* app, choose *Create*.
2. Enter a unique identifier for the material type.

   You can enter up to 40 characters.

3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The material is created and available for use in your master data.

Related Information

Configure Material Type and Material Group Combinations [page 32]
Create a Material [page 83]

4.3.2 Configure Material Groups

View, create, edit, activate, and deactivate material groups.

Context

You can use this app to configure material groups.

A material group joins together materials with similar attributes, for example blood, tissue, cells, and so on.

Every material must belong to a material group. You can maintain the material group for a material in the *Manage Materials* app.

Procedure

1. In the *Configure Material Groups* app, choose *Create*.
2. Enter a unique ID for the material group.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The material group is created and available for use in your master data.

Related Information

Configure Material Type and Material Group Combinations [page 32]

4.3.3 Configure Material Type and Material Group Combinations

View, create, edit, activate, and deactivate material type and material group combinations.

Context

With this app, you can configure valid combinations of material types and material groups that are always used together.

You can use material type and material group combinations to configure transportation lane rules.

Procedure

1. In the *Configure Material Type and Material Group Combinations* app, choose *Create*.
2. Enter a unique ID for the material type and material group combination.

   You can enter up to 40 characters.
3. Select a material type.
4. Select a material group.
5. Choose *Create*.

Results

The material type and material group combination is created and available for use when creating transportation lanes rules.

Related Information

Configure Material Groups [page 31]
Configure Material Types [page 30]
Create a Material [page 83]

4.3.4 Configure Packaging Types

View, create, edit, activate, and deactivate the type of packaging used to transport a material.

Context

Certain therapies require unique packaging and temperature parameters to comply with regulatory requirements and ensure patient safety. With this app, you can configure the type of packaging that is used to transport a material, such as a cryobag or thermal shipping system.

You can enter the packaging product type for a material in the **Manage Materials** app.

Procedure

1. In the *Configure Packaging Types* app, choose *Create*.
2. Enter a unique ID for the material group.

   You can enter up to 4 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The packaging product type is created and available for use in your master data.

Related Information

Create a Material [page 83]
Manage Transportation Lane Rules [page 92]

4.3.5 Configure Transportation Groups for Materials

View, create, edit, activate, and deactivate transportation groups for materials.

Context

You can create a transportation group to indicate the transportation requirements for a material, using the *Configure Transportation Groups* app. For example, you can create a transportation group for materials with similar attributes or shipping requirements.

The configured transportation group can then be used in the *Manage Transportation Lane Rules* app.

Procedure

1. In the *Configure Transportation Groups* app, choose *Create*.
2. Enter a unique ID for the transportation groups for materials.

   You can enter up to 4 characters.
3. Enter a description.

   You can enter up to 250 characters.

Results

The transportation group is available for use in the *Manage Materials* app, under *Shipping*.

Related Information

Create a Material [page 83]
Manage Transportation Lane Rules [page 92]

4.3.6 Configure Temperature Condition Codes

View, create, edit, activate, and deactivate temperature conditions for materials.

Context

With the *Configure Temperature Condition Codes* app, you can define the storage temperature conditions for a material. For example, you can configure a condition code to specify that a material must be maintained under room temperature. This information is used in biospecimen or finished product labels to specify its storage conditions.

A configured temperature condition code can be used when you configure a material in the *Manage Materials* app.

Procedure

1. In the *Configure Temperature Condition Codes* app, choose *Create*.
2. Enter a unique ID for temperature condition code.

   You can enter up to 2 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The configured temperature condition can be selected for a material in the *Plant Data* section of the *Manage Material* app.

4.3.7 Configure EAN Categories

View, create, edit, activate, and deactivate EAN category.

Context

The International Article Number (also known as European Article Number or EAN) is a barcode symbology and numbering system standard. This is used in global trade to identify a specific retail product type in the European market, in a specific packaging configuration, from a specific manufacturer.

EAN is a standard to encode product numbers and is made of either 8 or 13 digits (EAN-8 and EAN-13). These barcodes are product identification numbers used worldwide for marking products sold at retail points of sale.

EAN is required for the export of shipment materials and is used to identify articles at the point of sales using a barcode. You can configure different types of EANs such as in-store or perishable EANs using the *Configure EAN Categories* app.

Procedure

1. In the *Configure EAN Categories* app, choose *Create*.
2. Enter a unique ID for the EAN category.

   You can enter up to 2 characters.
3. Enter a description.

   You can enter up to 250 characters.

Results

The configured EAN category can be selected for a material in the *Basic Data* section of the *Manage Material* app.

Related Information

Create a Material [page 83]

4.4 Logistics Data

You can use the following apps to configure logistics data inSAP Cell and Gene Therapy Orchestration .

- Manage Transportation Lane Rules [page 92]
- Configure Location Rules [page 38]
- Configure Flow Section Types [page 37]

4.4.1 Configure Flow Section Types

View, create, edit, activate, and deactivate flow section types.

Context

With this app you can configure flow section types. A flow section type defines the details of a specific flow step throughout the supply chain.

You can use flow section types to create a flow definition in the *Manage Flow Definitions* app.

Procedure

1. In the *Configure Flow Section Types* app, choose *Create*.
2. Enter a unique ID. You can enter up to 20 characters.
3. Choose a *Category*.

   A flow section type can have the following categories:

Goods Flow	Determines how material is shipped.
Flow Node	Represents one step in a supply chain. It can be the pickup or delivery of a shipment, or it can be a manufacturing step in a plant.

4. Enter a *Description*.

   You can enter up to 250 characters.
5. If you have selected the category as *Goods Flow*, then indicate whether a shipment is required. If a shipment is required, then:
   1. Select a delivery address usage type. This indicates the type of delivery address.
   2. Select a delivery location type. This is the type of delivery location for the shipment.
6. If you have selected the category as *Flow Node*, then:
   1. Select the check box *Processing Activity Relevant* accordingly.

> **Note**
>
> This is required if the flow node is a processing activity, such as a plant where the manufacturing takes place.

2. Select the *Processing Activity Type* from the drop down depending on the manufacturing type. By default the value is set to **`Processing (PROC)`** in case the processing type is not maintained.
3. Enter the main address usage type. This is the primary address of the processing organization.
4. Enter the pickup address usage type. This indicates the pickup address of the processing organization.

7. Choose *Create*.

Results

The configured flow section types can then be used in the *Manage Flow Definitions* app.

Related Information

Configure Organization Location Types [page 24]
Configure Address Types [page 23]

4.4.2 Configure Location Rules

View, create, edit, activate, and deactivate location rules.

Context

Organizations can have more than one location type. For example, a treatment center can be a pick-up location, a drop-off location, and so on. With this app, you can create a location rule that maps an organization to one of its location types. When creating a biospecimen or finished product shipment, the location rule can be used to determine the location type for the shipment.

The configured location rule ID can be used in the *Manage Flow Definitions* app to define the flow definition of an order.

Procedure

1. In the *Configure Location Rules* app, choose *Create*.

2. Enter a unique rule ID for the location rule.

   You can enter up to 40 characters.
3. Select a location ID field.

   This is the technical field name used to determine the organization location ID for an entity.
4. Select a location type field.

   This is the technical field name used to determine the organization location type for an entity.
5. Select an entity.

   This is the field in the solution for which you are configuring the location rule.

   > ⓘ Note
   >
   > You can only configure a location rule for the listed entities in the drop-down.

Results

A *Rule ID* is created which can be selected in the *Manage Flow Definitions* app.

Related Information

Configure Flow Section Types [page 37]
Configure Entity Status Profiles [page 48]

4.4.3 Configure Milestones

Configure milestones for flow version definition.

Context

A milestone refers to each individual step in the flow that is defined for a treatment order. Some examples include biospecimen pick up and finished product delivery.

You can use the *Configure Milestones* app to view the *System Milestones* pre-configured and delivered with *SAP Cell and Gene Therapy Orchestration*, as well as configure *Custom Milestones* depending on the specific needs of a particular treatment process.

> ⓘ Note
>
> You can only configure custom milestones, but these are not yet available for flow version definition.

Procedure

1. Go to the *Configure Milestones* app.

   The initial screen displays the following list of *System Milestones* delivered with the solution:

   - *Biospecimen Shipment Delivery*
   - *Biospecimen Shipment Pickup*
   - *Finished Product Delivery*
   - *Finished Product Pickup*
   - *Processing Activity End*
   - *Processing Activity Start*

   These milestones are read-only and cannot be edited. You can only view their ID and descriptions (as provided above).

   > **Note**
   >
   > The system milestones always appear in alphabetical order.

2. Navigate to the tab *Custom Milestones* and choose *Create* to configure a new milestone.
3. Provide a *Milestone ID*.

   You can maintain an alphanumeric input, except any special characters.
4. Maintain a *Description*, where you can define what kind of activity this milestone is for, for instance, courier preparation and dispatch.
5. Once done, choose *Create*.

Results

A new milestone should be created, with the status set to *Active*. The header should display the information on who created the milestone, when it was created, and when it was last changed and by whom.

The *General Information* section must display the milestone ID as well as the description that you maintained while configuring the milestone.

The *Change Log* section will display all the actions that have been carried out for the milestone. For a newly created milestone that hasn't yet been changed, the *Status*, *Description*, and *ID* are displayed in the logs.

Next Steps

You can perform the following next steps for your newly configured milestone:

- You can use the milestone within a flow step in the flow version definition.

  > **Note**
  >
  > As described above, you can only use system milestones for flow version definition.

- You can choose *Edit* and update the description for the milestone.
- You also have the option to *Activate* a deactivated milestone or *Deactivate* an active one.

You must provide a reason for editing, activating, or deactivating a milestone, along with a description (which is optional). These changes are recorded in the *Change Log* section.

4.5 Change Reasons and Reason Codes

Define and configure change reasons and reason codes.

When users create or change an existing record, you can require them to enter a reason for the change. You can specify when a reason must be entered as well as make a list of reasons available for selection.

> ⓘ Note
>
> You must maintain reason codes for all supported actions that can be performed in the configuration apps while setting up the system. For configuration and master data apps in SAP Cell and Gene Therapy Orchestration, you maintain reason codes in the *Configure Change Reasons* app. For transactional apps, you maintain reason codes in the *Configure Reason Codes* app.
>
> The system uses the reason codes defined in the respective apps mentioned above to apply the change reason selected by you to the record. If no reason codes are found, the *Save* action will fail and the system will throw an error.

Apps	When to Use Them
Configure Change Reasons [page 42]	Change reasons to use when creating or editing records in the business configuration apps and master data apps. Need more information? See the Administration Guide under Change Reason.
Configure Reason Codes [page 43]	Reason codes to use when editing records in the manufacturing apps and other transactional apps. Need more information? See the Administration Guide under Reason Codes for Processing Updates.

4.5.1 Configure Change Reasons

View, create, edit, activate, and deactivate change reasons.

Context

When users change existing business configuration data or master data, you can require them to enter a change reason. With this app, you can configure when a change reason must be entered as well as make a list of change reasons available for selection. When a user changes an existing configuration and attempts to save their changes, a *Select Change Reason* dialog is displayed and they must select a change reason from the dropdown before saving.

Procedure

1. In the *Configure Change Reasons* app, choose *Create*.
2. Select an entity.

   > **Note**
   >
   > This is the entity that requires a reason when editing. The list of entities is pre-defined and delivered with the solution. Only one change reason can be configured for each entity.

3. Enter a description.

   You can enter up to 250 characters.
4. Under *Reason Codes*, choose *Create*. then create a list of reasons.

   Reason codes are pre-defined and delivered with the solution. These are the reasons users will select from the dropdown when entering a reason.
5. [Optional] Select a default reason.

   The default reason appears first in the dropdown list of reasons.
6. Save your entries.

Results

The configured change reasons are ready to be applied when users edit existing business configuration data or master data.

4.5.2 Configure Reason Codes

View, create, edit, activate, and deactivate reason codes.

Context

When a user changes an existing record in a *Processing* app, you can require them to enter a reason code. For example, you can require them to enter a reason code when they invalidate or reprint a label or change the expiration date for a biospecimen shipment. You can also require them to enter additional reason text.

With this app, you can configure when a reason code must be entered and state whether reason text is mandatory, as well as make a list of reasons available for selection. When a user changes a record and attemts to save their changes, a *Change Reason* dialog is displayed and they must select a reason code and enter required text before saving.

> **Example**
>
> You can require that one of the following reason codes is selected when a label is reprinted:
>
> (Entering additional text isn't necessary.)
>
> *Reason source*: Label
>
> *Reason Type*: Reprint
>
> *Reason Codes*:
>
> - REPR01 - Additional label needed
> - REPR02 - Label contained incorrect data
> - REPR03 - Poor print quality
> - REPR03 - Other
>
> **Is Reason Text Mandatory? No**

> **Note**
>
> - You can use the *Configure Reason Codes* app to configure reason codes for all applications other than the business configuration data and master data apps. For a list of reason sources and corresponding reason types, see the Administration Guide under Reason Codes for Manufacturing Updates.
> - To configure reasons for changes made in the business configuration and master data apps, see the Administration Guide under Change Reasons.

Procedure

1. In the *Configure Reason Codes* app, choose *Create*.
2. Select a *Reason Source*.

This is the entity for which the reason code is configured. For example, *Shipment Material*, *Biospecimen Collection*, *Biospecimen Processing Node*, and so on.

3. Select a *Reason Type*.

   This is the action or circumstance that gives cause for the reason, for example mismatched shipping conditions, expiration change reasons, document or label invalidation, premature termination, and so on.

4. Create the reasons that will appear in the *Select Reason* dropdown.

   a. In the *Reason Codes* tab, choose *Create*.

   b. Enter a *Reason Code*. You can enter up to 250 characters.

   c. Enter a *Description*. This is the reason text that appears in the *Select Reason* dropdown.

   d. Indicate whether additional reason text is mandatory. If you select **Yes**, the user is required to type additional justification in the comment section.

Results

The reason codes are created and are available for selection in the entities and situations for which they are configured.

4.6 Statuses

You can use the following apps to configure statuses in SAP Cell and Gene Therapy Orchestration.

- Configure User Statuses [page 44]
- Configure Status Profiles [page 46]
- Configure Entity Status Profiles [page 48]

4.6.1 Configure User Statuses

With this app, you can create, view, edit, activate, and deactivate user statuses.

Context

Statuses are used to document the current state or workflow of an object. For example, an order might have the status *Created*, *In Process*, or *Completed*.

> ⓘ Note
>
> SAP Cell and Gene Therapy Orchestration distinguishes between **user statuses** and **system statuses**. User statuses are configurable by users and can be manually selected to indicate the state of fields in the

application. System statuses are delivered as part of the solution and are set internally by the system within the framework of general status management when you perform certain business transactions.

You can use this app to configure user statuses needed to set the state of certain fields. You can enter a display description for each user status to suit your business needs. To ensure that the user and system statuses in the solution transition consistently, you must assign a system status that best corresponds to the user status you define.

> **Example**
>
> For the user status *Finished*, you can assign the system status *Complete (ST025)*.

Once user statuses are created, you can use the *Configure Status Profiles* app to group user statuses together and create status profiles. When a status profile is assigned to a status field, users can select from the statuses in the profile to set the status for that field.

> **Note**
>
> - For a list of system statuses delivered with the solution, see the Administration Guide under System Status.
> - For a list of status fields and corresponding user statuses, see the Administration Guide under Configure Status Profiles.

Procedure

1. To create a user status, open the *Configure User Status* app, and choose *Create*.
2. Enter a unique ID for the status.

   You can enter up to five characters.
3. Enter a description.

   > **Note**
   >
   > Users see this description in the dropdown, for example, *Created*, *In Progress*, *Completed*, and so on.
4. Select a system status that best corresponds to the user status description.

   > **Example**
   >
   > For the user status *Finished*, assign the corresponding system status *Complete (ST025*).

   > **Note**
   >
   > For a list and description of all system statuses delivered with the solution, see the Administration Guide under System Status.
5. Choose *Create*.

Next Steps

Group user statuses together to create a status profile. You can do this using the *Configure Status Profiles* app.

Related Information

Configure Status Profiles [page 46]
Configure Entity Status Profiles [page 48]

4.6.2 Configure Status Profiles

With this app, you can view, create, edit, activate, and deactivate status profiles.

Prerequisites

- One or more user statuses have been created.

  > ⓘ Note
  >
  > You can create user statuses in the *Configure User Statuses* app.

Context

A status profile is a series of user statuses logically grouped together in one profile. A status profile provides users with the statuses needed to set the status of or track the progress in a field. For example, for an order field, you might assign a profile with the statuses *Created*, *In Process*, *Approved*, and so on.

You can assign a status profile to a status field using the *Configure Entity Status Profile* app. The statuses included in the profile are then available for selection in a dropdown for that field.

Things to Consider:

- You can include any number of statuses in a status profile.
- Statuses are displayed in the dropdown in the order in which they are created.
- You can select an **Initial Status** to appear as the default status for a field. For example, you can configure an *Order* field to always start with the status *Created*.
- For each status, you can define a **next status**. By setting a next status you can restrict the sequence in which the status can be selected.

> **Note**
>
> For more on the recommended mapping between user statuses, system statuses, and next statuses, see the Administration Guide under Configure Status Profiles.

Procedure

1. In the *Configure Status Profiles* app, choose *Create*.
2. Enter a unique identifier for the status profile.

   You can enter up to 10 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Under *Mapping of Status Profile to Display Status*, choose *Create*, then select a status to add to the profile. Statuses appear in the dropdown in the order in which they're created.
5. [Optional] Select a "next status."

   Do this step if you want to restrict the order in which statuses can be selected.

   > **Example**
   >
   > If you want users to always select the status *Created*, followed by *In Progress*, then do the following:
   >
   > 1. Choose *Created* > *Details*.
   > 2. Under *Next Status*, use the dropdown to select *In Progress*.
   >
   >   > **Note**
   >   >
   >   > A status must be part of the status profile before you can designate it as a next status.
   >
   > 3. Choose *Apply*.
6. Continue adding statuses in this way until the profile is complete.
7. [Optional] Select an *Initial Status*.

   The initial status is the first status displayed by default in the field.
8. Choose *Create*.

Results

A status profile is created.

Next Steps

Assign the status profile to a status field using the *Configure Entity Status Profile* app.

Related Information

Configure User Statuses [page 44]
Configure Entity Status Profiles [page 48]

4.6.3 Configure Entity Status Profiles

View, create, edit, activate, and deactivate entity status profiles.

Prerequisites

- One or more user statuses have been created.
- A status profile has been created.

Context

With this app, you can configure an entity status profile. When you configure an entity status profile, you assign a status profile to a status field in the solution.

A status profile is one or more statuses grouped together, for example, *Created*, *In Process*, *Approved* , *Rejected* , and so on. The profile is used to set the status of or track the progress in a field. When you assign a status profile to a status field, the statuses included in the profile are available for selection in a dropdown for that field.

To create an entity status profile, you must first select the object where the status field is located. If the object has multiple types, you must manually enter the object type. You can then select the field where the profile is applied.

> ✤ Example
>
> The entity *Shipment* has different object types: *Biospecimen Shipment* and *Finished Product Shipment*. You can apply different status profiles to fields belonging to each object type.

> **Note**
>
> You must enter the **Object Type ID** exactly as it was configured or delivered with the system. For example, for the object *Shipment* enter the object type *BS* (for a biospecimen shipment) or *FS-FL* (for a finished product shipment).
>
> You can find a list of *Objects* and corresponding *Object Type IDs* in the administration guide under Configure Entity Status Profiles.

Procedure

1. In the *Configure Entity Status Profiles* app, choose *Create*.
2. Select a status profile object.

   This is the object, for example *Shipment* or *Order*, where the status field is located.
3. If the object has multiple object types, enter the object type ID.

   For a list of object type IDs, see Configure Entity Status Profiles
4. Select a status type.

   This is the status field where the status profile is used, for example the field *Shipment Status* or *Disposition Status*.
5. Select the status profile you want to use in the status field.
6. Choose *Create*.

Results

- The status profile is applied to the status field you selected.
- The initial status in the profile, for example *Created*, is displayed by default in the profiled field.
- Statuses in the status profile are available for selection from a dropdown in the status field while editing.

Related Information

Configure User Statuses [page 44]
Configure Status Profiles [page 46]
Configure Location Rules [page 38]

4.7 Label and Document Data

You can use the following apps to configure label and document data.

- Configure Label Types [page 50]
- Map Label Template to Therapy, Country/Region, and Material [page 51]
- Configure Document Types [page 52]

4.7.1 Configure Label Types

View, create, edit, activate, and deactivate label types.

Context

You can use the*Configure Label Types* to create different label types, such as biospecimen hangtag labels, finished product labels, secondary packaging labels, short labels, and so on.

A label type must be mapped to a therapy for donor identification during label generation for Finished Product, Secondary Packaging, and Finished Product Short Label.

The configured label type can then be mapped to a therapy or material using the *Map Label Template to Therapy* app.

Procedure

1. In the *Configure Label Types* app, choose *Create*.
2. Enter a unique ID.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 250 characters.

Results

The configured label type can be used in the *Manage Therapies* app and in the *Map Label Template to Therapy* app.

Related Information

Create a Therapy [page 80]

4.7.2 Map Label Template to Therapy, Country/Region, and Material

View, create, edit, activate, and deactivate label template mapping.

Context

You can configure a label template using the *Map Label Template to Therapy, Country/Region, and Material* app. A label template maps a therapy, country/region, material, plant, label type, and language. The configured template is used to print the biospecimen hangtag and finished product/secondary packaging labels.

> **Note**
>
> Only the records with approved label templates can be used for printing labels. If the label template is not approved, then the record for the template is marked as inactive.

Procedure

1. Go to the *Map Label Templates to Therapies, Countries/Regions, and Materials* application and choose *Create*.
2. Select the *Therapy*, *Material*, *Plant*, *Country/Region*, *Language*, and *Label Type* and choose *Continue*.

   > **Note**
   >
   > To maintain a single template for all countries/regions, choose `All` in the dropdown for *Country/Region*.
3. Enter the *Label Template ID*.
4. Review the entered details and choose *Create*.

4.7.3 Configure Document Types

View, create, edit, activate, and deactivate document types.

Context

With this app you can configure different document types for patient-related documents, shipment-related documents, and so on. Users select a document type when uploading documents to the system. Uploaded documents are linked in the *Documents* tab in the app where the upload originated, and the selected document type is displayed.

When configuring a document type, you must indicate:

- Whether protected health information (PHI) or patient identifiable information (PII) is included in the document.
  If sensitive patient information is included, only users with additional authorization can view these document types.
- Whether the configured document type can be uploaded into the system.
  Only document types that are marked as “allowed for upload” can be uploaded into the system.

Procedure

1. In the *Configure Document Types* app, choose *Create*.
2. Enter a unique identifier for the document type.

   You can enter up to 40 characters.
3. Indicate whether the document type includes PHI or PII information.
4. Indicate whether the document type can be uploaded into the system.

Results

When uploading a document in SAP Cell and Gene Therapy Orchestration, the document type dropdown displays the document types that are “allowed for upload."

Related Information

Upload Documents [page 180]

4.8 ID-Related Data

You can use the following apps to configure ID-related data.

- Configure COI Types [page 53]
- Configure COI Generation Rules [page 183]
- Configure Number Ranges [page 54]

4.8.1 Configure COI Types

View, create, edit, activate, and deactivate COI types.

Context

For an order, a unique Chain of Identity (COI) ID is generated for each patient therapy number. With the *Configure COI Types* app, you can configure different COI types which is then used to generate a COI ID.

Procedure

1. In the *Configure COI Types* app, choose *Create*.
2. Enter a unique ID for COI types.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 250 characters.

Results

The configured COI type can be used to generate COI IDs.

4.8.2 Configure Number Ranges

View, create, and edit a number range.

Context

With this app, you can create a number range for automatically generated object IDs, for example a shipment ID.

A number range is the possible series of numbers for a given object. It includes a starting number, increment, current number, index, and validity year. Each time a new object is created, the most current number increases by the increment defined.

> **Example**
>
> If the starting number for a shipment ID is 100 and the increment is 10, the next three shipment IDs generated are 110, 120, and 130. The current number is 130.

For every object type you can create multiple number range options and can activate only one.

The supported object types are:

- Order
- Shipment
- Collection
- Processing Node
- Batch
- Subunit Batch
- Exception
- Task

> **Note**
>
> Editing a number range is possible but not recommended. If you do edit, make sure the starting number is greater than the current number generated in the system.

Procedure

1. In the *Configure Number Range* app, click *Create*.
2. Select an object type, for example *Collection* or *Shipment*, then choose *Continue*.
3. In the *Valid Until* field, enter the year until when this is valid upto.
4. In the *From Number* field, enter a starting number.

   You must enter a number greater than the current number.

5. In the *To Number* field, enter the highest number where you want to end this number range.
6. In the *Increment* field, enter the increment in which the IDs should occur. For example *10* or *100*.
7. Click *Create*.
8. Click *Activate*.

Results

The number range is now ready for use.

4.9 Destination Data

You can use the following apps to configure destination data.

- Configure Destinations [page 55]

4.9.1 Configure Destinations

View, create, edit, activate, and deactivate destinations.

Prerequisites

You have created one or more destinations in the SAP BTP Cockpit.

For more information, see SAP BTP Connectivity under Managing Destinations.

Context

A destination is the URL or endpoint for an external system that you can integrate with SAP Cell and Gene Therapy Orchestration in order to exchange data or perform some action. For example, this might be the URL for an application programming interface (API) to book a courier or to upload documents.

With this app, you can map pre-defined rule providers with destinations created in the SAP BTP cockpit. The destinations configured in SAP Cell and Gene Therapy Orchestration are then used to instruct the application router how to process incoming requests with the specific path.

Procedure

1. In the *Configure Destinations* app, choose *Create*.
2. Select a rule provider.

   These are pre-defined integration options delivered with the solution, for example, *Default Courier*, *Default Document Uploader*, and so on.
3. Choose *Continue*.
4. Enter a destination name.

   This is the name of the destination exactly as it appears under *Destinations* in your subaccount in the SAP BTP cockpit.

   You can enter up to 40 characters.
5. Optionally choose the *Object Type* and *Order Attribute*.
6. Choose *Create*.

Results

The destination is configured and available for use. For specific information regarding configuring destinations, see the Administration Guide under:

- Configuration for Document Status Management
- Courier Booking
- E-Signature

4.10 Event Data

You can use the following apps to configure event data in SAP Cell and Gene Therapy Orchestration.

- Configure Post-Processing Events [page 58]
- Configure Post-Processing Events [page 58]

4.10.1 Configure Rules

View, create, edit, activate, and deactivate rules.

Context

Using this app, you can configure rules to initiate workflows or trigger business rules whenever an entity is changed. To configure rules, you must select an entity (on which the rule is applied), scenario (when the rule is applied), rule provider (workflow or business rule), and the rule provider ID.

Procedure

1. In the *Configure Rules* app, choose *Create*.
2. Select an entity and a scenario.
3. Enter the *Object Type*. The value of the *Object Type* is based on the entity you select. For example, object type for entity *Order* must be *Order Type* of the *Treatment Order*. Refer to the following table. If the entity is *Order*, enter **`Order Type`**. If the entity is *Shipment*, enter **`Shipment Type`**.

Entity	Type
Order	Order Type
Shipment	Shipment Type
Processing Activity	Processing Activity Type
Material	Material Type
Sub Unit	Sub Unit Type
Label	Label Type
Therapy	Therapy Type

4. Select a rule provider (*Workflow* or *Business Rule*). For more information on how to configure workflows and business rules, see .
5. Enter the rule provider ID. This refers to the workflow or business rule ID.

   You can enter up to 250 characters.

> **Note**
>
> See Configure Rules topic in the Administration Guide for a complete list of supported workflow rules in SAP Cell and Gene Therapy Orchestration.

Results

The configured rule is available for use in the master data.

4.10.2 Configure Post-Processing Events

SAP Cell and Gene Therapy Orchestration is connected to the post-processing framework (PPF) and can be configured to automatically generate events. Events are signals to the background processing system that a particular status has been achieved and that subsequent actions should be triggered based on certain conditions.

With this app, you can configure any number of events to occur in different business contexts. For each event, you can add a precheck rule that creates an added condition that must be true for the event to occur. You can deactivate and activate events as needed.

Example

You want to trigger an automatic request for approval of treatment orders and limit the approval to orders originating in the United States. You enter the following to create the post-processing event:

Business Context	Event	Precheck Rule
`Create_Order` Note The event is triggered when an order is created.	`WorkflowEvent: Create Order Approval Workflow (Order_Approval)` Note When a treatment order is created, a workflow instance for the creation of an approval is triggered.	`<Precheck Rule ID - U.S. Only>` Note The **Precheck Rule ID** is the ID of the business rule created in SAP Workflow Management. In this case, the precheck rule limits the business context to treatment orders originating in the U.S.

Things to Consider

- Business contexts and events are predefined and delivered with the solution.
- Not all events work in all business contexts.
  For a table of business contexts and corresponding events, see Configure Post-Processing Framework Event.
- Precheck rules are configured in SAP Workflow Management and are optional. For more information on how to configure precheck rules, see Business Rules for ERP Sales Order Integration.

Procedure

To configure a business context with one or more events:

1. Open the *Configure Post Processing-Events* app.
2. Choose *Go* to access a list of available business contexts.

   > **Note**
   >
   > You can also use the filters to find a specific business context.

3. Choose a business context, then choose *Edit*.
   For a list of business contexts and descriptions, see the Administration Guide under Configure Post-Processing Framework Event.
4. Under *Event*, choose *Create*.
   A new event is added. You can select the desired event using the dropdown.

   > **Note**
   >
   > You can also use the dropdown to change events for business contexts at any time.

5. [Optional] Enter a **Precheck Rule** ID.

   > **Note**
   >
   > - Add a precheck rule to limit how the event is triggered.
   > - The **Precheck Rule ID** is the ID of the business rule created in SAP Workflow Management.
   > - If you don't enter a precheck rule, the event (if active) is always triggered in this business context.

6. Continue adding events as needed and save your entries.

Result

New events are created for the business context are set to *Active* by default. You can deactivate an event at any time.

4.10.3 Notifications

Learn all about notification functionality in SAP Cell and Gene Therapy Orchestration.

A notification is a mail or task triggered to the user. Notification is an important tool used in an application to improve operational effectiveness. SAP Cell and Gene Therapy Orchestration triggers multiple notifications to users to communicate important information and initiate necessary action. The purpose is to notify and remind the users to initiate action, avoid lapses, timely treatment, loss of time and money.

Configuring Notification Functionality

The notification functionality is available in SAP Cell and Gene Therapy Orchestration and has to be configured.

Follow these steps:

Step	Action	Detailed Information or Reference
1	Refer to the main features of notification functionality available in SAP Cell and Gene Therapy Orchestration.	• Solution Overview [page 7] • Feature Scope Description > *Chapter 3 Features*
2	Assign the following necessary roles for the super user or administrator to configure rules and to configure Post Processing Framework applications: • `CGT_ConfigAdmin_Write_Srv` • `CGT_ConfigAdmin_Read_Srv`	Assigning Role Collections to Users
3	Configure BTP Workflow Service.	Using Workflow Service
4	Configure the necessary rules and select the scenarios. Refer to the details mentioned in the table below.	Configure Rules [page 57]
5	Configure Post Processing Framework Workflow.	Configure Post-Processing Events [page 58]

Rules and Scenarios

Select an entity and a scenario from the options to apply the rule. You can choose the following details to configure notifications.

Entity	Scenario	Object Type	Rule Provider
`Shipment (Shipment Dose)`	Finished Product Sales Order Created	Not Applicable	WF (Workflow)
`ProcessingNodeMaterialItem (Processing Activity Material Item)`	Finished Product Label Printing	Not Applicable	WF (Workflow)
`ProcessingNodeDetails (Processing Activity Details)`	Finished Product Label Printing	Not Applicable	WF (Workflow)
`ProcessingNodeMaterialItem (Processing Activity Material Item)`	Finished Product Label Reprinting	Not Applicable	WF (Workflow)

Entity	Scenario	Object Type	Rule Provider
`Shipment (Shipment Dose)`	Finished Product Shipment Delivered	`FS-IL`	WF (Workflow)
`Shipment (Shipment Dose)`	Finished Product Shipment Delivered	`FS-FL`	WF (Workflow)
`Shipment (Shipment Dose)`	Finished Product Shipment Shipped	`FS-IL`	WF (Workflow)
`Shipment (Shipment Dose)`	Finished Product Shipment Shipped	`FS-FL`	WF (Workflow)

> **Note**
>
> In the *Rule Provider ID* field, enter the corresponding *Workflow Definition ID*. It is a unique identifier associated with each workflow that is deployed for specific business cases. These deployed workflows can be verified in the *Workflow Management Dashboard* of the *Workflow Definitions* app. For more information on configuring workflows for business events, refer to Using Workflow Service in the SAP Cell and Gene Therapy Orchestration Administration Guide.

4.11 Control Profiles

You can configure two types of control profiles: Field Control Profiles and Copy Control Profiles.

Field Control Profiles

Field control profiles enable you to control the display of fields and field groups for different treatment order types. For example, by configuring a field control profile for treatment orders of clinical trial order type, you can selectively determine the order details (fields and field groups) that will be shown for orders of the given type. Similarly, you can configure field control profiles for shipments and processing activities, and associate the configured field control profiles with the required order types. Based on the configured field control profiles for treatment orders, shipments, and processing activities, specific fields and field groups will be shown in the order, shipment, and processing activity sections of the *Manage Orders* app. For information on how to configure field control profiles, see Configure Field Control Profiles [page 62].

Copy Control Profiles

Copy control profiles are configured to enable you to clone orders with complete or partial data. You can configure the following copy control profiles:

- Treatment Order
- Shipment
- Processing Activity

When you configure a copy control profile, you can select or deselect specific field groups to customize the copy control profile. For example, when configuring a copy control profile for shipments, you can deselect the field groups, ERP Data and Documents from the profile. As a result, during cloning you will be shown all the shipment field groups except ERP Data and Documents. During cloning, you can further select or deselect field groups from the list. This determines whether partial or complete data of the parent order is cloned. Similarly,

you can configure copy control profiles for treatment orders and processing activities to select the field groups that will be a part of these two profiles.

> **Note**
>
> When an order is cloned through an event, the field groups of the associated copy control profile(s) are automatically copied to the cloned order. You cannot select or deselect field groups before cloning is done.

For information on how to configure copy control profiles,see Configure Copy Control Profiles [page 68].

After configuring field and copy control profiles, you can select specific field control profiles or copy control profiles to group them into a single field control profile group or copy control profile group respectively. A profile group is a group of control profiles (copy control profiles or field control profiles). For information on how to configure profile groups, see Configure Profile Groups [page 70].

Finally, the field control profile groups are associated with specific order types to control the display of fields and field groups in treatment orders. The control profile groups are associated with follow on order types to enable cloning of orders. For information on how to associate profile groups with order types, see Configure Order Types [page 72].

Related Information

Configure Field Control Profiles [page 62]
Configure COC Event Profiles [page 184]
Configure COI Event Profiles [page 187]
Configure Profile Groups [page 70]
Configure Order Types [page 72]

4.11.1 Configure Field Control Profiles

View, create, edit, activate, and deactivate field control profiles.

SAP Cell and Gene Therapy Orchestration supports different therapies, such as clinical therapies and commercial therapies. For each therapy, different order details, shipment details, and processing activity details can be viewed in the *Manage Orders* app. The fields and field groups that are displayed depend on the country/region and the type of therapy prescribed. Not all fields and field groups are relevant for all countries/regions and therapy types.

With the *Configure Control Profiles* app, you can create profiles to control which fields and field groups are displayed in the treatment order details.

> **Example**
>
> Clinical fields (for example, *Clinical Trial Subject ID*), are displayed in the solution by default. For commercial therapies, you can create an order profile that excludes all clinical fields.

Using this app, you can also create field control profiles for label printing in the *Print Biospecimen Hangtag Labels* and *Print Finished Product/Secondary Packaging Labels* apps, as well as field controls for the *Patient Viewer* app.

After you have created field control profiles, you can group them together with other profiles using the *Configure Profile Groups* app. You can then use the *Configure Order Types* app to apply the profile group to an order type. The profile group determines which fields and field groups are enabled for a given order type.

Steps

You can configure the following field control profiles:

- Treatment Order
- Shipping
- Processing Activity
- Patient
- Document View Request
- Document Upload Request
- Label

The steps to configure each of the above profiles are identical. Execute the following steps to configure a field control profile for treatment orders (order field control profile):

1. Go to the *Configure Control Profiles* app and choose *Create*.
2. Enter a unique alphanumeric *ID*.
   You can enter a maximum of 40 alphanumeric characters. Spaces and special characters are not allowed.
3. Select the profile type from the dropdown; for example, *Order Profile*, and choose *Continue*.
4. On the *General Information* tab, enter a description.
   You can enter a maximum of 250 alphanumeric characters. Spaces and dashes (-) are allowed. Other special characters are not allowed.
5. On the *Attributes* tab, select the fields and field groups to be used.
   Shown below are the order profile attributes:

   Order Profile

Attribute	Type
Therapy Protocol ID	Field
Biospecimen Shipment	Field Group
Clinical Trial Subject Number	Field
Clinical Randomization Variable	Field
Intermediate Product Shipment	Field Group

6. Choose *Save*.

This creates a field control profile for treatment orders (order field control profile). Similarly, you can configure the other field control profiles.

> **Note**
>
> You can change the configuration of an existing field control profile. Choose *Edit* to modify the configuration.

The attributes of each of the field control profiles are shown below.

Shipment Profile

Attribute	Type
Dosage Quantity	Field
Healthcare Org. PO Number	Field
Out of Specification	Field
Inventory Status	Field

Processing Activity Profile

Attribute	Type
Date of Formulation	Field
Process Order Batches (Components)	Field Group

Patient Profile

Attribute	Type
Given Name	Field
Middle Name	Field
Family Name	Field
Formatted Name	Field
Date of Birth	Field
Gender	Field
Suffix	Field

Label Profile

Attribute	Type
Manufacturing Date	Field
Component Material	Field
Patient Date of Birth	Field

Attribute	Type
COI Type Patient ID	Field
Sponsor Address Line 1	Field
Expiration Date	Field
Subunit Qualifier Value	Field
National Drug Code	Field
Preparation Date	Field
Formatted Address Line 2	Field
Reprint Reason Text	Field
Treatment Center	Field
Sponsor Address Line 2	Field
Subunit ID	Field
Timezone of Preparation Date/Time	Field
Local Suffix	Field
Preparation Time	Field
Local Last Name	Field
Order ID from SAP Cell and Gene Therapy Orchestration	Field
Collection Time	Field
Local Middle Name	Field
Last Name	Field
Manufacturing Plant Description	Field
Healthcare Org. PO Number	Field
Collection ID Qualifier	Field
COI Type	Field
Protocol ID	Field
Collection Date	Field
Component Batch ID	Field

Attribute	Type
Suffix	Field
Local First Name	Field
Delivery Location	Field
Reprint Reason Code	Field
Formatted Address Line 3	Field
Therapy ID	Field
Subunit Serial Number	Field
First Name	Field
Formatted Name	Field
Storage Condition	Field
Sponsor Address Line 3	Field
Middle Name	Field
Manufacturing Plant ID	Field
Formatted Address Line 1	Field
Patient Weight	Field
Hospital Patient ID	Field
Process Order Number	Field
Full Name of Principal Investigator or Prescriber	Field
Number of Subunits	Field
Formatted Local Name	Field
Clinical Trial Subject Number	Field
Sponsor Title or Sponsor Name	Field
Therapy Type	Field
Object Type	Field
Full Name of Pharmacist	Field
Time zone of Collection Date/Time	Field

Document Profile

Attribute	Type
Therapy	Field
Country	Field
Clinical Randomization Variable	Field
Patient Number	Field
Treatment Center	Field
Region	Field
Clinical Trial Subject Number	Field
Order Type	Field
Protocol Number	Field

> **Note**
>
> When configuring a document profile, select *Document Upload Request Profile* or *Document View Request Profile* as *Profile Type* depending on whether you want to create a profile to upload or view a document.

Next Steps

Assign the field control profiles to a profile group using the *Configure Profile Groups* app.

Related Information

Configure Profile Groups [page 70]
Configure Order Types [page 72]

4.11.2 Configure Copy Control Profiles

You can configure copy control profiles to clone orders with complete or partial data.

Context

You can configure copy control profiles for:

- Treatment orders: Determines treatment order specific field groups that will be made available during cloning.
- Shipments: Determines shipment specific field groups that will be made available during cloning.
- Processing activities: Determines processing activity specific field groups that will be made available during cloning.

Execute the following steps to configure a copy control profile:

Procedure

1. Go to the *Configure Control Profiles* app and choose *Create*.
2. Enter a unique alphanumeric *ID*.

   You can enter a maximum of 40 alphanumeric characters. Spaces and special characters are not allowed.
3. Select *Profile Type* from the dropdown, then choose *Continue*. The dropdown has the following values:
   - *Treatment Order Copy Control Profile*
   - *Shipment Copy Control Profile*
   - *Processing Activity Copy Control Profile*
4. On the *General Information* tab, enter a description.

   You can enter a maximum of 250 alphanumeric characters. Spaces and dashes (-) are allowed. Other special characters are not allowed.
5. On the *Attributes* tab, all the attributes (field groups) that are a part of the profile type are shown as selected by default. Deselect the attributes that are not to be copied to the new copy control profile. Only the selected field groups will be copied to the new copy control profile.
6. Choose *Create*.

   This creates a copy control profile with the selected attributes.

   > **Note**
   >
   > You can change the configuration of an existing copy control profile. Choose *Edit* to modify the configuration.

   Shown below are the attributes for each of the copy control profiles.

Treatment Order Copy Control Profile

Attribute
Business Partners
*General Data
Order Texts
Order Dates
Documents
COI ID
Order Details

Shipment Copy Control Profile

Attribute
Logistics
Documents
ERP Data
Approval Info
*General Data
*Materials and Subunits
*Locations
*Shipment Dates

Processing Activity Copy Control Profile

Attribute
*General Data
Documents
*Processing Location
*Materials and Subunits
*Processing Dates
ERP Data

> **Note**
>
> The attributes marked with an asterisk (*) are mandatory and will be copied by default to the new copy control profile. For example, if you configure a copy control profile for treatment orders, General Data will be copied to the new copy control profile.

4.11.3 Configure Profile Groups

View, create, edit, activate, and deactivate profile groups.

A profile group is a collection of control profiles (field control profiles or copy control profiles). You can configure two types of profile groups:

- Field Control: This is a group of field control profiles. You can assign different field control profile types to configure a field control profile group.
- Copy Control: This is a group of copy control profiles. You can assign different copy control profile types to a configure a copy control profile group.

With this app, you can assign an order profile, shipment profile, processing activity profile, COI event profile, COC event profile, as well as a process flow profile to a profile group. The fields that are enabled in these profiles are then visible for the order type to which the profile group is applied.

Procedure

1. Open the *Configure Profile Groups* app and choose *Create* to configure a new profile group.
2. Enter a unique *ID*.
   The ID must be alphanumeric. You can enter a maximum of 40 characters. Spaces and special characters are not allowed.
3. Choose *Continue*.
4. Select *Profile Group Type* (Field Control or Copy Control).
5. On the *General Information* tab, enter a description.
   You can enter a maximum of 250 characters. Spaces and dashes (-) are allowed. Other special characters are not allowed.
6. If you are configuring a field control profile group, select the following field control profiles:
   - *Order Profile*
   - *COI Profile*
   - *COC Profile*
   - *COC Certificate Template*
   - *Process Flow Profile*

   > ⓘ Note
   >
   > There are two types of process flow profiles: `DEFAULT (Default Profile)` and `PROCWOL (Processing without Labels)`. *DEFAULT* contains all the process steps. *PROCWOL* contains all the process steps excluding the process steps associated for labels.

   > ⓘ Note
   >
   > It is not mandatory to select *Patient Profile*.

   Enter the Adobe form and template names (form and template names configured in SAP Forms service by Adobe) in the *Traceability Report Template* section of the field control profile group created for the relevant order type to generate traceability report. You cannot generate traceability report if the Adobe form and

template names are not configured. For more information about the configurations required to generate traceability report, see Generate COI Traceability Report in the Administration Guide for SAP Cell and Gene Therapy Orchestration.
For more information about SAP Forms Service by Adobe and Object Store Service, see SAP Forms Service by Adobe and Object Store Service on SAP BTP in the Administration Guide for SAP Cell and Gene Therapy Orchestration.
For more information about traceability report, see Generate Traceability Report.
When you are configuring a copy control profile group, select *Order Profile* from the dropdown.

> **Note**
>
> When configuring a copy control profile group, select copy control profiles for each entity. Similarly, when configuring a field control profile group, select field control profiles for each entity.

7. On the *Shipment Profiles* tab, you can associate a control profile (copy control or field control) configured for shipments with the shipment types (biospecimen shipments, intermediate product shipments, finished product shipments).

   > **Note**
   >
   > Select a shipment field control profile if creating a field control group else select a shipment copy control profile for a copy control group.

   The steps to associate a control profile with a shipment type are as follows:
   1. Choose *Create*. This adds a blank row.
   2. Select a shipment type from the dropdown.
   3. Select the copy control or the field control profile for the selected shipment type from the dropdown.
   4. Choose *Create*

   You can create multiple entries, one for each shipment type.
8. On the *Document Profiles* tab, you can associate a control profile (copy control or field control) configured for documents with the document profile types (document view request, document upload request). The steps to associate a control profile with a shipment type are as follows:
   1. Choose *Create*. This adds a blank row.
   2. Select a document profile type from the dropdown.
   3. Select the copy control or the field control profile for the selected document profile type from the dropdown.
   4. Choose *Create*

   You can create multiple entries, one for each shipment type.
9. On the *Processing Activity Profile* tab, you can associate a control profile (copy control or field control) configured for processing activities with the required processing activity types. The steps to associate a control profile with an activity type are as follows:
   1. Choose *Create*. This adds a blank row.
   2. Select a processing activity type from the dropdown.
   3. Select the copy control or the field control profile for the selected processing activity type from the dropdown.
   4. Choose *Create*

   You can create multiple entries, one for each activity type.
10. Choose *Create*.

Result

A profile group is created with all the required profiles grouped together.

> **Note**
>
> You can change the configuration of existing profile groups. Choose *Edit* to modify the configuration.

Next Steps

Assign the profile group to an order type. For more information, see Configure Order Types [page 72].

Related Information

Control Profiles [page 61]
Configure COI Certificate Templates [page 225]
Configure COC Event Profiles [page 184]
Configure COI Event Profiles [page 187]
Configure Address Types [page 23]

4.11.4 Configure Order Types

View, create, edit, activate, and deactivate order types.

Context

When an order is created, an order type is automatically determined for the order based on the therapy prescribed and the country/region in which the treatment is provided. With this app, you can assign a field control profile group to an order type. The field control profile group determines the fields and field groups that will be visible for the order type in the application.

> **Example**
>
> For an order type that is used for commercial orders, you can assign a field control profile group that hides irrelevant clinical-trial fields.

Using this app, you can also configure follow on order types. Follow on order types are used to validate the order type to which an existing order (of a given type) can be cloned. You can also associate a follow on order with a copy control profile group. The copy control profile group determines the field groups that can be copied to the cloned order. During cloning, the field groups of the treatment order, shipments, and processing

activity sections are determined by the copy control profile group associated with the follow on order type. It is, however, not mandatory to associate a copy control profile group with a follow on order. In this case, only the mandatory field groups are copied to the cloned order. For more information, see Configure Copy Control Profiles [page 68].

With this app, you can assign a profile group to an order type to control which fields and field groups are visible for the order type.

> **Example**
>
> For an order type that is used for commercial orders, you can assign a profile group that hides irrelevant clinical-trial fields.

In addition, you can select one order type as the default order type. The default order type is assigned to an order if there is no order type configured for a particular therapy and country/region combination.

> **Note**
>
> The system can only have one active default order type at a time.

You can view the order type of an order in the *Manage Orders* app on the *General Information* tab. After the order type is determined, you cannot change the order type. Execute the following steps to configure an order type:

Procedure

1. Go to the *Configure Orders Types* app and choose *Create*.
2. Enter a unique *ID* for the order type.

   You can enter up to 40 alphanumeric characters. Spaces and special characters are not allowed.
3. On the *General Information* tab, enter a description.

   You can enter up to 250 alphanumeric characters. Spaces and dashes (-) are allowed. Other special characters are not allowed.
4. [Optional] Select a *Field Control Profile Group*.

   This profile group will be used with all the orders of the given order type. Based on the associated field control group, specific fields and field groups will be displayed in the application. If, however, a field control profile group is not assigned to an order type, all the fields and fields groups will be displayed in the application.
5. [Optional] Select the *Default* checkbox to make this order type as the default order type.
6. On the *Follow On Order Types* tab, choose *Create*.
7. Select a follow on order type from the dropdown.
8. [Optional] Select a copy control profile group to be associated with it. The copy control profile group determines the field groups to be copied during cloning.

   You can configure multiple follow on order types for a given order type.

   You can select one follow on order type as the default type. This means that during cloning, unless you select a different follow on order type, the default follow on order type will be used to validate the order

type being cloned. The control profile group of the default follow on order type will determine the field groups to be made available for copying to the cloned order. If there is no copy control profile group associated with the follow on order type, the mandatory field groups will be copied to the cloned order.

By default, all the follow on order types are active. You can deactivate or activate them as per requirement.

9. Choose *Create*.

Results

The order type is available for use in your master data.

> **Note**
>
> You can change the configuration of existing order types. Choose *Edit* to modify the configuration.

Related Information

Control Profiles [page 61]
Configure Field Control Profiles [page 62]
Configure Profile Groups [page 70]
Create a Therapy [page 80]

4.12 Configure Custom Text Types

View, create, edit, activate or deactivate custom text types.

Context

Custom text types are used to specify and maintain additional information about treatment orders and shipments, which is otherwise not maintained in the treatment order or shipment. This app enables you to create and maintain custom text types.

Follow the steps listed below to create custom text types:

Procedure

1. Go to the *Configure Custom Text Types* app and choose *Create*.

2. Enter a unique ID not exceeding four characters and choose *Continue*.
3. Enter a description for the custom text type, for example, Packing Instructions, Shipment Instructions, then choose *Create*.

> **Note**
>
> By default, the custom text type is created in active state. You can deactivate it at any time if required by choosing *Deactivate*. To change it back to active state, choose *Activate*. The system prompts you to select a reason for deactivation or activation.

4. You can only change the description of a custom text type. To do so, choose *Edit* and make changes, then choose *Save*. The system prompts you to select a reason code for making changes. Select the reason code and choose *Save*.

5 Setting Up Master Data

You can use configured business data to set up your master data. The data created in the *Master Data* apps is used to create a treatment order.

> → Remember
>
> You must maintain reason codes for all supported actions that can be performed in the configuration apps while setting up the system. For configuration and master data apps in SAP Cell and Gene Therapy Orchestration, you maintain reason codes in the Configure Change Reasons [page 42] app.
>
> When you create a new record or edit an existing record in any configuration, master data, or transactional app, the system uses the reason codes defined in the respective apps mentioned above to apply the change reason selected by you to the record. If no reason codes are found, the *Save* action will fail and the system will throw an error.

You can do the following in the master data apps:

- Create a Contact Person for an Organization [page 77]
- Create an Organization [page 78]
- Create a Therapy [page 80]
- Map Treatment Center to Pickup or Drop Off Location [page 82]
- Create a Material [page 83]
- Create a Flow Definition [page 87]
- Create a Transportation Lane [page 91]

> ⓘ Note
>
> In SAP Cell and Gene Therapy Orchestration, master data once created, cannot be deleted. The records, however, can be deactivated and activated as required.

> ⓘ Note
>
> In the *Master Data* apps, any record you create remain in draft mode until you save the changes. Similarly, any changes you make to a record are stored in draft mode until saved. You can save, modify, or delete a draft record and can also exit the record without saving your data. A record in draft mode can be edited by another user after a system-defined timeout has elapsed.

5.1 Create a Contact Person for an Organization

Create and manage contacts for an organization.

Context

You can add a contact peson and their details for a particular organization using the *Manage Contact Persons* app. You can then add these contact details when configuring an organization in the *Manage Organizations* app.

Procedure

1. Go to the *Manage Contact Persons* app and choose *Create*.
2. Enter a unique identifier for the contact person.
3. Provide the personal details of the contact.

   The *Correspondence Language* specifies the language for informal communication. The *Communication Language* specifies the language for formal communication.
4. Provide the address details of the contact.
5. Provide the communication details and the preferred method of communicating with the contact.
6. Confirm the entered details and choose *Create*.

Results

An active record is created for the contact. If required, you can also edit the contact details. Any changes made to the contact details are recorded in the change log. If the contact is no longer applicable for the organization, then you can deactivate the record.

Related Information

Create an Organization [page 78]
Configure Countries/Regions [page 26]

5.2 Create an Organization

Create and manage organizations.

Context

An organization is any location involved in the supply chain, from the biospecimen pickup to the finished product delivery. You can create an organization and define its structure and function using the *Manage Organizations* app.

Organizational data is made of several types of information. Listed below are the different information types that are used to create an organization (the mandatory ones are marked with an asterisk *):

- *Address types
- *Organization location types
- Plants
- Contact Persons
- Business Partner Roles
- Sales Areas
- *Countries/Regions
- Purchasing Organizations
- Sales Organizations
- Distribution Channels
- Divisions

An organization is used to:

- create a therapy specific to the organization using the *Manage Therapy* app.
- map an organization and its therapy to a collection center, pickup, and drop off locations using the *Manage Organization-Location-Therapy Rule* app.

Location Category Details

Location	Location Category
Collection Center	COL
Pickup	PUL
Drop off	SHL

Procedure

1. Go to the *Manage Organizations* app and choose *Create*.

2. Enter a unique identifier for the therapy.
3. Provide the general information of the organization.
4. Add the addresses of the organization and specify the type of each address.

   The available address types are configured in the *Configure Address Types* app.

   You must add one standard address for the organization.

   > **Note**
   >
   > SAP Cell and Gene Therapy Orchestration offers custom address fields to accommodate the specific format requirements of each country. This allows you to create or modify the address details, ensuring they comply with the specific format requirements of the selected country. For countries like the United Kingdom, including unique address components such as the locality in dispatch and destination addresses will ensure accurate identification and delivery.

5. For each address type, select a location type.

   A location type determines the function of the organization in the supply chain. For example, if the organization is a treatment center, then location type must also be a treatment center.

   If an organization has multiple addresses, then you can specify the location type for each address.
6. Confirm the entered details and choose *Create*.

Results

An active record is created for the organization. If required, you can also edit the details of the therapy. Any changes made to the organization details is recorded in the change log.

If the organization is no longer required, you can deactivate the record.

Related Information

Create a Contact Person for an Organization [page 77]
Configure Purchasing Organizations [page 25]
Configure Business Partner Roles [page 22]
Configure Organization Location Types [page 24]
Configure Address Types [page 23]
Create a Contact Person for an Organization [page 77]
Map Treatment Center to Pickup or Drop Off Location [page 82]

5.2.1 Manage Plants

View, create, edit, activate, and deactivate plants.

Context

A plant is a processing unit where the biospecimen shipment materials are processed. With this app, you can configure plants where materials are processed.

Procedure

1. In the *Configure Plants* app, choose *Create*.
2. Enter a unique ID for the plant.

   You can enter up to 4 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Choose *Create*.

Results

The plant information is available for use in the master data.

5.3 Create a Therapy

Create and manage therapies.

Context

You can configure a therapy based on its therapy type or category, using the *Manage Therapies* app. For each therapy, you can list the organizations that perform the therapy, and the types of labels used for the therapy.

A configured therapy can then be used to:

- Create an order and determine the flow version of the order.
- Map a treatment center to a pickup location in the *Manage Organization-Location-Therapy Rules* app.

- Specify the therapy for a biospecimen or finished product in the *Manage Materials* app.
- Map to a label type for donor identification during label generation for Finished Product, Secondary Packaging, and Finished Product Short Label.

Procedure

1. Go to the *Manage Therapies* app.
2. Click *Create*.
3. Enter a unique identifier for the therapy.
4. Click *Continue*.
5. Enter a *Name* on the *General Information* tab.
6. Select *Therapy Type* and *Therapy Category* from the drop down.

   The available therapy types and categories are configured in the *Configure Therapy Types* and *Configure Therapy Categories* apps.
7. On the *Organizations* tab, add the organizations that perform the therapy.

   The available organizations are configured in the *Manage Organizations* app. Only the organizations which have at least one location type as treatment center are displayed here.
8. On the *Countries/Regions* tab, add the countries/regions to which the therapy is applicable as required.
9. On the *Label Types* tab, add the label types to be used for the therapy.

   The available label types are configured in the *Configure Label Types* app.
10. Choose the *Collection Identifier* from the drop down list. For a specific therapy and label type combination, any one of the following values can be selected:
    - EarliestDIN - Earliest Donation Identification Number
    - MultipleDINs - Multiple Donation Identification Numbers

    This is applicable during label generation of label types like *Finished Product*, *Secondary Packaging*, and *Finished Product Short Label*.

    > **Note**
    >
    > In case this is not configured, then the value *EarliestDIN - Earliest Donation Identification Number* is selected by default.
11. Confirm the entered details and click *Create*.

Results

An active record is created for the therapy. If required, you can also edit the details of the therapy. Any changes made to the therapy details is recorded in the change log.

If the therapy is no longer required, you can deactivate the record.

Related Information

Configure Label Types [page 50]
Configure Indications [page 29]
Configure Therapy Types [page 28]
Configure Therapy Categories [page 27]
Configure Order Types [page 72]
Map Treatment Center to Pickup or Drop Off Location [page 82]

5.4 Map Treatment Center to Pickup or Drop Off Location

For a therapy, assign the treatment center and its associated pickup or drop off location.

Context

You can create a rule to assign a pickup or drop off location for a treatment center. This rule is configured for therapies performed at a treatment center. You can configure this rule in the *Manage Organization-Location-Therapy* app.

When an order or shipment is created for a therapy, the configured rule is used to validate the treatment center and its associated pickup or drop off locations.

Procedure

1. Go to the *Manage Therapies* app and choose *Create*.
2. Select the treatment center.

   Only the organizations with a treatment center location are displayed. These organizations are configured in the *Manage Organizations* app.
3. Select the pickup or drop off location in the *Target Organization ID*.
4. Add the therapies or therapy categories to specify therapies carried out by the treatment center.
5. Confirm the entered details and choose *Create*.

Results

An active record is created for the rule. If required, you can also edit the details of the pickup or drop off locations, therapies, and therapy categories. Any changes made to the therapy details is recorded in the change log.

If the configured rule is no longer required, you can deactivate the record.

Related Information

Configure Therapy Categories [page 27]
Create a Therapy [page 80]
Create an Organization [page 78]

5.5 Create a Material

Create and manage materials.

Context

A material can be a biospecimen or a finished product. You can create a material based on the material type or group created in the configuration apps. In the *Manage Materials* app, you can create a material and specify its processing, shipment, and therapy details.

Procedure

1. Go to the *Manage Material* app and choose *Create*.
2. Enter a unique identifier for the material.
3. Specify the material type or group.

   The material type is configured in the *Configure Material Types* app, and the material group in the *Configure Material Groups* app.
4. Provide the basic details and weight information of the material.
5. Add the plant at which the material is delivered to or processed at, and provide its processing details.
   - The available plants are created in the *Configure Plants* app.
   - If the material is batch managed, then you can perform the following in the processing apps:
     - Disposition the material in the *Manage Biospecimen Disposition* and *Manage Product Disposition* apps.
     - Print biospecimen hangtag labels for the material.
     - Maintain batch management and auto batch generation fields.
   - If the material is relevant for disposition, then you can set a status for the material in the *Manage Biospecimen Disposition* and *Manage Product Disposition* apps.

- You can maintain the unit of measurement for the dosage quantity in the *Dosage Quantity UoM* field. This UoM field will be reflected in the finished product shipment by default, if the dosage quantity does not have an associated UoM.
  The UoM is determined after flow version confirmtion, and is passed in the outbound sales order interface along with the dosage quantity.
- The maximum number of subunits determine the number of subunits to be processed. This is displayed in the *Process Order Yield* section in the processing apps.
- Choose the plant name to edit the plant, subunit, and shelf life details. On the *Subunit* tab, define values for:
  - *Subunit ID Mode*: This is the mode in which each subunit is allocated an ID. There are two modes:

Mode	Description
Auto Generate	Subunit is assigned a serial number as the ID.
Batch	Subunit is assigned the material batch number as the ID.

  - *Subunit Type*: A subunit can be of three types:
    - Cryobag
    - Bag
    - Vial
  - *Subunit Qualifier*: Depending on the subunit type, select the subunit qualifier:
    - Cryobag ID
    - Bag ID
    - Vial ID

    The subunit values that you configure here for the material are applied at the time of creation of subunits and shown as default values for the finished product subunits, which use this material and plant combination. If you do not assign values to the subunit fields here, the finished product subunit fields are blank. You must define the values manually when processing the finished product subunits for orders.
- The shelf life details determine the expiration date of the material. The expiration date is displayed in the batch details of the processing apps.

6. Provide the details of the courier in the *Shipping* section.
7. Specify the sales organization and its distribution channel through which the material is transported.
8. Specify the country/region-specific therapy for which the material is used.
9. Confirm the entered details and choose *Create*.

Results

An active record is created for the material. If required, you can also edit the material details except for the base unit of measure. Any changes made to the material details are recorded in the change log.

If the material is no longer required, then you can deactivate the record.

Related Information

Configure EAN Categories [page 36]
Configure Material Types [page 30]
Configure Packaging Types [page 33]
Configure Material Type and Material Group Combinations [page 32]

5.5.1 Manage Inbound Materials

View, create, edit, activate, and deactivate inbound materials for biospecimen shipments.

Context

With the *Manage Inbound Materials - Biospecimen Shipments* app, you can associate an inbound biospecimen material with the following:

- Country/region
- Patient weight
- Therapy or therapy category

Procedure

1. In the *Manage Inbound Materials - Biospecimen Shipments* app, choose *Create*.
2. Enter a unique ID for the inbound biospecimen shipment material.

   You can enter up to 40 characters.
3. Select a therapy.

   This is the therapy you are assigning to the inbound biospecimen shipment material.
4. Select a therapy category.

   This is the therapy category you are assigning to the inbound biospecimen shipment material.
5. Select a country/region.

   > ⓘ Note
   >
   > Please do not select *All* from the dropdown. The system does not support it.
6. Enter minimum and maximum patient weight.

   Patient's weight is required to determine the material for certain therapies.
7. Select a biospecimen material.

> **Note**
>
> The biospecimen material is configured in the *Manage Materials* app.

8. Choose *Create*.

Results

An active record is created for the inbound biospecimen shipment material.

5.5.2 Manage Outbound Materials

View, create, edit, activate, and deactivate outbound material for shipments.

Context

With this app, you can configure different types of outbound material for finished product and biospecimen kit shipments. You can determine the therapy, processing plant, and country/region for the biospecimen kit shipment and finished product shipment material.

Procedure

1. In the *Manage Outbound Materials* app, choose *Create*.
2. Enter a unique ID for the shipment material.

   You can enter up to 40 characters.
3. Select a therapy.

   This is the therapy to be assigned to the outbound shipment material.
4. Select a material group and type.

   This is the material group and type to be assigned to the shipment material.
5. Select a country/region.
6. Select a processing plant.

   This is where the processing of the material takes place.
7. Enter minimum and maximum patient weight.

   Patient's weight is required to determine the material for certain therapies.
8. Select a material.

   This is the shipment material that is determined based on the above criteria.

9. Choose *Create*.

Results

The outbound material for shipment is created.

5.6 Create a Flow Definition

Create and manage flow definitions.

Context

A flow definition encompasses and outlines the processing activities and logistical stages involved in the handling and transportation of a product in SAP Cell and Gene Therapy Orchestration, from a biospecimen to finished product.

In SAP Cell and Gene Therapy Orchestration, these (the processing activities and logistical stages) are subsumed under the following key activities:

- Biospecimen pickup
- Biospecimen shipment
- Manufacturing
- Shipment and delivery of finished product

The number of processing activities and transportation stages may vary from finished product to finished product, depending on the complexity of the related manufacturing processes, as well as of the geographies concerned. You can create a flow definition using the *Manage Flow Definitions* app.

> **Note**
>
> A flow definition is used to define the processing activities and logistical stages for a treatment order. You can see the process flow for an order in the *Manage Orders* app.

Follow the steps given below to create a flow definition.

Procedure

1. Go to the *Manage Flow Definitions* app and choose *Create*.
2. Enter a unique identifier for the flow definition.
3. Provide a description for the flow definition.

4. Create the process steps in the *Flow Steps* section.

> **Note**
>
> The number of steps to be defined depends on the complexity of the logistical stages and processing activities. Given below are a few manufacturing process scenarios.
>
> *Scenario A*: A simple manufacturing process flow in which a biospecimen is processed into a finished product and shipped for delivery. There can also be a biospecimen kit shipment, which involves biospecimen kit pickup from a location and its shipment to a delivery location.
>
> - *Biospecimen Kit Pickup > Biospecimen Kit Shipment (BKS) > Biospecimen Kit Delivery*
> - *Biospecimen Pickup > Biospecimen Shipment (BS) > Processing Plant > Finished Product Shipment - Final Leg (FS-FL) > Finished Product - Final Leg Delivery*
>
> *Scenario B*: Consider a complex manufacturing process flow that involves multiple processing plants. The first plant processes a biospecimen into an intermediate product. The intermediate product is shipped to another plant where it is further processed into another intermediate product. The intermediate product is then shipped to a third processing plant where it is again processed into a finished product.
>
> - *Biospecimen Pickup > Biospecimen Shipment (BS) > Processing Plant > Intermediate Product Shipment (IS) > Processing Plant > Intermediate Product Shipment > Processing Plant > Finished Product Shipment - Final Leg (FS-FL) > Finished Product - Final Leg Delivery*
>
> There can be a number of processing plant and intermediate product combinations based on the complexity of the process.
>
> *Scenario C*: There can be a process flow that requires a finished product to be shipped (finished product transit leg shipment) to an intermediate drop-off center before the final delivery of the finished product.
>
> - *Biospecimen Pickup > Biospecimen Shipment (BS) > Processing Plant > Intermediate Product Shipment (IS) > Processing Plant > Finished Product Shipment - Transit Leg (FS-IL) > Intermediate Drop-off Center > Finished Product Shipment - Transit Leg (FS-IL) > Intermediate Drop-off Center > Finished Product Shipment - Final Leg (FS-FL) > Finished Product Final Leg Delivery*
>
> There can be multiple intermediate drop-off centers in a process flow.
>
> Therefore, you can have different logistical stages, which determine the different shipment types that must be defined in the flow steps.

1. As an example, add the following steps in the listed order for *Scenario B*. By default a blank row is already available to add the first step. *Choose Create* to add another blank row.
    1. Add a step to select the location from where the biospecimen is to be picked.
    2. Add a step to specify the shipment type and material of the biospecimen.
    3. Add a step to select the processing location of the biospecimen.
    4. Add a step to specify the shipment type and material of the intermediate product to be shipped.
    5. Add a step to select the processing location of the intermediate product.
    6. Add a step to specify the shipment type and material of the intermediate product to be shipped.
    7. Add a step to select the processing location of the intermediate product.
    8. Add a step to specify the shipment type and material of the finished product to be shipped.
    9. Add a step to select the delivery location of the finished product.

- Since a flow definition is a sequence of processing steps to be followed, you must specify the step number in *Step ID* and the next step number in *Subsequent Step ID*. Without specifying *Subsequent Step ID* for each step, there would be no flow.
  As an example, consider the flow steps given below.

Step ID	Description	Subsequent Step ID
10	Biospecimen Pickup	20
20	Biospecimen Shipment	30
30	Biospecimen Processing	40
40	Finished Product Shipment - Final Leg	50
50	Finished Product Final Leg Delivery	

- In situations when the yield of a processing activity includes one or more co-products in addition to the main product, the next step for each co-product must also be specified. To specify the next step for a co-product, enter the step number in *Additional Step ID*. Since the next step for each co-product will also differ, you must enter the step number for each co-product in *Additional Step ID*. The step number of the main product is entered in *Subsequent Step ID*. Each of these flows, for the main and co-products, will be processed in parallel.

> **Note**
>
> *Additional Step ID* is applicable only to the processing steps. You can enter one or more step numbers in *Additional Step ID* depending on the number of parallel flows applicable to co-products.

For example, consider the processing flow steps given below where the processing activity at Step ID 60 yields a main product (*MainProd1*) and a co-product (*CoProd1*). The next step for *MainProd1* is Step ID 70 (finished product shipment), and for *CoProd1*, it is Step ID 90 (processing) where the co-product is processed further to a finished product. The two flows, one for the main product and the other for the co-product, will be processed in parallel.

> **Note**
>
> This is an example of a process flow involving different shipment types.

Step ID	Description	Subsequent Step ID	Additional Step ID	Main Product	Co-Product
10	Biospecimen Kit Pickup	20			
20	Biospecimen Kit Shipment	30			
30	Biospecimen Kit Delivery	40			
40	Biospecimen Pickup	50			
50	Biospecimen Shipment	60			

Step ID	Description	Subsequent Step ID	Additional Step ID	Main Product	Co-Product
60	**Biospecimen Processing**	**70**	90	**MainProd1**	**CoProd1**
70	Finished Product Shipment - Final Leg	80		**MainProd1**	
80	Finished Product Final Leg Delivery			**MainProd1**	
90	Processing in Plant 2	100		**Intermediate-Prod1**	
100	Intermediate Product Shipment	110		**Intermediate-Prod1**	
110	Processing in Plant 3	120		**Intermediate-Prod1**	
120	Finished Product Shipment - Transit Leg	130		**MainProd2**	
130	Intermediate Drop-off Center	140		**MainProd2**	
140	Finished Product Shipment - Final Leg	150		**MainProd2**	
150	Finished Product Final Leg Delivery			**MainProd2**	

- Select a flow section type. A flow section type can be a node or a goods flow. A node can either be the pickup or delivery of a shipment, or it can be a processing activity in a plant. Goods flow determines how material is shipped. Flow section types are configured in the *Configure Flow Section Types* app. For more information, see Configure Flow Section Types [page 37].
- For a shipment pickup or drop-off, you must specify a location. Each node in the flow steps must specify the location using a location ID or location rule ID. Location ID is configured in the *Manage Organizations* app and location rule ID in the *Configure Location Rules* app. For information on how to configure location IDs, see Create an Organization [page 78]. For information on how to configure location rule IDs, see Configure Location Rules [page 38].
- Each goods flow node in the flow steps must specify the shipment type, and the material type and group combination. The supported shipment types are biospecimen kit shipment (BKS), biospecimen shipment (BS), intermediate product shipment (IS), finished product shipment - transit leg (FS-IL), and finished product shipment - final leg (FS-FL). The material type and group combination is configured in the *Configure Material Type and Group Combinations* app. For more information, see Configure Material Type and Material Group Combinations [page 32].
- If the flow definition includes a finished product transit leg shipment, select the ERP document type (either *Stock Transport Order* or *Sales Order*) to be associated with it. When you confirm the schedule of a treatment order, a request is sent to your ERP system to generate the ERP document associated with the shipment.

5. Confirm the entered details and choose *Create*.

Results

An active record is created for the flow definition. If required, you can also edit the flow steps and descriptions in the record. Any changes made to the flow definition are recorded in the change log. To edit a flow definition record, open the record and choose *Edit*. You can search for a given flow definition record using the flow version ID or any other filter, and choose *Go*.

If the flow definition is no longer required, you can deactivate the record.

5.7 Create a Transportation Lane

Create and manage transportation lanes.

Context

You can create a transportation lane between a pickup and drop off location of a shipment using the *Manage Transportation Lanes* app. A transportation lane created in the app consists of the following:

- Basic details of the lane such as courier organization, pickup and delivery times, means of transport and shipment weight.
- The costs involved in moving the shipment in the transportation lane.

The transportation lane can then be configured for an order when you create a transportation lane rule in the *Manage Transportation Lane Rules* app.

Procedure

1. Go to the *Manage Transportation Lanes* app and choose *Create*.
2. Enter a unique identifier for the lane.
3. Enter the basic details of the lane.

   The available couriers are created in the *Manage Organizations* app. The drop-down list includes the organizations with a courier business partner role.
4. Provide the costs included in transporting the shipment using the lane.

   The total estimated cost is automatically calculated based on the packaging, lane, and miscellaneous costs.
5. Confirm the entered details and choose *Create*.

Results

An active record is created for the transportation lane. If required, you can also edit the details of the lane. Any changes made to the lane are recorded in the change log.

If the transportation lane is no longer required, then you can deactivate the record.

Related Information

Manage Transportation Lane Rules [page 92]

5.7.1 Manage Transportation Lane Rules

View, create, edit, activate, and deactivate transportation lane rules.

Prerequisites

Depending on the type of rule you create, one of the following has occurred:

- A material type and material group combination have been configured
- A transportation group and packaging product type have been configured

Context

A transportation lane defines the pickup and drop-off location for a shipment as well as basic information such as the courier, times, means of transport, weight, cost, and so on. With this app, you can create transportation lane rules to automatically determine which transportation lane is used for a shipment.

The following attributes can be used to create a transportation lane rule:

- Material type and material group combination
- Transportation group and packaging product type

When the material being shipped matches the attributes defined in the rule, the transportation lane defined for that rule is used.

Procedure

1. Open the *Manage Transportation Lane Rules* app and choose *Create*.
2. Enter a unique ID for transportation lane rule.

   You can enter up to 40 characters.
3. Select a determine type.

   This is the set of attributes that determines which transportation lane is used. Choose one:

   - Transportation Group and Packaging Product Type
   - Material Type and Material Group Combination
4. If you choose *Transportation Group/Packaging Product Type*:
   1. Select a transportation group and a packaging product type.
   2. Enter the source location address details.
      These are the address details of the ship-from location.
   3. Enter destination location address details.
      These are the address details of the ship-to location.
   4. Select a transportation lane ID.
      When the material being shipped has the transportation group and packaging product type defined here, this transportation lane will be used.
   5. [Optional] Indicate whether this is the default transportation lane when this combination of attributes is used.
5. If you choose *Material Type/Material Group*:
   1. Select a material type and group combination.
   2. Enter the source location address details.
      These are the address details of the ship-from location.
   3. Enter destination location address details.
      These are the address details of the ship-to location.
   4. Select a transportation lane ID.
      When the material being shipped has the material type and material group defined here, this transportation lane will be used.
   5. [Optional] Indicate whether the transportation lane rule created is the default rule.

Results

The transportation rule you have created is available for use in your master data. When the transportation lane rule is applied to an order and the material being shipped matches the attributes defined in the rule, the transportation lane defined for that rule is used.

Related Information

Configure Transportation Groups for Materials [page 34]

Create a Transportation Lane [page 91]

6 Managing Treatment Orders

SAP Cell and Gene Therapy Orchestration provides apps that enable you to view and update treatment orders, confirm the flow version determined for treatment orders, confirm the manufacturing schedule, view orders by status, process flow, and process steps, as well as manage biospecimen shipments, processing activity, and finished product shipments.

You can manage these activities using the following apps:

- Order Overview [page 95]
- Manage Orders [page 98]
- Confirm Flow Version [page 136]
- Schedule Biospecimen Pickup Slot [page 139]
- Manage Scheduling Requests [page 142]
- Confirm Schedules [page 145]
- Manage Inbound Logistics [page 150]
- Manage Outbound Logistics [page 153]
- Manage Exceptions [page 156]
- Manage Tasks [page 159]

> **Note**
>
> Transactional data once created or received in SAP Cell and Gene Therapy Orchestration, can neither be deleted nor deactivated.

> **Note**
>
> In the *Treatment Management* apps, any record you create will remain in draft mode until you save the changes. Similarly, any changes you make to a record are stored in draft mode until saved. You can save, modify, or delete a draft record and can also exit the record without saving your data. A record in draft mode can be edited by another user after a system-defined timeout has elapsed.

6.1 Order Overview

View orders by status, process flow, and process steps.

Context

You can use this application to get an overview of the orders.

With the *Order Overview* app, you can display:

- *Orders By Overall Status*
- *Orders Waiting For Flow Version Confirmation*
- *Orders By Approval Status*
- *Orders By Actual vs Planned Dates*
- *Orders By Processing Status*

Procedure

1. Go to the *Order Overview* app.
2. Set your filters and choose *Go* to display available records. For example, you can use *Therapy* in order to find a list of orders pertaining to that therapy.
3. You must be authorized to view the orders for a specific therapy, country/region, treatment center, or the plant. Click on the card to view the details.

Tile	Description
Orders By Overall Status	Displays the number of orders against the status in a donut chart. You can click on each of the sections of the donut chart to view the details on specific status. You can navigate to the *Order List* page.
Orders Waiting For Flow Version Confirmation	Displays a subset of orders that are pending for flow version confirmation. Flow version confirmation is the process flow from creating an order, planning for shipment, the place where the biospecimen is picked up, the plant where it is processed, and the treatment center that receives this final product. This card may not display all the orders that are pending flow version confirmation due to space constraints. You can click on the card to navigate to the *Confirm Flow Version* app which contains the complete list of all those orders that are pending flow version confirmation.

Tile	Description
Orders By Approval Status	Displays orders based on approval and rejection status. There are 3 scenarios for approval: • *Order Create*: Displays the approval status for create order requests. It is displayed in a donut chart. The possible statuses are *Approved*, *Rejected*, and *Sent For Approval*. • *Order Change*: Displays the approval status for change order requests. It is displayed in a donut chart. The possible statuses are *Approved*, *Rejected*, and *Sent For Approval*. • *Order Cancel*: Displays the approval status for cancellation order requests. It is displayed in a donut chart. The possible statuses are *Approved*, *Rejected*, and *Sent For Approval*.
Orders By Actual vs Planned Dates	Displays the different stages of Treatment Order activities for Shipment and Processing Activity based on the planned date against actual date. Displays the orders delayed. The delay is measured in the dates specified in the following events: • *Finished Product Pickup* • *Biospecimen Delivery* • *Processing Completion* • *Biospecimen Pickup* • *Processing Start* • *Finished Product Delivery*
Orders By Processing Status	Displays the orders based on different processing step statuses. The following are the processing steps: • *Incoming Biospecimen* • *Biospecimen Labels* • *Biospecimen Receipt* • *Biospecimen Disposition* • *Process Order Batches* • *Processing Start* • *Finished Product Labels* • *Processing Yield* • *Finished Product Disposition* • *Allocate Batches* • *Confirm Pickup*

6.2 Manage Orders

View, approve, and update treatment orders.

Context

You can use this application to manage orders received from a treatment center. A chain of identity (COI) ID is used to track each order from creation to the delivery of a finished product, then back to the treatment center.

You can do the following based on your assigned roles:

- View the list of orders and update the details of each order as needed.
- View the flow steps associated with an order.
- View the patient information associated with an order using the *View* link in the order details view. You will be redirected to the *Patient Viewer* screen.
- View the biospecimen kit, biospecimen, intermediate product, and finished product (finished product transit leg (FS-IL) and finished product final leg (FS-FL)) shipments associated with an order. You can navigate to the *Processing* apps to view and update the processing information related to the shipments.
- View the processing activities associated with an order and create new processing activities, if required. You can navigate to the *Processing* apps to view and update all information related to the processing activities.
- View the open tasks and exceptions associated with an order.
- Create new tasks for an order. You will be redirected to the *Manage Tasks* app to create the task. For more information on how to create a task, see Manage Tasks [page 159].
- View and update order dates, order business partners, and order texts.
- View, reschedule, and cancel the scheduling requests associated with an order.
- Clone an order. Refer to Clone Orders [page 160] for details.
- Approve or reject orders, and view the approval details.
- Approve or reject cancellation requests, if any.
- View the post processing framework (PPF) events executed from the *Manage Orders* application.
- View, upload, or invalidate documents related to an order.
- View e-signatures and change logs associated with an order.

Follow the steps given below to view, approve, and update order details.

Procedure

1. Go to the *Manage Orders* app.
2. Choose *Go* in the filters section to view the list of orders. Alternatively, you can use the filter options to search for a specific order.

   For example, you can use the *COI ID* of an order to find the required order.

3. Open the required order to view the details.
4. **To approve an order or cancellation request,** choose *Approve* on the order details screen, enter the required details, and confirm.
5. **To reject an order or cancellation request,** choose *Reject* on the order details screen, enter the required details, and confirm.
6. **To update an order,** choose *Edit* on the order details screen, update the required details, and *Save* the changes.

Tab	Details
General Information	You can view the basic details about an order. • *Order Number* – Displays the order number, which is used to identify an order within the solution. • *Patient Therapy Number* – Patient therapy number is received from the treatment center and can be updated. In case it is left blank, then COI ID is considered as the patient therapy number. • *Patient ID* – Displays the unique anonymized identifier of a patient. • *Treatment Center* – Displays the unique identifier of the treatment center from which the order was initiated. • *Therapy* – Displays the unique identifier of the therapy associated with the order. • *Flow Version* – Displays the unique identifier of the confirmed flow version for the order. • *Country/Region* – Displays the country/region of the treatment center. • *Order Type* – Displays the order type. • *Overall Status* – Indicates the status of the order. • *Cancellation Status* – Indicates the status of the cancellation request, if any. • *Clinical Trial Subject ID* – Displays the unique identifier of the clinical trial subject. The ID is received from the treatment center and is applicable for clinical trials. • *Clinical Randomization Variable* – Displays the unique identifier of a medical condition. The ID is received from the treatment center. • *Open Tasks*: Displays the open tasks associated with the order. Choose the hyperlink under *Open Tasks* to view the details of the open tasks in the *Manage Tasks* app. • *Open Exceptions*: Displays the open exceptions associated with the order. Choose the hyperlink under *Open Exceptions* to view the details of the open exceptions in the *Manage Exceptions* app. • *Source Systems*: Displays the external system or application from which the data is transferred or action is triggered to the SAP system. • *Is COI ID External*: Indicates whether the Chain of Identity (COI) ID was generated in an external system or in SAP Cell and Gene Therapy Orchestration. • If *Yes*, the COI ID was generated in an external system and replicated to SAP Cell and Gene Therapy Orchestration.

Tab	Details
	• If *No*, the COI ID was generated in SAP Cell and Gene Therapy Orchestration.
Process Flow	Visual representation of the steps an order goes through, for example, from biospecimen collection to finished product delivery. For more information about flow definition, see Create a Flow Definition [page 87].
Order Dates	Displays the key dates applicable for the order. You can update the following dates in this tab. • *Final Product Delivery Date* - This date is received from the treatment center, but can be updated. • *Order Created* - This date is received from the treatment center, but can be updated. • *Reference Order Change Date/Time* - Indicates the date on which the order details were last updated from the treatment center.
Business Partners	You can view the details of the business partners associated with the order. For example, principal investigator/prescriber.
Shipments	You can view details of biospecimen kit shipments, biospecimen shipments, intermediate product shipments, and finished product shipments (finished product transit leg (FS-IL) and finished product final leg (FS-FL)) associated with the order. You can navigate to the *Processing* apps to view and update the processing information related to shipments. Choose the shipment ID to access links to the related *Processing* apps. Similarly, you can also navigate to the *Manage Shipments* apps to view and update shipment details. Choose *Create Subsequent* to create a subsequent shipment. This is applicable to biospecimen and finished product final leg shipments. For information on how to create subsequent shipments, see Create Subsequent Shipments and Processing Activities [page 130].

Tab	Details
Processing Activities	You can view details of the processing activities associated with the order and create new processing activities, if required. You can also navigate to the *Processing* apps to view and update all the information related to the processing activities. Choose the processing activity ID to access the links to the related *Processing* apps. Choose *Create Subsequent* to create a subsequent processing activity. For information on how to create subsequent processing activities, see Create Subsequent Shipments and Processing Activities [page 130].
Related Orders	Displays the relationship of the order with the follow on orders. For each related order, you can see the state (*Active* or *Inactive*), therapy, relationship (*Clone*), relationship context, and the reason for cloning. Choose the order (under *Related* column) to view details.
Additional Order Information	You can provide additional information (custom texts) about the treatment order. For example, "This is a high-priority clinical trial order". To add information, go to the edit mode and choose *Create*. Select the ID with which to associate the additional order information. The description associated with the ID is displayed. Select the language in which to save this information. In *Value*, enter the additional information. Choose *Apply*. This saves and associates the additional information with the ID in the selected language. It is recommended that you keep the ID and language combination unique across a treatment order and its shipments. You can also delete or modify existing entries. Select the line item and choose *Delete*. To modify additional order information, select the line item and make the required changes. The system prompts you to select a reason code on adding or modifying additional order information.

Tab	Details
Approval Details	View approvals pending for order creation, order changes, and order cancellation. You can approve or reject orders received from the treatment center. When an order is received, the approval workflow is triggered and an approval entry is logged on this tab. When the authorized user approves or rejects an order, the approval status is logged on this tab. You can see the name of the person who approves or rejects the order in the *Decision By* field. Choose *Pending Approvals* to approve or reject an order workflow. The *Pending Approvals* dialog shows all the workflows of the order that are pending for approval. For example, approvals pending for creating an order, order changes, and order cancellation. You can choose *Approve* or *Reject* for each workflow. On selecting *Approve* or *Reject*, you are prompted to select a reason code for approval or rejection. The system does not allow you to proceed without selecting a reason code. Therefore, you must configure reason codes in the application before any approval or rejection is done. For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the workflows or scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals. After you approve or reject an order, a workflow notification about the approval decision is triggered. In addition, an outbound event about the approval decision is sent. **Note** • Order approval is an optional process step. You can continue with the processing activities without approving the order. • When an order cancellation request is received from the treatment center, you must check the status of the dependent activities and then decide if the request must be approved or rejected. For example, *Shipment Status*. • In scenarios where the cancellation request is approved, you must check and cancel the dependent activities manually. • A workflow needs to be configured to trigger order cancellation approval process. After the required workflow is configured, if an order cancellation request is received from the treatment center, then the order cancellation request can

Tab	Details
	be reviewed and approved/rejected through the *Pending Approvals* button. You can only approve an order cancellation if the order profile has *Order Cancelled* set as the next possible status.
PPF Events	Displays the logs generated as a result of triggering post processing framework events for the given treatment order. Each log displays the following information for a triggered event: • Event Type: Business, Workflow, Process, Notification • Event Status: Triggered, Started, Completed, Failed, Ignored • Error Message: Message appears if a triggered event fails or is ignored. • Created On: Date of triggering the event. You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event. **Note** Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems. For more information, see Configure Post-Processing Events [page 58].

Tab	Details
Cancellation Request Details	When a cancellation request is received from the treatment center, the cancellation workflow is triggered, and the cancellation details are logged in this tab. Choose *Pending Approvals* to approve or reject the cancel order workflow. Choose *Approve* or *Reject* to approve or reject the workflow. You can approve or reject if you have the required authorization. On selecting *Approve* or *Reject*, you are prompted to select a reason code for approval or rejection. The system does not allow you to proceed without selecting a reason code. Therefore, you must configure reason codes in the application before any approval or rejection is done. Refer to Configure Reason Codes [page 43] for information on how to configure reason codes. For information on the workflows or scenarios for which reason codes must be configured, refer to Reason Codes for Order and Shipment Approvals in the *Administration Guide*. **Note** • When a cancellation request is received from the treatment center, you must check the status of the dependent activities and then decide if the request must be approved or rejected. For example, biospecimen shipment status, processing activity status, and finished product shipment status. • In scenarios where the cancellation request is approved, you must check and cancel the dependents activities manually. • You can only approve an order cancellation if the order profile has *Order Cancelled* set as the next possible status.
Documents	Displays the documents associated with the order. You can upload new documents or invalidate existing documents by choosing the respective buttons. **Note** You will be redirected to the *Document Upload* screen to upload a document. You can also generate the traceability report for active orders using the *Generate Traceability Report* button. For more information, see Generate Traceability Report [page 132].

Tab	Details
Logs	You can view the document, e-signature, change, and approval logs related to the order. For example, the *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Change Log* section displays the logs of all changes related to the order, and the *Approval Log* section displays logs related to approvals for order creation, order changes, and order cancellations. For each approval or rejection done, you can see the name of the person in the *Decision By* field.

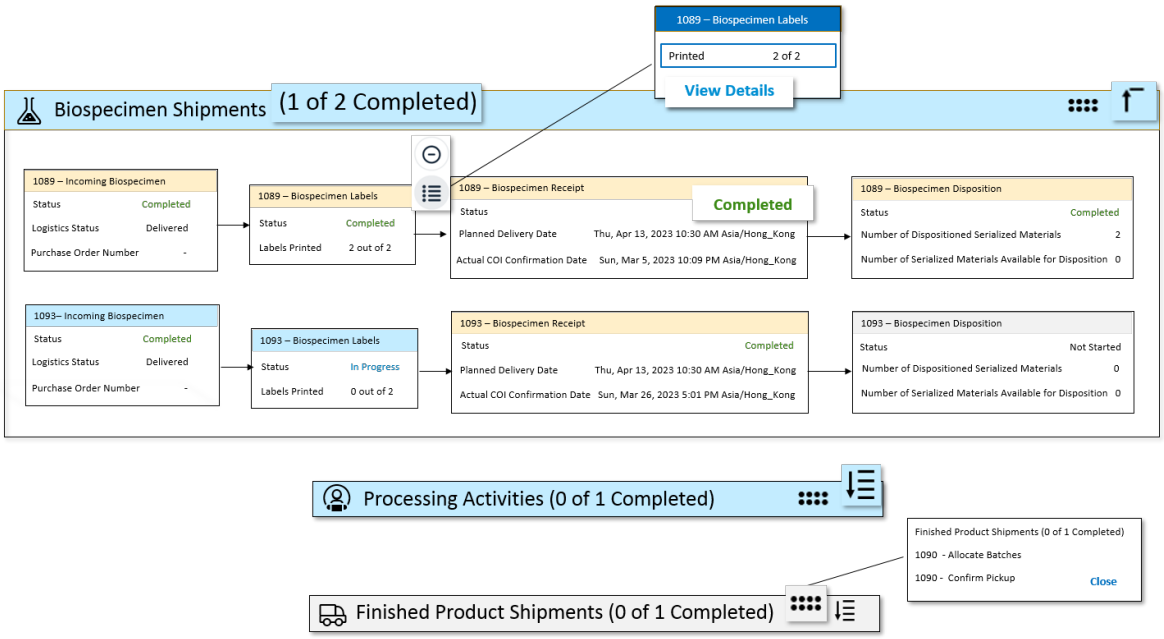
6.2.1 Process Flow

In the *Manage Orders* app under *Process Flow*, you can access a dynamic diagram that provides an overview of the order processing steps.

Depending on the flow definition created for the order, you'll see one or more of the following process groups: *Biospecimen Shipments*, *Processing Activities*, *Finished Product Shipments*.

> ⓘ Note
>
> Each process group can have multiple processes, for example the process group *Biospecimen Shipments* can have multiple shipments. You can expand each process group to see a standard set of process steps for each proces (for example, a biospecimen shipment always has the steps: Incoming Biospecimen, Biospecimen Labels, Biospecimen Receipt, and Biospecimen Disposition). You can open any of the process steps in the diagram to view or update the details.

Process Flow Diagram



- Process Flow [page 106]
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- Process Flow [page 106]
- Process Flow [page 106]

Understanding the Statuses

Each process step has the status *Not Started*, *In Progress*, or *Completed*. These statuses help you understand where you are in the manufacturing process and what is still pending. The following tables tells you when the status of a process step is in progress and what you need to do for the status of the process step to change to completed.

Biospecimen Shipments

Process Step	Status: Not Started	Status: In Progress	Status: Completed
Incoming Biospecimen	Batch numbers are not available for any material or subunit in the biospecimen shipment.	Batch numbers are available for one or more, but not all, batch-managed materials in the biospecimen shipment. **Note** The batch numbers can be present at the material or subunit level, or at both.	Batch numbers are available for all batch- managed materials in the shipment. **Note** The batch numbers can be present at the material or subunit level, or at both. For more information, see Manage Incoming Biospecimen.
Biospecimen Labels	No labels for the biospecimen shipment are printed.	One or more, but not all, labels for the biospecimen shipment are printed.	All labels for the biospecimen shipment are printed. For more information, see Print Hangtag Labels.
Biospecimen Receipt	No materials or subunits marked as received and no *Actual COI Confirmation Date* or *Receipt Confirmation* details are provided.	One or more materials or subunits are marked as received but no *Actual COI Confirmation Date* or *Receipt Confirmation* details are provided.	The *Actual COI Confirmation Date* and *Receipt Confirmation* details are provided for the biospecimen shipment. For more information, see Confirm Shipment Receipt.
Biospecimen Disposition	For disposition relevant materials, all batch statuses or subunit disposition statuses are either not specified or are *In Quality Inspection*.	For disposition relevant materials, one or more batch statuses or subunit disposition statuses are not specified or are *In Quality Inspection*.	• For serialized materials that are disposition relevant, all subunits in the shipment have a disposition status of *Unrestricted* or *Released with Restrictions*. OR • For non-serialized materials that are disposition relevant, all batches in the shipment have a batch status of *Unrestricted* or *Released with Restrictions*. For more information, see Manage Biospecimen Disposition

Processing Activities

Process Step	Status: Not Started	Status: In Progress	Status: Completed
Process Order Batches	The batch number is not updated for any batch-managed finished product material.	The batch number is updated for at least one batch-managed finished product material.	The batch numbers are updated for all batch-managed finished product materials For more information, see Manage Process Order Batch Details.
Processing Start	The *Actual Processing Start Date* is not specified for the finished product batches.	Not Applicable	The *Actual Processing Start Date* is specified for all finished product batches. For more information, see Report Processing Start.
Finished Product Labels	No labels for the finished product shipment are printed.	The batch numbers are updated for all batch-managed finished product materials	All labels for the finished product shipment are printed. For more information, see Print Finished Product Labels.
Processing Yield	The *Actual Processing End Date* is not reported and none of the subunits have been marked as produced.	• The *Actual Processing End Date* is reported and none of the subunits have been marked as produced. OR • At least one of the subunits is marked as produced but the *Actual Processing End Date* is not reported.	• The *Actual Processing End Date* is reported and at least one subunit is marked as produced. OR • If the manufacturing is terminated, then the *Processing Status* is marked as terminated. For more information, see Report Processing Completion.

Process Step	Status: Not Started	Status: In Progress	Status: Completed
Product Disposition	For disposition relevant materials, all batch statuses or subunit disposition statuses are either not specified or are *In Quality Inspection*.	For disposition relevant materials, one or more batch statuses or subunit disposition statuses are not specified or are *In Quality Inspection*.	• For serialized materials that are disposition relevant, all subunits in the shipment have a disposition status of *Unrestricted* or *Released with Restrictions*. OR • For non-serialized materials that are disposition relevant, all batches in the shipment have a batch status of *Unrestricted* or *Released with Restrictions*. Fore more information, see Manage Product Disposition [page 175].

Finished Product Shipments

Process Steps	Status: Not Started	Status: In Progress	Status: Completed
Allocate Batches	No finished product material is allocated for shipment	Not Applicable	At least one finished product batch is allocated for shipment. For more information, see Allocate Batches to Shipment.
Confirm Pickup	The *Actual Pickup Date* and *Shipment Confirmation* details are not provided.	• The *Actual Pickup Date* is provided but not the *Shipment Confirmation* details. OR • The *Shipment Confirmation* details are provided but not the *Actual Pickup Date*.	The *Actual Pickup Date* and *Shipment Confirmation* details are provided. For more information, see Confirm Shipment Pickup.

6.2.2 Manage Biospecimen Kit Shipments

View and manage biospecimen kit shipment information.

To manage a biospecimen kit shipment, go to the *Shipments* tab in the *Manage Orders* app. Choose the shipment ID under *Biospecimen Kit Shipment* and choose *Manage Shipments*.

Using this app, you can:

- Manage shipment information.

- Confirm receiving the shipment.
- Check the chain of identity (COI) of the shipment.
- Allocate batches to the shipment.

- On the *General Information* tab, you can view and edit general information about the shipment. You can change the shipment status, cancellation status, COI confirmation status, and the shipment reason.
- On the *Locations* tab, you can view and change the shipment source and destination location address details. You can also maintain primary and alternate contacts for both the locations.
- On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. However, it is mandatory to add at least one business partner to the following business partner categories:
  - Bill-To Party (CRM004)
  - Sold-To Party (CRM000)
  - *Goods Recipient (CRM002)
    *Goods Recipient is the same as Ship-To Party.
  - To add or remove a business partner, choose *Edit*.
    - On the *Business Partners* tab, choose *Add*.
    - Select a business partner category.
    - Enter the business partner function.
    - Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
    - Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

  > **Note**
  >
  > Prerequisites to add business partners to a business partner category:
  > - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
  > - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

- Determine the transportation lane for the biospecimen kit shipment. Choose *Determine Transportation Lane* to get the courier details, that is, courier contact person, courier ID, account number, and the transportation lane for the shipment if this information is not already available in the *Logistics Details* section on the *Logistics* tab. If the information is available and you still choose *Determine Transportation Lane*, the system displays a warning message to confirm whether you want to overwrite the existing information and determine the courier details and transportation lane again.
- Book a courier for the shipment.
  - Choose *Book Courier*.
  - On the *General Information* tab, you can see the courier ID, courier contact name, and transportation lane name.
  - The *Dates* tab displays the planned pickup and delivery dates.
  - On the *Shipper* tab, you can see the shipper name and address.
  - The *Consignee* tab displays the consignee name and address.
  - The *Shipped Items* tab shows information (material name, quantity, gross weight, packaging type) about the items to be shipped.

- On the *Instructions* tab, provide the pickup and delivery instructions. Specify the number of shippers required and choose *Save*.
    - If you do not specify a value, the system takes one (1) as the default value for the number of shippers required. The courier booking request will now be placed, and the information you provided will be sent to the courier system through the courier booking event. Based on the number of shipping containers requested, the courier sends shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link). If due to some technical issue, this information is not received, you can manually provide the information. This information is seen in the *Waybill Details* section on the *Logistics* tab.
- The details on the *Logistics* tab are generated after you determine the transportation lane. The *Logistics* tab displays the courier details and waybill details. Courier details include the courier ID, courier contact person name, and the transportation lane name. Waybill details include the waybill number, shipper serial number, and shipper tracking link (GPS of shipper). There can be multiple shipper serial numbers per waybill number. Each shipper serial number, however, must be unique.
- On the *Shipment Dates* tab, verify the planned and actual delivery schedule for the shipment.
- On receiving a shipment, you must confirm the receipt of the shipment and shipper, and check whether the shipment and shipper meet the acceptance criteria. The *Product Acceptable* tab has two sections: *Shipment Confirmation* and *Receipt Confirmation*.
    - In the *Shipment Confirmation* section, you must check and specify the following:
        - The serial number on the shipper matches the serial number in the system.
        - The product packed in the shipper can be identified by the shipper serial number.
    - In the *Receipt Confirmation* section, enter the following information:
        - Names of the users who approved and verified the shipper and shipper content.
        - Dates of approving and verifying the shipper and shipper content.
        - Check the *Verified* box. The *Product Review Status* changes to *Accepted*.
- On the *Biospecimen Kit Batches* tab, you can allocate batches for shipment. Only batches with inventory status, *Available to Ship* and disposition status, *Unrestricted Use* or *Released with Restrictions* can be allocated for shipment. To allocate a batch:
    - Choose *Allocate Batches*. This opens a popup window.
    - Choose *Create*. This adds a blank row.
    - Select the batch material from the dropdown.
    - Specify the batch number, quantity of material to be allocated, and the unit of measure.
    - Choose *Next*.
    - In the *E-Signature* popup window, specify your signature and select the reason code for this action. Choose *Save*.

  Repeat the above steps to allocate another batch. You can deallocate batches, if required. To deallocate a batch, select the batch and choose *Remove Allocated Batch*.
- On the *Biospecimen Kit Batches* tab, you can view and edit the biospecimen kit material specifications such as the vendor details, shipper serial number, batch status, dispositioned quantity, inventory status, and expiry date. Choose the biospecimen kit material line item to view and edit the batch details that primarily include the:
    - Material and vendor details
    - Shipment and order status
    - Batch and inventory status of the biospecimen kit
    - Shipping serial number and item category

- On the *Additional Shipment Information* tab, you can provide information (custom texts) about the shipment that is not maintained in standard fields. For example, you can provide packing or shipment instructions.
  To add information:
  - In the *Edit* mode, choose *Create*.
  - Select the ID using the dropdown.
  - Select the language in which you want to save this information. This saves and associates the information with the ID in the selected language.
  - In *Value*, enter the information and choose *Apply*.

  It is recommended that you keep the ID and language combination unique for the associated treatment order and its shipments.
  You can modify or delete the information. To modify it, select the line item and make the required changes. To delete it, select the line item and choose *Delete*.
  The system prompts you to select a reason code on adding or modifying additional shipment information.
- The *PPF Events* tab displays the logs generated as a result of triggering post processing framework events for the shipment. Each log displays the following information for a triggered event:
  - Event Type: Business, Workflow, Process, Notification
  - Event Status: Triggered, Started, Completed, Failed, Ignored
  - Error Message: Message appears if a triggered event fails or is ignored.
  - Created On: Date of triggering the event.

  You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event.

  > **Note**
  >
  > Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems.

  For more information, see Configure Post-Processing Events [page 58].
- On the *Documents* tab, upload or invalidate documents associated with the biospecimen kit shipment. For more information on how to upload documents, see Upload Documents [page 180].
- On the *Logs* tab, you can view the document, e-signature, approval, and change logs related to the shipment. The *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Approval Log* section displays the logs related to shipment approvals, and the *Change Log* section displays the logs of all changes related to the shipment.
- You can request for cancellation of a shipment, if required. You must have the necessary authorization to request for a cancellation. To cancel a shipment, choose *Request for Cancellation*. The *Shipment Cancellation Status* changes to *Cancellation Requested*. The cancellation request is logged on the *Cancellation Request Details* tab.

  > **Note**
  >
  > You can configure the statuses to be displayed on the user interface. For more information, see , , and

  To automatically trigger the shipment cancellation approval process, a workflow is configured.
  The configured workflow triggers a notification and initiates the cancellation approval process in SAP Cell and Gene Therapy Orchestration.

For each cancellation request, an approval entry is logged on the *Approval Details* tab. You can approve or reject a cancellation request if you have the required authorization. Choose *Pending Approvals* to approve or reject a shipment. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable. For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals. After the authorized user approves or rejects the shipment cancellation request, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approves or rejects the shipment in the *Decision By* field. An entry is also added in the *Approval Logs* section on the *Logs* tab. When a shipment cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.
A workflow notification about the approval decision is triggered. In addition, an outbound event about the approval decision is also sent.
For more information on the notifications generated during the cancellation process, see Configure Post Processing Framework Events.

> **Note**
>
> Cancellation of the shipment triggers *Sales Order Cancellation*, an outbound event to cancel the sales order in *S/4HANA*. This sales order is linked with the shipment in SAP Cell and Gene Therapy Orchestration.

- You can create tasks for the shipment and assign the tasks to yourself or to another user. Choose *Create Task*. On doing so, you will be redirected to the *Manage Tasks* app to create the task. For more information on how to create a task, see Manage Tasks [page 159].

6.2.3 Manage Biospecimen Shipments

View and manage biospecimen shipment information.

To manage a biospecimen shipment, go to the *Shipments* tab in the *Manage Orders* app. Choose the shipment ID under *Biospecimen Shipments*, and choose *Manage Shipments*.

Using this app, you can:

- Manage incoming biospecimen material.
- Confirm receiving the shipment.
- Check the chain of identity (COI) of the shipment.
- Manage the disposition status of the material.
- On the *General Information* tab, you can view and edit general information about the shipment. You can change the shipment status, cancellation status, COI confirmation status, and the shipment reason.
- On the *Locations* tab, you can view and change the shipment source and destination location address details. You can also maintain primary and alternate contacts for both the locations.
- On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. It is however mandatory for you to add at least one business partner each to the **Vendor (BBP000)** and **Supplier (CRM007)** categories.
  - To add or remove a business partner, choose *Edit*.
    - On the *Business Partners* tab, choose *Add*.

- Select a business partner category.
- Enter the business partner function.
- Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
- Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

> **Note**
>
> Prerequisites to add business partners to a business partner category:
> - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
> - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

- Choose *Determine Transportation Lane* to get courier information, that is, courier contact person, courier ID, account number, and the transportation lane for the shipment if this is not already available on the *Logistics* tab. If the details are seen and you still determine the transportation lane, the system displays a warning message to confirm whether you want to overwrite the existing information and determine the courier details and transportation lane again.
- Book a courier for the shipment.
  - Choose *Book Courier*.
  - On the *General Information* tab, you can see the courier ID, courier contact name, and transportation lane name.
  - The *Dates* tab displays the planned pickup and delivery dates.
  - On the *Shipper* tab, you can see the shipper name and address.
  - The *Consignee* tab displays the consignee name and address.
  - The *Shipped Items* tab shows information (material name, quantity, gross weight, packaging type) about the items to be shipped.
  - On the *Instructions* tab, provide the pickup and delivery instructions. Specify the number of shippers required and choose *Save*.
    - If you do not specify any value, the system takes one (1) as the default value for the number of shippers required. A courier booking request is placed, and the information you provided is sent to the courier system through a courier booking event. Based on the number of shipping containers requested, the courier will send shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link).

    This information is seen in the *Waybill Details* section on the *Logistics* tab. If due to some technical issue, this information is not received, you can manually enter the information.
- The *Logistics* tab displays the courier details and waybill details. Courier details include the courier ID, courier contact person name, and the transportation lane name. Waybill details include the waybill number, shipper serial number, temperature monitoring serial number, and shipper tracking link (GPS of shipper and temperature). There can be multiple shipper serial numbers per waybill number. Each shipper serial number, however, must be unique.
- On receiving a shipment, you must confirm the receipt of the shipment and shipper, and check whether the shipment and shipper meet the acceptance criteria.
  The *Shipment and Receipt* tab has two sections: *Receipt Confirmation* and *Shipment Confirmation*.
  - In the *Receipt Confirmation* section, you must check and specify the following:
    - Are the shipping conditions within acceptable parameters.

        - Do the patient attributes on the cryobag match the details on the biospecimen data form and biospecimen hangtag labels.
    - In the *Shipment Confirmation* section, enter the following information:
        - Names of the users who approved and verified the shipment.
        - Dates of approving and verifying the shipment.
- On the *Additional Shipment Information* tab, you can provide additional information (custom texts) about the shipment. For example, you can provide packing instructions for the shipment.
  To add information:
    - In the *Edit* mode, choose *Create*.
    - Select the ID using the dropdown.
    - Select the language in which you want to save this information. This saves and associates the information with the ID in the selected language.
    - In *Value*, enter the information and choose *Apply*.

  It is recommended that you keep the ID and language combination unique for the associated treatment order and its shipments.
  You can modify or delete the additional shipment information. To modify it, select the line item and make the required changes. To delete it, select the line item and choose *Delete*.
  The system prompts you to select a reason code on adding or modifying additional shipment information.
- The *PPF Events* tab displays the logs generated as a result of triggering post processing framework events for the shipment. Each log displays the following information for a triggered event:
    - Event Type: Business, Workflow, Process, Notification
    - Event Status: Triggered, Started, Completed, Failed, Ignored
    - Error Message: Message appears if a triggered event fails or is ignored.
    - Created On: Date of triggering the event.

  You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event.

  > **Note**
  >
  > Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems.

  For more information, see Configure Post-Processing Events [page 58].
- On the *Biospecimen Materials* tab, you can view and edit the biospecimen material specifications such as the shipper serial number, consumption status, and received status.

  > **Note**
  >
  > The shipper serial number is associated at the material or subunit level. For serialized material, the shipper serial number is associated at the subunit level. For non-serialized material, the shipper serial number is associated at the material level.

- Select the biospecimen material line item to view and edit the batch and subunit details that primarily include the:
    - Batch and subunit batch numbers
    - Receipt confirmation of the shipment

    - Batch and disposition status of the biospecimen based on quality checks
    - Consumption status of the batch and subunits
- On the *Collection Details* tab, view the collection center details of the biospecimen batch. A collection center is an organization with location type, Collection Location (COL). It requires a new configuration in which a valid relationship between a treatment center and collection center should be established and maintained. The collection center is derived when collection information is sent for the biospecimen shipment.
- On the *Release Decision History* tab, view the different release types and the release decision taken for each release type of the biospecimen batch. The release decision for a batch is taken in the SAP Batch Release Hub. For more information about the release decision process, refer to the SAP Batch Release Hub for Life Sciences User Guide. After the release decision is taken in the SAP Batch Release Hub, this information is updated in *S/4HANA*. Refer to the User Guide for SAP S/4HANA add-on for SAP Cell and Gene Therapy Orchestration to know more about the process. *S/4HANA* then passes the abstract information to SAP Cell and Gene Therapy Orchestration that helps the user to coordinate with other supply chain stakeholders and take correct action. For each release type, the following information is seen:
    - Release Decision: Decision taken for the release type.
    - Decision Set By: Name of the person who has taken the decision.
    - Decision Set On: Date and time of the decision.
    - Comments
    - Usage Decision: Usage decision text and code. For example, Accepted (A). Use the *Settings* button to enable this column.

Select a line item to view whether the biospecimen batch is suitable for release across geographical locations. The decision to release a given biospecimen batch can be different for countries and regions depending on the release checks and compliances required to release a given shipment batch.

> **Note**
>
> The release decision history of biospecimen shipments is visible only when the release decision feature is enabled for a given tenant. In addition, the release decision history is not applicable to biospecimen material that is not batch managed.

- On the *Additional Material Batch Information* tab, you can provide additional information (custom texts) about the selected biospecimen material batch item. The steps to add, edit, and delete additional information are identical to the steps listed for maintaining additional information at the shipment level.
- You can request for the cancellation of a shipment, if required. To cancel a shipment, choose *Request for Cancellation*. You must have the necessary authorization to request for a cancellation. When you request to cancel a shipment, the *Shipment Cancellation Status* changes to *Cancellation Requested* and the cancellation request is logged on the *Cancellation Request Details* tab.

  > **Note**
  >
  > You can configure the statuses to be displayed on the user interface. For more information, see , , and .

- To automatically trigger the shipment cancellation approval process, a cancellation approval workflow is configured.
  The configured workflow triggers a notification and initiates the cancellation approval process in SAP Cell and Gene Therapy Orchestration.
- For each cancellation request, an approval entry is logged on the *Approval Details* tab. You can approve or reject a cancellation request if you have the required authorization. To approve or reject a cancellation

request, choose *Pending Approvals*. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable. For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals. After an authorized user approves or rejects the shipment cancellation request, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approved or rejected the cancellation request in the *Decision By* field.
An entry is also added in the *Approval Logs* section on the *Logs* tab. When a cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.
A workflow notification about the approval decision is triggered. In addition, an outbound event about the approval decision is also sent.
For more information on the notifications generated during the cancellation process, see Configure Post Processing Framework Events.

> **Note**
>
> Cancellation of the shipment triggers *Purchase Order Cancellation*, an outbound event to cancel the purchase order in *S/4HANA*. This purchase order is linked with the shipment in SAP Cell and Gene Therapy Orchestration.

- On the *Documents* tab, upload or invalidate documents associated with the biospecimen shipment. For more information on how to upload documents, see Upload Documents [page 180].
- On the *Logs* tab, you can view the document, e-signature, change, and approval logs related to the shipment. For example, the *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Change Log* section displays the logs of all changes related to the shipment, and the *Approval Log* section displays details related to shipment approvals. For each approval or rejection done, you can see the name of the person who approved or rejected the shipment in the *Decision By* field.
- You can create tasks for the shipment and assign the tasks to yourself or to another user. Choose *Create Task*. On doing so, you are redirected to the *Manage Tasks* app to create the task. For more information on how to create a task, see Manage Tasks [page 159].
- View and edit the expiration date and time of the biospecimen. If the expiration date and time is sourced through inbound events, then it cannot be edited manually, or through the *Calculate Expiry Date* field, or through a configured post processing framework event.

Related Information

Create a Contact Person for an Organization [page 77]

6.2.4 Manage Intermediate Product Shipments

View and manage intermediate product shipment information.

To manage intermediate product shipments, go to the *Shipments* tab in the *Manage Orders* app. Choose the shipment ID under *Intermediate Product Shipments*, and then choose *Manage Shipments*. You can view, edit, and manage shipment details.

Using this app, you can:

- Manage shipment information.
- Allocate batches to the shipment.
- Confirm receiving the shipment.
- Check the chain of identity (COI) of shipment.
- Manage the disposition status of shipment batches and subunits.
- On the *General Information* tab, you can view and edit information about the shipment. You can change the shipment status, cancellation status, COI confirmation status, and shipment reason.
- The *Locations* tab displays the shipment source and destination location address details. You can change the address details and also maintain primary and alternate contacts for both the locations.
- On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. However it is mandatory for you to add at least one business partner to each of the following categories:
  - Bill-To Party (CRM004)
  - *Goods Recipient (CRM002)
  - Sold-To Party (CRM000)
  - Vendor (BBP000)
  - Supplier (CRM007)

  *Goods Recipient is the same as Ship-To Party
  - To add or remove a business partner, choose *Edit*.
    - On the *Business Partners* tab, choose *Add*.
    - Select a business partner category.
    - Enter the business partner function.
    - Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
    - Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

  > **Note**
  >
  > Prerequisites to add business partners to a business partner category:
  > - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
  > - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].
- Choose *Determine Transportation Lane* to get the transportation lane and courier information (courier contact person, courier ID, account number) for the shipment if this is not already available on the *Logistics* tab. If available and you still determine the transportation lane, the system displays a warning message to confirm whether you want to overwrite the existing information.
- The *Logistics* tab displays courier details in the *Logistics Details* section. You can maintain alternate contacts in the *Alternate Contact Persons* section. The *Waybill Details* section displays the waybill number, shipper serial number, and other information received when a courier is booked.
- Book a courier for the shipment.
  - Choose *Book Courier*.

- On the *General Information* tab, you can see the courier ID, courier contact name, and transportation lane name.
- The *Dates* tab displays the planned pickup and delivery dates.
- On the *Shipper* tab, you can see the shipper name and address.
- The *Consignee* tab displays the consignee name and address.
- The *Shipped Items* tab shows information (material name, quantity, gross weight, packaging type) about the items to be shipped.
- On the *Instructions* tab, provide the pickup and delivery instructions. Specify the number of shippers required and choose *Save*
    - If you do not specify a value, the system takes one (1) as the default value for the number of shippers required. The courier booking request will now be placed, and the information you provided will be sent to the courier system through the courier booking event. Based on the number of shipping containers requested, the courier sends shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link). If due to some technical issue, this information is not received, you can manually provide the information. This information is seen in the *Waybill Details* section on the *Logistics* tab. There can be multiple shipper serial numbers per waybill number. Each shipper serial number, however, must be unique.

- On receiving a shipment, you must confirm the receipt of the shipment and shipper, and check whether the shipment and shipper meet the acceptance criteria.
    - The *Shipment and Receipt* tab has two sections: *Shipment Confirmation* and *Receipt Confirmation*.
        - In the *Shipment Confirmation* section, you must check and specify the following:
            - The serial number on the shipper matches the serial number in the system.
            - The product packed in the shipper can be identified by the shipper serial number.
        - In the *Receipt Confirmation* section, enter the following information:
            - Names of the users who approved and verified the shipper and shipper content.
            - Dates of approving and verifying the shipper and shipper content.
            - Check and specify whether the shipping conditions are within acceptable parameters.
            - Check and specify whether the patient attributes match the details given on the shipment's hangtag labels.
- On the *Additional Shipment Information* tab, you can provide additional information (custom texts) about the shipment. For example, you can provide packing instructions for the shipment.
  To add information:
    - In the *Edit* mode, choose *Create*.
    - Select the ID using the dropdown.
    - Select the language in which you want to save this information.
    - In *Value*, enter the information and choose *Apply*. This saves and associates the information with the ID in the selected language.

  It is recommended that you keep the ID and language combination unique for the associated treatment order and its shipments.
  You can modify or delete information. To modify it, select the line item and make the required changes. To delete it, select the line item and choose *Delete*.
  The system prompts you to select a reason code on adding or modifying additional shipment information.
- The *PPF Events* tab displays the logs generated as a result of triggering post processing framework events for the shipment. Each log displays the following information for a triggered event:
    - Event Type: Business, Workflow, Process, Notification

- Event Status: Triggered, Started, Completed, Failed, Ignored
- Error Message: Message appears if a triggered event fails or is ignored.
- Created On: Date of triggering the event.

You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event.

> **Note**
>
> Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems.

For more information, see Configure Post-Processing Events [page 58].

- On the *Intermediate Product Shipment Batches* tab, you can allocate and deallocate batches for shipment. Only batches with inventory status, *Available to Ship* and disposition status, *Unrestricted Use* or *Released with Restrictions* can be allocated for shipment. Choose *Allocate Batches* to allocate batches for shipment. A popup window showing the batches available for allocation appears. Select the material to be allocated. Choose *Confirm*. You are prompted for authentication. Enter your password, select a reason code for this action, and choose *Save*. The allocated batches are shown in the *Allocated* section. You can deallocate a batch, if required. Select the batch to be deallocated and choose *Remove Allocated Batch*.
  - Select the allocated batch material line item to view and edit batch and subunit details such as the shipper serial number, batch status, disposition status, dispositioned quantity, shipped quantity, and other information.

    > **Note**
    >
    > You can assign a shipper serial number to the batch (if the batch is non-serialized) and its subunits (if the batch is serialized).

  - On the *Release Decision History* tab, view the different release types and the release decision taken for each release type of the intermediate product batch. The release decision for a batch is taken in the SAP Batch Release Hub. For more information about the release decision process, refer to the SAP Batch Release Hub for Life Sciences User Guide. After the release decision is taken in the SAP Batch Release Hub, this information is updated in *S/4HANA*. Refer to the User Guide for SAP S/4HANA add-on for SAP Cell and Gene Therapy Orchestration to know more about the process. *S/4HANA* then passes the abstract information to SAP Cell and Gene Therapy Orchestration that helps the user to coordinate with other supply chain stakeholders and take correct action. For each release type, the following information is seen:
    - Release Decision: Decision taken for the release type.
    - Decision Set By: Name of the person who has taken the decision.
    - Decision Set On: Date and time of the decision.
    - Comments
    - Usage Decision: Usage decision text and code. For example, Accepted (A). Use the *Settings* button to enable this column.

> **Note**
>
> For a stock transport order scenario for an intermediate product shipment, the release decision information sent to SAP Cell and Gene Therapy Orchestration originates from the quality process of the batch that has been received at the receiving plant.

- You can request for the cancellation of a shipment, if required. To cancel a shipment, choose *Request for Cancellation*. You must have the necessary authorization to request for a cancellation. The *Shipment Cancellation Status* changes to *Cancellation Requested*. The cancellation request is logged on the *Cancellation Request Details* tab.

  > **Note**
  >
  > You can configure the statuses to be displayed on the user interface. For more information, see , , and .

- To automatically trigger the shipment cancellation approval process, a workflow is configured. The configured workflow triggers a notification and initiates the cancellation process in SAP Cell and Gene Therapy Orchestration.
- For each cancellation request, an approval entry is added on the *Approval Details* tab. You can approve or reject a cancellation request if you have the required authorization.
  - Choose *Pending Approvals* to approve or reject a shipment cancellation request. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable.
    For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals.
    After the authorized user approves or rejects the shipment, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approves or rejects the shipment in the *Decision By* field.
    An entry is also added in the *Approval Logs* section on the *Logs* tab. When a cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.
    A workflow notification about the approval decision is triggered. An outbound event about the approval decision is also sent. For more information on the notifications generated during the cancellation process, see Configure Post Processing Framework Events.
- After you confirm the schedule of a treatment order, a *Stock Transport Order Create* request is sent to your ERP system (such as *S/4HANA*). On the *ERP Data* tab, you can see the following information about the processing status of the request:
  - *Overall Response Status*: Displays the response sent by the ERP system. For example, if SAP Cell and Gene Therapy Orchestration sends a *Stock Transport Order Create* request, the ERP system sends the status, *Created*, on successful creation. The response status can be *Updated*, *Update Failed*, or *Create Failed*, depending on the type of request sent and the success or failure of the action.
  - *Source System*: The ERP system where the stock transport order is generated.

  Select the line item to view further details. On the *Goods Movement* tab, you can see the *Goods Issued* and *Goods Received* documents generated for the stock transport order.
- On the *Documents* tab, upload or invalidate documents associated with the intermediate shipment. For more information on how to upload documents, see Upload Documents [page 180].
- On the *Logs* tab, you can view the document, e-signature, approval, and change logs related to the shipment. The *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Approval Log* section displays details related to shipment approvals. For each approval or rejection done, you can see the name of the person who approved or rejected the shipment in the *Decision By* field. The *Change Log* section displays the logs of all changes related to the shipment.
- You can create tasks for the shipment and assign the tasks to yourself or to another user. Choose *Create Task*. On doing so, you will be redirected to the *Manage Tasks* app to create the task. For more information on how to create a task, see Manage Tasks [page 159].

6.2.5 Manage Processing Activities

View or edit the details of a processing activity.

To manage a processing activity, go to the *Processing Activities* tab in the *Manage Orders* app. Choose the processing activity, then choose *Manage Processing Activity*.

You can do the following in the *Manage Processing Activity* screen:

- Monitor the status of the order and processing activity.
- View or edit the details of the processing activity, such as the general information, manufacturing location, or processing dates. You can also view the open tasks and exceptions associated with the processing activity.
- View the processing type. The value is sourced from the corresponding flow section type for the processing step within the flow version.
- Specify the materials used for processing in the *Process Order Batches (Components)* section.

  > **Note**
  >
  > In scenarios where the flow version consists of a co-product, that is, a processing activity yields a main material and co-products, and the co-product needs to be consumed in the subsequent processing activity in the same plant, you can use the *Add* button to view and add the yield material from the relevant processing activity for consumption. In scenarios where a material from a processing activity is consumed by another processing activity, you can only add the materials for which the *Inventory Status* is *Available to Ship*.

- Manage the details of the manufactured batch under the *Process Order Batches (Yield)* section such as:
  - Batch numbers and subunit type, qualifier, and ID of the batches to be manufactured.
  - Disposition or batch status of the manufactured product.
- Choose the batch line item to view batch and subunit details.
  - On the *Release Decision History* tab, view the different release types and the release decision taken for each release type of the process order batch. The release decision for a batch is taken in the SAP Batch Release Hub. For more information about the release decision process, refer to the SAP Batch Release Hub for Life Sciences User Guide. After the release decision is taken in the SAP Batch Release Hub, this information is updated in *S/4HANA*. Refer to the User Guide for SAP S/4HANA add-on for SAP Cell and Gene Therapy Orchestration to know more about the process. *S/4HANA* then passes the abstract information to SAP Cell and Gene Therapy Orchestration that helps the user to coordinate with other supply chain stakeholders and take correct action. For each release type, the following information is seen:
    - Release Decision: Decision taken for the release type.
    - Decision Set By: Name of the person who has taken the decision.
    - Decision Set On: Date and time of the decision.
    - Comments
    - Usage Decision: Usage decision text and code. For example, Accepted (A). Use the *Settings* button to enable this column.

    Choose a line item to view whether the process order batch is suitable for release across geographical locations. The decision to release a given batch can be different for countries and regions depending on the release checks and compliances required to release a given batch.

> **Note**
>
> The release decision history of process order batches is visible only when the release decision feature is enabled for a given tenant. In addition, the release decision history is not applicable to material that is not batch managed.

- The *PPF Events* tab displays the logs generated as a result of triggering post processing framework events for the process order. Each log displays the following information for a triggered event:
  - Event Type: Business, Workflow, Process, Notification
  - Event Status: Triggered, Started, Completed, Failed, Ignored
  - Error Message: Message appears if a triggered event fails or is ignored.
  - Created On: Date of triggering the event.

  You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event.

  > **Note**
  >
  > Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems.

  For more information, see Configure Post-Processing Events [page 58].
- Upload or invalidate documents associated with the processing activity. For more information on how to upload documents, see Upload Documents [page 180].
- Close the process order. Before you can close the process order, the disposition of the product batches must be completed, the processing status must be set to *Completed*, and all relevant documents for the processing activity must be uploaded.
- Create new tasks for a processing activity. You'll be redirected to the *Manage Tasks* app to create new tasks. For more information on how to create a task, see Manage Tasks [page 159].

6.2.6 Manage Finished Product Shipments (Final Leg and Transit Leg)

View and manage finished product shipment (finished product transit leg (FS-IL) and finished product final leg (FS-FL)) information.

To manage finished product shipments (FS-IL and/or FS-FL), go to the *Shipments* tab in the *Manage Orders* app. Choose the shipment ID corresponding to the shipment type in the *Finished Product Shipments* section and then choose *Manage Shipments*.

Using this app, you can:

- Manage shipment information
- Confirm receiving the shipment
- Check the chain of identity (COI) of shipment
- Manage the disposition status for finished product transit leg shipments

- Allocate batches for shipment
- Confirm shipment pickup

- On the *General Information* tab, you can view and maintain information about the shipment. You can change the shipment status, cancellation status, COI confirmation status, and shipment reason.
- The *Locations* tab displays the shipment source and destination location address details. You can change the address details and also maintain primary and alternate contacts for both the locations.
- Choose *Determine Transportation Lane* to get the transportation lane and courier information (courier contact person, courier ID, account number) for the shipment if this is not already available on the *Logistics* tab. If available and you still determine the transportation lane, the system displays a warning message to confirm whether you want to overwrite the existing information.
- The *Logistics* tab displays courier details in the *Logistics Details* section. You can maintain alternate contacts in the *Alternate Contact Persons* section. The *Waybill Details* section displays the waybill number, shipper serial number, and other information received when a courier is booked.
- Book a courier for the shipment.
  - Choose *Book Courier*.
  - On the *General Information* tab, you can see the courier ID, courier contact name, and transportation lane name.
  - The *Dates* tab displays the planned pickup and delivery dates.
  - On the *Shipper* tab, you can see the shipper name and address.
  - The *Consignee* tab displays the consignee name and address.
  - The *Shipped Items* tab shows information (material name, quantity, gross weight, packaging type) about the items to be shipped.
  - On the *Instructions* tab, provide the pickup and delivery instructions. Specify the number of shippers required and choose *Save*
    - If you do not specify a value, the system takes one (1) as the default value for the number of shippers required. The courier booking request will now be placed, and the information you provided will be sent to the courier system through the courier booking event. Based on the number of shipping containers requested, the courier sends shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link). If due to some technical issue, this information is not received, you can manually provide the information. This information is seen in the *Waybill Details* section on the *Logistics* tab. There can be multiple shipper serial numbers per waybill number. Each shipper serial number, however, must be unique.
- On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. However, it is mandatory for you to add at least one business partner to each of the following categories. This is applicable to finished product transit leg shipments associated with a sales order and finished product final leg shipments.
  - Bill-To Party (CRM004)
  - *Goods Recipient (CRM002)
  - Sold-To Party (CRM000)

  * Goods Recipient is the same as Ship-To Party

  For finished product transit leg shipments associated with a stock transport order, you must add at least one business partner to each of these categories:
  - Bill-To Party (CRM004)
  - Goods Recipient (CRM002)
  - Sold-To Party (CRM000)

- Vendor (BBP000)
- Supplier (CRM007)
- To add or remove a business partner, choose *Edit*.
  - On the *Business Partners* tab, choose *Add*.
  - Select a business partner category.
  - Enter the business partner function.
  - Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
  - Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

> **Note**
>
> Prerequisites to add business partners to a business partner category:
> - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
> - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

- On receiving a shipment (FS-IL or FS-FL), you must confirm the receipt of the shipment and shipper, and check whether the shipment and shipper meet the acceptance criteria.
  - *Finished Product Transit Leg Shipments*
    The *Shipment and Receipt* tab has two sections: *Shipment Confirmation* and *Receipt Confirmation*.
    - In the *Shipment Confirmation* section, you must check and specify the following:
      - The serial number on the shipper matches the serial number in the system.
      - The product packed in the shipper can be identified by the shipper serial number.
    - In the *Receipt Confirmation* section, enter the following information:
      - Names of the users who approved and verified the shipper and shipper content.
      - Dates of approving and verifying the shipper and shipper content.
      - Check and specify whether the shipping conditions are within acceptable parameters.
      - Check and specify whether the patient attributes match the details given on the shipment's hangtag labels.
  - *Finished Product Final Leg Shipments*
    The *Product Acceptable* tab has two sections: *Shipment Confirmation* and *Receipt Confirmation*.
    - In the *Shipment Confirmation* section, you must check and specify the following:
      - The serial number on the shipper matches the serial in the system.
      - The product packed in the shipper can be identified by the shipper serial number.
    - In the *Receipt Confirmation* section, enter the following information:
      - Names of the users who approved and verified the shipper and shipper content.
      - Dates of approving and verifying the shipper and shipper content.
      - Check the *Verified* box. The *Product Review Status* changes to *Accepted*.
- On the *Additional Shipment Information* tab, you can provide additional information (custom texts) about the shipment. For example, you can provide packing instructions for the shipment.
  To add information:
  - In the *Edit* mode, choose *Create*.
  - Select the ID using the dropdown.

- Select the language in which you want to save this information.
- In *Value*, enter the additional information and choose *Apply*. This saves and associates the information with the ID in the selected language.

It is recommended that you keep the ID and language combination unique for the associated treatment order and its shipments.
You can modify or delete additional information. To modify it, select the line item and make the required changes. To delete it, select the line item and choose *Delete*.
The system prompts you to select a reason code on adding or modifying additional shipment information.

- The *PPF Events* tab displays the logs generated as a result of triggering post processing framework events for the shipment. Each log displays the following information for a triggered event:
  - Event Type: Business, Workflow, Process, Notification
  - Event Status: Triggered, Started, Completed, Failed, Ignored
  - Error Message: Message appears if a triggered event fails or is ignored.
  - Created On: Date of triggering the event.

  You can retrigger a business event, if required. Retriggering is enabled for events in all statuses (Triggered, Started, Completed, Failed) except Ignored. You can use the *Request Payload* option to view the data sent in the event.

  > **Note**
  >
  > Please exercise caution when retriggering an event as it may result in process disruptions and inaccuracy of results. Retriggering an event without proper checks may also adversely impact the integration setup with external systems.

  For more information, see Configure Post-Processing Events [page 58].
- On the *Finished Product Batches* tab, you can allocate batches for shipment. Only batches with inventory status, *Available to Ship* and disposition status, *Unrestricted Use* or *Released with Restrictions* can be allocated for shipment. The batches available for allocation are shown in the *Requested section*. To allocate a batch:
  - Choose *Allocate Batches*. A popup window showing the batches available for allocation appears.
  - Select the material to be allocated. Choose *Confirm*.
  - You are prompted for authentication. Enter your password, select a reason code for this action, and choose *Save*.
  - The material you select for allocation appears in the *Allocated section*.

  You can deallocate batches, if required. To deallocate a batch, select the batch and choose *Remove Allocated Batch*.
- Select the allocated batch material line item to view and edit batch and subunit details such as the shipper serial number, batch status, disposition status, dispositioned quantity, shipped quantity, and other information.

  > **Note**
  >
  > You can assign a shipper serial number to the batch (if the batch is non-serialized) and its subunits (if the batch is serialized).
- On the *Release Decision History* tab, view the different release types and the release decision taken for each release type of the finished product batch. The release decision for a batch is taken in the SAP Batch Release Hub. For more information about the release decision process, refer to the SAP Batch Release Hub for Life Sciences User Guide. After the release decision is taken in the SAP Batch Release Hub,

this information is updated in *S/4HANA*. Refer to the User Guide for SAP S/4HANA add-on for SAP Cell and Gene Therapy Orchestration to know more about the process. *S/4HANA* then passes the abstract information to SAP Cell and Gene Therapy Orchestration that helps the user to coordinate with other supply chain stakeholders and take correct action. For each release type, the following information is seen:

- Release Decision: Decision taken for the release type.
- Decision Set By: Name of the person who has taken the decision.
- Decision Set On: Date and time of the decision.
- Comments
- Usage Decision: Usage decision text and code. For example, Accepted (A). Use the *Settings* button to enable this column.

> **Note**
>
> For a stock transport order scenario for a finished product transit leg shipment, the release decision information sent to SAP Cell and Gene Therapy Orchestration originates from the quality process of the batch that has been received at the receiving plant.

- Select a release decision line item to check whether the batch is suitable for release across geographical locations. The decision to release a given batch can be different for countries and regions depending on the release checks and compliances required to release a given shipment batch.

> **Note**
>
> The release decision history of shipments is visible only when the release decision feature is enabled for a given tenant. In addition, the release decision history is not applicable to material that is not batch managed.

- You can request for the cancellation of a shipment (FS-FL, FS-IL), if required. To cancel a shipment, choose *Request for Cancellation*. You must have the necessary authorization to request for a cancellation. The *Shipment Cancellation Status* changes to *Cancellation Requested*. The cancellation request is logged on the *Cancellation Request Details* tab.

> **Note**
>
> You can configure the statuses to be displayed on the user interface. For more information, see , , and .

- To automatically trigger the shipment cancellation approval process, a workflow is configured. The configured workflow triggers a notification and initiates the cancellation approval process in SAP Cell and Gene Therapy Orchestration.
- For each cancellation request, an approval entry is logged on the *Approval Details* tab. You can approve or reject a shipment if you have the required authorization.
  - Choose *Pending Approvals* to approve or reject a shipment. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable.
    For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals.
    After the authorized user approves or rejects the cancellation request, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approves or rejects the shipment in the *Decision By* field.
    An entry is also added in the *Approval Logs* section on the *Logs* tab. When a shipment cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.

A workflow notification about the approval decision is triggered. An outbound event about the approval decision is also sent. For more information on the notifications generated during the cancellation process, see Configure Post Processing Framework Events.

> **Note**
>
> Cancellation of the shipment triggers *Sales Order Cancellation*, an outbound event to cancel the sales order in *S/4HANA*. This sales order is linked with the shipment in SAP Cell and Gene Therapy Orchestration.

- After you confirm the schedule of a treatment order:
  - A *Sales Order Create* request is sent to your ERP system (such as *S/4HANA*) for the finished product final leg shipment.
  - A *Stock Transport Order Create* request is sent to your ERP system (such as *S/4HANA*) for the finished product transit leg shipment.

  On the *ERP Data* tab, you can see the following information about the processing status of the request:
  - *Overall Response Status*: Displays the response sent by ERP. For example, if SAP Cell and Gene Therapy Orchestration sends a *Sales Order Create* request, the ERP system sends the status *Created* on successfully creating the sales order. The response status can be *Updated*, *Update Failed*, or *Create Failed*, depending on the type of request sent and the success or failure of the action.
  - *Source System*: The ERP system where the sales order or stock transport order is generated.

  If you want to view the different statuses a sales order goes through in ERP, select the sales order and choose *View Response Status*. The statuses help you track and monitor the sales order throughout the sales process.
  Select the sales order row to view further details. On the *Goods Movement Documents* tab of the subsequent screen, you can see:
  - The *Goods Issued* and *Goods Received* documents generated for a stock transport order.
  - The *Goods Issued* document generated for a sales order.
- On the *Documents* tab, upload or invalidate documents associated with the finished product shipment. For more information on how to upload documents, see Upload Documents [page 180].
- On the *Logs* tab, you can view the document, e-signature, and change logs related to the shipment. The *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Change Log* section displays the logs of all changes related to the shipment, and the *Approval Log* section displays details related to shipment approvals. For each approval or rejection done, you can see the name of the person who approved or rejected the shipment in the *Decision By* field.
- You can create tasks for the shipment and assign the tasks to yourself or to another user. Choose *Create Task*. On doing so, you will be redirected to the *Manage Tasks* app to create the task. For more information on how to create a task, see Manage Tasks [page 159].

6.2.7 Create Subsequent Shipments and Processing Activities

A subsequent shipment or processing activity is created for an existing shipment or processing activity based on the requirement for additional shipment (biospecimen or finished product) and processing. You can create subsequent shipments for biospecimen and finished product – final leg shipments.

You may have to create a subsequent shipment and related subsequent processing activities under the following conditions, among others:

- The treatment center requires additional quantities of a finished product.
- To process additional batches of the finished product, further quantities of biospecimen may be required.

Procedure

1. Go to the *Manage Orders* app.
2. Select the shipment ID of the parent shipment or the processing activity ID of the parent processing activity.
3. Choose *Create Subsequent*.
4. Confirm the action.
5. After confirmation, enter your e-signature and password for authentication.

Based on your selection, this creates a subsequent shipment or processing activity.

The following information is copied from the parent shipment to the subsequent shipment:

- Flow version
- Flow section type
- Flow step
- Plant
- Material details
- Locations (pick-up and drop-off)
- Primary and alternate contacts

> **Note**
>
> The status of the subsequent shipment is set to the initial status based on your status configuration settings.

The following information is copied from the parent processing activity to the subsequent processing activity:

- Flow version
- Flow section type
- Flow step
- Plant
- Yield material (copied only when the organization location category is contract manufacturing organization) and corresponding subunits

- Locations (pick-up and drop-off)
- Primary and alternate contacts

> **Note**
>
> The status of the subsequent processing activity is set to the initial status based on your status configuration settings.

6.2.8 Collection Details

Learn all about the collection details.

Collection details are an integral part of the biospecimen. The collection details comprise of collection ID, collection quantity, collection date, cryopreservation date, etc.

Procedure

1. Navigate to the *Manage Shipments (Biospecimen)* app.
2. Click on one of the shipments in the list.
3. Click *Biospecimen Materials* tab.
4. Click on the collection number under the *Collection* column which has a hyperlink. The page displays all the collection details of the biospecimen.

6.2.9 Generate COI Certificate (Manage Orders)

Generate, view, save, and print COI certificates using the *Manage Orders* app.

Context

A chain of identity (COI) certificate contains information about the patient, biospecimen, and product. You can generate COI certificates for finished product final leg shipments (FS-FL) at shipment and batch levels. For shipments, the COI certificates can be generated irrespective of whether the batch is allocated or not. SAP CGTO prefills all the required information to generate the COI certificate.

You can use the *Manage Orders* and *Manage Shipments - Finished Product* apps to generate COI certificates at shipment level. If there are multiple batches, all the batch details will be added to the *Product Information* section of the COI certificate. COI certificate generation is enabled only for FS-FL shipments of active orders. For information about generating COI certificate through *Manage Shipments - Finished Product* app, see Generate COI Certificate (Manage Shipments - Finished Product) [page 181].

To generate COI certificates at batch level, you can use the *Allocate Batches to Finished Product Shipment* app. For more information, see Generate COI Certificate (Allocate Batches to Finished Product Shipment) [page 178].

Generating a COI certificate requires a template that is customized for your requirements. The details displayed in the COI certificate depend on the COI certificate template configuration. For more information, see Configure COI Certificate Templates [page 225].

Follow the steps given below to generate COI certificate at shipment level using the *Manage Orders* app.

Procedure

1. Go to the *Manage Orders* app.
2. Choose *Go* in the filters section to view the list of orders. You can also use the filter options to search for a specific shipment. For example, use the *COI ID* or *Finished Product Shipment* ID to find the required finished product final leg shipment (FS-FL).
3. Open the required order and navigate to the *Shipments* tab.
4. In the *Finished Products Shipments* section, identify the finished product final leg shipment (FS-FL) for which you need the COI certificate and choose the *Generate* button in the *COI Certificate* column.

   > **Note**
   >
   > The *Generate* button is enabled only for FS-FL shipments of active orders.

5. In the *E-Signature* window, enter the required details and choose *Save*.

   You can use the *Comments* field in the *E-Signature* window to add information related to the finished product. The comments you enter in this field will be updated in the *Additional Comments* section of the COI Certificate.
6. You will be redirected to Data and Document Integration for SAP Cell and Gene Therapy to view the document.

   You can also print or save the COI certificate using the respective buttons.

   In the *Documents* tab, you can view the certificate generated and saved last. To view the certificates saved earlier, go to *Logs* > *Document Log* in the *Mange Shipments - Finished Product* app.

6.2.10 Generate Traceability Report

Generate, view, save, and print traceability reports.

Context

A traceability report contains information about internal and external chain of identity (COI) and chain of custody (COC) events, which helps in tracking and tracing events in the cell and gene therapy supply chain

to comply with regulatory requirements. The traceability report is generated based on the COI / COC event details available in SAP Cell and Gene Therapy Orchestration at the time of generation of the report.

You can generate traceability report for active orders. All COI / COC events triggered for create and update actions are included in the traceability report. The events are sorted in descending order by time.

> **Note**
>
> You must configure the traceability report template details in the *Configure Profile Groups* app to generate traceability report. For more information, see Configure Profile Groups [page 70].

Follow the steps given below to generate traceability report using the *Manage Orders* app.

Procedure

1. Go to the *Manage Orders* app.
2. Choose *Go* in the filters section to view the list of orders. You can also use the filter options to search for a specific order. For example, use the *COI ID* of an order to find the required order.
3. Open the required order and navigate to the *Documents* tab and choose *Generate Traceability Report*.

   > **Note**
   >
   > The *Generate Traceability Report* button is enabled only for active orders.

4. In the *E-Signature* window, enter the required details and choose *Save* to view the generated report.

   You can also print or save the traceability report using the respective buttons.

   In the *Documents* tab, you can view the traceability report generated and saved last. To view the traceability reports saved earlier, go to *Logs* > *Document Log*.

   You can view the following details in the traceability report:

   Columns in Traceability Report

Column Title	Description
Event	Contains the event description for internal events and the event name for external events. For example, COI Creation and Order Creation.
Event Description	Contains the event description. The long description for internal events and the description for external events.
Event Date and Time	Contains the event timestamp in local time zone.
Performed By	Details of the user who performed the create or update action that triggered the event. If the create or update actions are triggered via events, the technical ID is displayed.
Material	Contains the material ID.
Batch	Contains the material batch number.
Bag Identifier	Contains the material subunit ID for applicable events.

Column Title	Description
Related Object	Contains the business object identifier for which the event was triggered.
Treatment Order	Contains the order number or the follow-on order number.
Location	Contains the event location details.
Additional Information	Contains the usage decision code and text.

6.3 Order Approval Process

Learn all about the order approval process.

SAP Cell and Gene Therapy Orchestration allows you to configure approval process for order create, order change, and order cancel scenarios.

Approval is also required for shipment cancel scenario.

Prerequisites

Ensure to comply with the following prerequisites for setting up the order approval process:

1. System Attributes
2. Authorization Roles
3. Scenarios

System Attributes

The following configuration has to be maintained in the system to set up the approval process:

System	Attributes

SAP Cell and Gene Therapy Orchestration	• Status Management:
	  • *Configure User Status*
	  • *Configure Status Profiles*
	  • *Configure Entity Status Profile*
	• Configure Rules [page 57]
	• Change Reasons and Reason Codes [page 41]

Workflow	• Using Workflow Service • Business Rules Framework

> **Note**
>
> See Configure Status Profiles and Configure Entity Status Profiles for the values to be used in status management.

> **Note**
>
> Refer to the following topics for more information:
>
> - Configure User Statuses [page 44]
> - Configure Entity Status Profiles [page 48]
> - Configure Status Profiles [page 46]

Authorization Roles

See Assigning Role Collections to Users for more information on the necessary authorization required for the administrator or approver.

Scenarios

The following triggers manage the approval process in each case:

Scenario	Trigger
Order Create Approval	Event for Create Treatment Order
Order Change Approval	Event for Update Treatment Order
Order Cancellation Approval	• Event for Cancel Treatment Order • Manual Order Cancellation
Shipment Cancellation Approval	Manual Shipment Cancellation

A workflow is created based on the above trigger points. The workflow is a custom implementation activity. See the following sections for more information on events for triggers for order approval:

- Configure Post-Processing Events [page 58]
- Configure Post Processing Framework Event

The workflow can be of the following types:

- One that requires an approval
- One that does not require an approval

The workflow that requires an approval must be defined to invoke the following API `Post Approval Info`. See Public APIs for more information. This creates an entry in the *Approval Details* and *Approval Logs* section. Accordingly, the related *Approval* action buttons are displayed. The approver who has relevant authorization roles, can approve or reject the entry. Upon approval the approver must provide the e-signature. Upon

rejection, the approver has to provide a reason for rejection along with the e-signature. The status is updated after approval or rejection and accordingly displayed in the *Approval* section along with *Approval Logs*.

6.4 Confirm Flow Version

Confirm flow version for treatment orders.

Context

A flow definition outlines the processing activities and logistical stages for a treatment order. Each flow definition has a flow version ID.

Confirming the flow version is a prerequisite for finalizing the manufacturing schedule and starting the processing activities. Flow version confirmation is a one-time activity. It cannot be changed after confirmation. Confirmation can be manual or automatic.

On confirming the flow version, the following activities take place:

- Intermediate product and finished product transit leg shipments are created.
- Processing activities are created.

  > → Remember
  >
  > Biospecimen, biospecimen kit, and finished product final leg shipments are created through events, not as a result of flow version confirmation.

- The pick-up and drop-off locations of the following shipments are determined:
  - Intermediate product
  - Finished product transit leg
- The pick-up location of the finished product final leg and the drop-off location of the biospecimen shipments are determined.

  > ⓘ Note
  >
  > The material and pick-up & drop-off locations for biospecimen kit shipments are received through the *Biospecimen Kit Shipment Create* event. If the pick-up location is missing in the event, the location is determined using the configured business rules. For more information on how to determine the pick-up location for biospecimen kit shipments, see Business Rules for Pickup Location Determination for Biospecimen Kit Shipment. If any of the information (material, pick-up location, drop-off location) cannot be determined, the flow version cannot be confirmed.

- The yield material for processing activities at processing plants, which are contract manufacturing organizations is determined. If the plant is an in-house manufacturing organization, the yield material is received through an event.
- Processing plants are determined.
- Timezones are determined based on the pick-up and drop-off locations.

- Primary and alternate contacts for the biospecimen shipment pick-up and drop-off locations are determined.
- Primary and alternate contacts for the finished product shipment pick-up and drop-off locations are determined.
- Primary and alternate courier contacts are determined.
- Flow version details are updated in the treatment order, processing activities, and the associated shipments.

If the following information is received through an event, the system does not determine it through flow version confirmation:

- Drop-off location for the biospecimen shipment
- Pick-up location for the finished product shipment
- Primary and alternate contacts for the biospecimen shipment drop-off location
- Primary and alternate contacts for the finished product shipment pick-up location
- Primary and alternate courier contacts
- Material for biospecimen and finished product shipments
- Processing Plants

After the flow version for an order is confirmed, the system creates the complete process flow for the order. You can see the process flow in the *Manage Orders* app.

The process flow for an order usually comprises of the following key activities:

1. Biospecimen collection from the collection center.
2. Biospecimen shipment to the processing plant.
3. Biospecimen processing at the plant.
4. Finished product shipment and delivery to the treatment center.

> **Note**
>
> The number of activities can increase depending on the type of processing and shipments required.

- Material Group and Material Type:
  - Material Group and Material Type are important attributes in determining the flow version node and material. A maximum of five material type and material group combinations can be defined for a step. You can also create a business rule to determine the material group ID and material type ID for biospecimen shipments and finished product shipments using custom material identifiers. For information on the prerequisites and detailed steps to derive material type and material group ID, see Business Rules for Material Group and Type Determination.
  - It is not mandatory to derive the material type and group through custom material identifiers. Instead, they can be directly specified when the biospecimen shipment or finished product shipment are created through the event interface. This method of directly specifying the material type and material group in the event interface during shipment creation takes precedence over using a business rule to determine the material type and material group with the help of custom material identifiers.
  - You can also create a business rule to determine the material ID(s) to be used for an intermediate product shipment. A combination of the following attributes is used to determine the material ID(s) in the business rule:
    - Therapy
    - Country

- Order Type
- Treatment Center
- Processing Plant

For information on how to create the business rule, see .

Automatic Flow Version Confirmation

To enable automatic flow version determination, a post processing framework event must be configured for the Shipment Created business context. When SAP Cell and Gene Therapy Orchestration receives a finished product shipment through an event for an order whose flow version has not been confirmed, the post processing framework event triggers the business rules to determine the flow version. If a single unique match is found, the flow version is confirmed. If there are multiple matches are found, then you need to select a flow version and manually confirm it. Flow version confirmation is subject to validation and checks.

Flow Version Confirmation for Co-Products

Generally, when a biospecimen is processed, it yields one material (main product), which is processed further into a finished product. However, depending on the *S4/HANA* configuration, a process can yield two types of products, a main product, and a co-product. A co-product is the additional yield material of a processing activity. There can be one or more co-products, but there must be at least one main product.

When a processing activity yields a co-product and a main product, the process flow branches into two parallel flows, one for the main product and the other for the co-product. There can be multiple parallel flows depending on the number of co-products. A co-product may need further processing to yield a finished product.

In parallel flows, the flow step of each finished product processing is used to identify the previous step of the flow and thereby its complete process flow. The flow step (*Requested Flow Step*) of a finished product shipment is sent in the *Create Finished Product Shipment* event. You can also manually enter it in the *Manage Shipments - Finished Product* app until the flow version is confirmed.

Note: If the *Requested Flow Step* is not as per the confirmed flow version, an error is generated. This check also applies to subsequent shipments created through events.

If the *Requested Flow Step* is missing for the finished products that is, the main products or co-products, the material type and material group combination for the finished products is checked to determine the correct flow step for each product.

The check might determine the following scenarios:

1. The shipment material type and group combination differs for both the products: In such a case, the products can be mapped to the correct flow step based on their material combination.
2. The shipment material type and group combination is identical for both the products: In such a case, the products cannot be mapped to the correct flow step, and as a result, the flow version cannot be confirmed.
3. On confirming the flow version of an order having a co-product:
   - The processing plant locations, and the shipment pick-up and delivery locations are determined.
   - Material for intermediate product, finished product transit leg, and finished product final leg shipments is determined.

> **Note**
>
> Co-products can be processed only at in-house plants associated with an ERP system. The yield material for a co-product is always received from the ERP.

Flow Version Confirmation for Follow On Orders

You can clone orders to create follow on orders. For information on how to clone orders, see Clone Orders [page 160]. During cloning, shipments with status *Shipped* or *Delivered* are copied to the follow on order along with the processing activity that follows it (as per the flow version step). When confirming the flow version of a follow on order:

- the shipments and processing activities that have been copied to the follow on order are validated.
- the additional shipments and processing activities that are not cloned but required as per the flow version, are created. Confirming the flow version determines the required information for each shipment and activity (locations, finished product material, yield material, processing plants, and time zones).

  > **Note**
  >
  > If the yield material of the cloned processing activity does not match the yield material determined by the new flow version, the existing material is deleted, and the new yield material is used for the subsequent processing and shipment activities.

- the treatment order, and the associated shipments and processing activities are updated with the flow version details.

Follow the steps given below to confirm flow version:

Procedure

1. Go to the *Confirm Flow Version* app.
2. Choose *Go* in the filters section to view the list of orders. Alternatively, you can use the filter options to search for a specific order.

   For example, you can use the *COI ID* of an order to find the required order.
3. Select the required order using the radio button and choose *Confirm Flow Version*.
4. In the *Select a flow version to confirm* window, select the flow version applicable for the order, and choose *Confirm*.

   You can view the flow steps associated with a flow version by choosing the flow version ID in the *Select a flow version to confirm* window.

6.5 Schedule Biospecimen Pickup Slot

Schedule or reschedule a biospecimen pickup slot.

With this app, you can schedule the time and date a biospecimen is picked up from a treatment center and delivered to the correct plant for processing. Additional processing steps from biospecimen shipment delivery to the delivery of the finished product are also calculated. You can schedule or reschedule a biospecimen pickup slot for an existing order. If the treatment order doesn't exist at the time of booking, you can create a new order when you book a pickup slot.

Prerequisites

1. The following destinations are configured in the *Configure Destinations* app:
   - Slot Scheduling
   - Scheduling
   - Rescheduling

   For more information, see Configuring Destinations for Scheduling.
2. The following business configuration data is created in your system:
   - Therapy types
   - Material types
   - Material groups
   - Plants

   For more information, see Creating Business Configuration Data [page 17].
3. The following master data is set up in your system:
   - Therapies are created in the *Manage Therapies* app.
   - Organizations are created and the organizations and therapies are mapped to pickup locations in the *Manage Organization-Location-Therapy Rules* app.
   - Materials with relevant processing, shipment, and therapy details are created in the *Manage Materials* app.
   - Flow definitions that include biospecimen collections are created in the *Manage Flow Definitions* app.

   For more information, see Setting Up Master Data [page 76].

Context

Given the sensitive and perishable nature of biospecimen shipments, efficient scheduling is critical to the success of the treatment order process. Biospecimen pickup slots and subsequent processing steps are automatically calculated based on the master data in your S/4 HANA system. When you enter a treatment center, therapy, and plant, the system displays all biospecimen pickup slots matching the data entered. Available slots are shown in green. Booked slots are shown in red. You can change the time-frame to narrow or broaden your search. You can enter multiple plants to see available slots for each.

When you book a slot, the following processing steps are also calculated:

- Biospecimen shipment pickup
- Biospecimen shipment delivery
- Processing activity start
- Processing activity end
- Planned finished product pickup
- Finished product delivery

> **Note**
>
> The system doesn't automatically display updated availability. You must manually refresh the system to retrieve available slots and see updated bookings.

Procedure

To book a biospecimen pickup slot:

1. Open the *Schedule Slot for Biospecimen Pickup* app.
2. Enter the following:
   - Treatment Center and therapy.

     > **Note**
     >
     > The combination for therapy and treatment center is determined based on the combinations maintained in the *Manage Organization-Location-Therapy Rules* app.

   - Plant

     > **Note**
     >
     > This is the plant where the biospecimen is processed. You can enter multiple plants. The system breaks down the bookings according to plant.
3. Choose *Go*.
   A calendar of all available (green) and booked (red) slots, including planned pickup dates, are displayed for the criteria you entered. Slots booked for existing orders also include the COI ID.
4. [Optional] To find available slots, adjust the interval in which the slots are displayed, for example by the hour, day, year, or month.
5. If you want to create an order in the S4 HANA system:
   1. Select an available (green) slot.
   2. Enter the COI ID.
   3. Under *Order Creation Mode*, choose *Automatic Order Creation*, then choose *Confirm*.
   4. In the *E-Signature* dialog, enter your password, a reason code, and a comment (if necessary), then choose *Save*.
      Result: The slot is booked for the COI ID you entered. The shipment and processing activity are automatically created.
6. If you don't have a COI ID:
   1. Leave the COI ID field blank.
   2. Under *Order Creation Mode*, choose *Automatic Order Creation*, then choose *Confirm*.
   3. In the *E-Signature* dialog, enter your password, a reason code, and a comment (if necessary), then choose *Save*.
      Result: The slot is reserved without any order information. You can update the slot with the COI ID once it becomes available.

Reschedule a Biospecimen Pickup Slot

If you've scheduled a biospecimen pickup slot and need to change the appointment, you can use this app to reschedule.

> **Note**
>
> You can also change the COI ID to give the slot to a different order.

To reschedule an appointment:

1. Select the scheduled (red) slot.
2. Choose *Reschedule*.
3. Select an available (green) slot, then choose *Confirm*.
4. In the *E-Signature* dialog, enter your password, a reason code, and a comment (if necessary), then choose *Save*.

Result: The slot is rescheduled. Double-click on the slot to see the order schedule, including the processing start, processing end, finished product pickup date, biospecimen pickup date, finished product delivery date, and biospecimen delivery date.

Next Steps

You can manage your scheduling requests in the *Manage Scheduling Requests* app.

For more information, see Manage Scheduling Requests.

6.6 Manage Scheduling Requests

Create and manage scheduling requests.

Context

Scheduling is the process of planning the exact dates and times for the movement of biospecimen and finished products while processing a treatment order. This can include various milestones including, but not limited to, biospecimen pickup, biospecimen shipment receipt, processing completion, finished product disposition, and finished product delivery.

Given the sensitive and perishable nature of biospecimens and finished products, scheduling is extremely critical to the efficiency of the treatment order process.

You can use the *Manage Scheduling Requests* application to create and manage requests for specific treatment dates, based on either the requested date for biospecimen pickup (forward scheduling) or the target date for finished product delivery (backward scheduling). Depending on the dates provided, the system proposes options for schedules out of which you can choose the slot that best meets your requirements and book it for a particular treatment order.

Procedure

1. Go to the *Manage Scheduling Requests* app and choose *Create*.

2. Under *Treatment Order Details*, select *Existing Order* or *New Order* depending on whether the COI ID exists or not.
3. Enter details for the *Therapy* and *Treatment Center*.

   > **Note**
   >
   > The combination for therapy and treatment center is determined based on the combinations maintained in the Manage Organization-Location-Therapy Rules [page 82] app.

4. Based on the combination of therapy and treatment center, the confirmed flow versions would be determined. Select the applicable *Flow Version* for your case.

   You can choose more than one flow versions to compare the schedules generated and choose the one that you prefer.
5. Next, select your preferred *Input Type*:
   - Forward scheduling, in case you have a planned date for the biospecimen shipment pickup and wish to determine the milestone dates that come next in the treatment process, or
   - Backward scheduling, in case you have a target date for the finished product shipment delivery and wish to determine the milestone dates that lead up to it in the treatment process
6. Enter the date that you wish to use as the basis of the scheduling logic in the *Requested Date* field.
7. **Optional:** Define the *Priority* of the treatment at hand.

   Higher the priority, better the chances for you to get a more suitable schedule for the treatment, based on the available slots as well as the priority of other treatments competing for the same slots.
8. Select the *Order Creation Mode*.

   Automatic Order Creation means that the order would be created in the system right away. *Trigger Order Creation* means the slots are reserved, but the order is not created right away. Instead, an outbound interface is triggered with the details of the request, and based on the response, another inbound interface is eventually triggered to create the order.
9. Provide a *Description* for the scheduling request.
10. Select *Propose Schedules*.

    A Gantt chart would be displayed in the *Schedule* section, displaying the alternative schedules available to you, including the process steps, their respective dates, and the plant where the processes would be carried out.
    - If you are not satisfied with any of the proposed slots, repeat the steps above with different input parameters to generate a new set of schedules.
    - If you find a schedule that works for you, select it, and choose *Confirm*.
    - You can also choose to *Discard* the draft scheduling request.
11. If you choose *Confirm*, the *E-Signature* dialog would pop up.

    Enter your password, a reason code, and a comment (if required), and then choose *Save*.

Results

The scheduling request you created is successfully saved, reserving the slots from the schedule that you confirmed. If you selected *Automatic Order Creation*, an actual treatment order would also be created in the

system, however, in case you selected *Trigger Order Creation*, no order will be created but the order creation API would be triggered.

The result page displays the following details:

Header section:

- The *COI ID*, *Treatment Center*, and *Therapy* for which the scheduling request was created
- Your details, as the scheduler, and the date-time information for the scheduling request creation
- The *Request Type*, which would be set as *Initial*, since this is the first time a request has been created for this combination of COI ID, treatment center, and therapy
  The type can change to *Reschedule*, if this request is modified and rescheduled to a different set of slots.
- The *Version* of the scheduling request, which in this case should be set to *1*, since this is the first version of the request
  With any changes in the scheduling request, this version will change incrementally, and at any time, this field will display the last created version, whereas the *Version* tab would display the version history right from the initial version to the most recent one.
- The *Version Status*, which should be set to *Active*, since this is the latest version of the request
  In case of older version, the status is set to *Inactive*.
- The *Request Status*

General Information:

- All the input parameters that you had maintained while creating the request (*Description*, *Flow Version ID*, *Priority*, *Input Type*, *Requested Date*, *Order Creation Mode*)
- The *Date Request Status*, which is set to *Accepted* if the proposed and confirmed dates are the same, or *Modified* in case the proposed slots were booked before they were confirmed for this request and a different set of slots were confirmed for this scheduling request
- The *Simulation Mode* field which determines whether slot have been reserved (field value *No*) or only simulated (field value *Yes*)

Order Schedule:

- The *Process Steps* depending on the milestones configured for the selected flow version
- The *Scheduled Dates*, which were the requested dates from the chosen proposal
- The *Order Dates*, which are the actual dates as allotted in the resulting treatment order that was created
  Depending on the priority of your therapy, the scheduled and order dates may or may not be the same. As described before, the higher the priority, the better the chances of being allotted your preferred dates.

Previous Versions:

- The details for older versions of the scheduling request, which in your case should not display anything since this is the first version

E-Signature Log:

- The details of the schedulers who have signed off the creation of different versions of the scheduling request

PPF Events:

- Data related to post-processing activities based on the scheduling and order creation triggered during the process

Next Steps

You can now proceed with the next steps in the treatment order processing.

You also have the option to:

- *Cancel* the scheduling request, if it is no longer required, or
- *Reschedule* the request if the current schedule does not work and needs to be changed
  You can follow the same steps described above the reschedule the request and choose another schedule with a different set of slots for your treatment milestones.

6.7 Confirm Schedules

Confirm the processing schedule for treatment orders.

Prerequisites

Flow version confirmation is a prerequisite to confirm the processing schedule.

Context

Schedule confirmation is a prerequisite to start the processing of treatment orders. You can confirm the processing schedule of a treatment order manually or it can be automatically confirmed. Automatic schedule confirmation is possible only if it is supported by the post processing framework configuration. The following common checks and validations are done in both the modes:

1. The planned pickup and delivery dates must be available and valid for all the shipments.
   - Planned pickup date and delivery date must be the current or future date.
   - Planned pickup date must come before the planned delivery date.
2. The planned processing start, and end dates must be available and valid for all the processing activities.
   - Planned processing start date and delivery date must be the current or future date.
   - Planned processing start date must come before the planned processing end date.

If, after the flow version confirmation of a treatment order, all the shipments and processing activities pass the date availability and date validation checks, the schedule is automatically confirmed for the complete order. If, on the other hand, there are shipments or processing activities with planned pickup/start or delivery/end dates missing, then:

- The planned pickup and delivery dates of the biospecimen shipment are copied to the corresponding blank dates. This is not done for biospecimen kit shipments.
- If the treatment order does not have a biospecimen shipment, then the planned pickup and delivery dates of the finished product shipment are copied to the corresponding blank dates. This is not done for biospecimen kit shipments.

The shipment (biospecimen or finished product) dates are validated before these are copied to the other shipment and processing activity dates. The schedule is automatically confirmed if the date validation checks are successful.

On confirming the schedule for a treatment order:

- The status of each shipment and processing activity is updated, enabling relevant users to begin order processing activities.
- *Schedule Confirmed On* and *Schedule Confirmed By* are updated for each shipment and processing activity.
- The planned delivery date of the finished product final leg shipment is communicated to the treatment center.

You can confirm the schedule of the treatment order, which automatically confirms the schedule of all the shipments and processing activities, or you can confirm the schedule of specific shipments and processing activities of the order.

The following ERP document requests are generated and sent to the ERP system on confirming the schedule of processing activities and different shipments:

Processing Activity/Shipment	ERP Document Request
Processing Activity	Process Order Create
Biospecimen Kit Shipment	Sales Order Create
Biospecimen Shipment	Purchase Order Create
Intermediate Product Shipment	Stock Transport Order Create The request to create a Stock Transport Order depends on the configuration in the flow definition. If there is no ERP configuration for the shipment, no request is generated.
Finished Product Transit Leg Shipment	Stock Transport Order Create The request to create a Stock Transport Order depends on the configuration in the flow definition. If there is no ERP configuration for the shipment, no request is generated.
Finished Product Final Leg Shipment	Sales Order Create

Note

During schedule confirmation of a finished product shipment (FS-FL, FS-IL), a check is made to verify whether at least one business partner is associated with each of the following categories:

- Bill-To Party (CRM004)
- Sold-To Party (CRM000)
- *Goods Recipient (CRM002)

* Goods Recipient is the same as Ship-To Party.

A similar check is made to verify whether a business partner is associated with each of the following categories on confirming the schedule of a biospecimen shipment:

- Vendor (BBP000)
- Supplier (CRM007)

For intermediate product shipments and finished product transit legs associated with a stock transport order, a check is made to verify whether there is at least one business partner associated with each of these categories:

- Bill-To Party (CRM004)
- Sold-To Party (CRM000)
- Goods Recipient (CRM002)
- Vendor (BBP000)
- Supplier (CRM007)

The missing business partners are determined using the business rules configured for it. For more information on how the business rules determine business partners, see Business Rules Configuration for ERP Document Integration. If multiple matches are found for a given category, business partners are not determined for it. In such a situation, you can manually add business partners to the category or maintain the required configuration in the business rules. For more information on how to manually add business partners for a finished product or biospecimen shipment, see Manage Finished Product Shipments (Final Leg and Transit Leg) [page 124] or Manage Biospecimen Shipments [page 114]. In the shipment apps (*Manage Shipments - Finished Product* and *Manage Shipments - Biospecimen*), the business partners are displayed and maintained on the *Business Partners* tab. On schedule confirmation, the business partners are passed to the *S4/HANA* system.

> → Remember
>
> You must create business partner roles for the categories before adding business partners. For information on how to create business partners roles, see Configure Business Partner Roles [page 22]. You must also associate business roles with relevant organization location types before adding business partners. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

Automatic Schedule Confirmation of Subsequent Shipments and Processing Activities

You can create subsequent shipments and processing activities through events. Each subsequent entity (shipment and processing activity) created through an event can be confirmed either manually or automatically.

The schedule for subsequently created entities is automatically confirmed if the following criteria are met:

- Planned pickup and delivery dates (for shipments), and planned start and end dates (for processing activities) are available.
- Dates are valid.
- The **auto confirm schedule** flag is set to true.

If any of the above checks is not successful, you must do a manual schedule confirmation using the app. The **auto confirm schedule** flag check is done for subsequent shipments and processing activities only if the schedule of the complete treatment order is confirmed.

> ⓘ Note
>
> Business rules are used to determine business partners, if not maintained for a shipment.

Follow the given steps to confirm the schedule:

Procedure

1. Go to the *Confirm Schedules* app.
2. Choose *Go* in the filters section to view the list of orders. Alternatively, you can use the filter options to search for a specific order.

   For example, you can use the *COI ID* of an order to find the required order.
3. Open the required order to view the details.

   You can either confirm the schedule of each shipment and processing activity separately or confirm the schedule of the complete treatment order, which automatically confirms the schedule of all the shipments and processing activities.
4. To confirm the schedule of the complete order, choose *Confirm Schedule*.
5. To confirm the schedule of specific shipments and/or processing activities, select the shipment IDs and/or processing activity IDs, and choose *Confirm*.
6. To edit the schedule of shipments and/or processing activities, choose *Edit Schedule*.
7. Make the required date changes in the specific shipments and/or processing activities and choose *Save Schedule*.
8. Choose *Confirm Schedule*.

   For information on the fields on each tab, see the table below.

Tab	Details
General Information	Displays the flow version and schedule confirmation details of the treatment order: • *Flow Version*: Flow version ID of the order. • *Flow Version Confirmed By*: User ID of the person who confirmed the flow version. • *Flow Version Confirmed On*: Date of confirming the flow version. • *Schedule Confirmed By*: User ID of the person who confirmed the schedule of the treatment order. • *Schedule Confirmed On*: Date of confirming the treatment order schedule.
Shipments	Displays the shipment and schedule confirmation details. • *Shipment ID*: ID assigned to the shipment. Each shipment has a unique ID. • *Shipment Type*: A treatment order can have different types of shipments: biospecimen kit shipment (BKS), biospecimen shipment (BS), intermediate product shipment (IS) and finished product transit leg (FS-IL) and finished product final leg shipment (FS-FL).

Tab	Details
	• *Flow Step*: Processing step number of the shipment in the processing workflow. • *Status*: Status of the shipment (Shipment Requested, Shipment Scheduled, Shipped, Delivered). The statuses are configurable. • *Planned Pickup Date*: Planned pickup date of the shipment. Planned pick up date must be a current or future date. • *Planned Delivery Date*: Planned delivery date of the shipment. This is the date by when the shipment is expected at the manufacturing or treatment center. The planned delivery date must be a current or future date and must be after the planned pickup date. • *Schedule Confirmed By*: User ID of the person who confirmed the schedule of the shipment. • *Schedule Confirmed On*: Date when the schedule of the shipment was confirmed.
Processing Activities	Displays the processing activities and schedule confirmation details. • *Processing Activity ID*: ID assigned to the processing activity. Each processing activity has a unique ID. • *Flow Step*: Processing step number of the activity in the processing workflow. • *Status*: Status of the processing activity (, Processing Scheduled, Processing Started, Processing Completed). The statuses are configurable. • *Planned Processing Start Date*: Planned start date of the processing activity. The planned processing start date must be a current or future date. • *Planned Processing End Date*: Planned end date of the processing activity. The planned processing end date must be a current or future date and must be after the planned processing start date. • *Schedule Confirmed By*: User ID of the person who confirmed the schedule of the processing activity. • *Schedule Confirmed On*: Date of confirming the schedule of the processing activity.

6.8 Manage Inbound Logistics

Used by the Inbound Logistics Coordinator to manage inbound logistics by maintaining data relevant to logistics and courier booking.

Context

You can use this application to manage inbound logistics, determine transportation lane, and for booking a courier.

Procedure

1. Go to the *Manage Inbound Logistics* app.
2. Set your filters and choose *Go*.
3. Select a specific shipment under *Biospecimen Shipments* to access detailed information. You can navigate to any of the following apps:
   - *Manage Orders*
   - *Order List*
   - *Order Overview*

   You can also choose the line item to view and manage inbound logistics.
4. Choose *Edit* to update or modify information.

Field	Description/Purpose
Collection Center	Collection center of the biospecimen material.
Shipment Reason	Reason for shipment.
Reference ERP Order	ERP order number.
Shipment Status	Status of shipment. The shipment can be in the requested, scheduled, shipped, partially delivered or delivered status.
Shipment Cancellation Status	Indicates whether the shipment has been canceled.
COI Confirmation Status	Indicates whether the chain of identity (COI) of the shipment is confirmed. If the shipment is delivered or partially delivered, the status is marked as *Pending*. Only after you confirm the COI details of the shipment, the status is changed to *Confirmed* or *Rejected*. The COI details are confirmed on receipt of the shipment.
Location	Displays the pickup and drop-off location address details, and the primary and alternate contact persons for both the locations.

Field	Description/Purpose
Shipment Dates	Displays the planned and actual pickup and delivery dates. Planned dates must be in the future. Actual dates must not be in the future. Displays the *Actual COI Confirmation Date*. This refers to the date when the COI details of the shipment are confirmed.
Logistics	Displays the courier and waybill information of the shipment.
Shipment and Receipt	Displays the shipment and receipt confirmation information. On receipt of shipment, the shipment condition is verified. COI confirmation is also provided based on the specified criteria. In addition, the shipment package is verified and approved.
Biospecimen Materials	Refers to material details (batch number, expected quantity, total quantity, unit of measure). You can also view the collection and subunit details for each material item.
Documents	Refers to the documents uploaded for the shipment.
Logs	Refers to the document, e-signature, and change logs.

5. Choose *Determine Transportation Lane* to get the courier details, that is, primary contact person, courier ID, account number, and transportation lane for the shipment if this data is not already available in the *Logistics Details* section on the *Logistics* tab. If the data is available and you still choose *Determine Transportation Lane*, the system displays a warning message to confirm whether you want to overwrite the existing data and determine the courier details and transportation lane again. If you choose to proceed, the existing data is overwritten.
6. Choose *Book Courier* to book a new courier request.

   Following are the prerequisites to request a courier:

   - The schedule for the treatment order must be confirmed.
   - The shipment must contain information of the sender and receiver organizations, the contact person for each of these organizations, and the materials contained in the shipment.

   On selecting *Book Courier*, you will see general information about the courier, such as the courier ID, courier contact person, courier account number, quantity and so on. On the *Dates* tab, you will see the planned pickup and delivery dates. The *Shipper* and *Consignee* tabs display the shipper and consignee information (name, address, and contact details).

   a. On the *Shipped Items* tab, the *Quantity* (based on the expected quantity), *Gross Weight*, and *Total Gross Weight* for each item are displayed. *Total Gross Weight* is calculated based on the quantity and gross weight of the material. You can configure the type of quantity to be considered to calculate the total gross weight. The trigger point for the calculation of total gross weight is *Flow Version Confirmation*. Refer to Business Rules to Configure Quantity Type for Shipment Weight Calculation in the *Administration Guide* for information on how to configure quantity. The total gross weight that is calculated here is then sent to the courier when sending the courier booking request.
   b. On the *Instructions* tab, provide the pickup and delivery instructions. Specify the number of shippers required, and choose *Save*.

      The courier booking request will now be placed, and the information you maintained will be sent to the courier system through the *Biospecimen Shipment Courier Booking* event. Based on the number

of shipping containers requested, the courier will send shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link).

7. On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. However, it is mandatory for you to add at least one business partner each to the Vendor (BBP000) and Supplier (CRM007) business partner categories.
   - To add or remove a business partner, choose *Edit*.
     - On the *Business Partners* tab, choose *Add*.
     - Select a business partner category.
     - Enter the business partner function.
     - Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
     - Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

   > **Note**
   >
   > Prerequisites to add business partners to a business partner category:
   > - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
   > - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

8. You can request for the cancellation of a shipment, if required. To cancel a shipment, choose *Request Shipment Cancellation*. You must have the necessary authorization to request for cancellation. The *Shipment Cancellation Status* changes to *Cancellation Requested*. The cancellation request is logged on the *Cancellation Request Details* tab. You can configure the statuses to be displayed on the user interface. For more information, see , , and . To automatically trigger the shipment cancellation approval process, a workflow is configured. The configured workflow triggers a notification and initiates the cancellation process in SAP Cell and Gene Therapy Orchestration. For each cancellation request, an approval entry is logged on the *Approval Details* tab. You can approve or reject cancellation request if you have the required authorization. Choose *Approval Details* to approve or reject a shipment. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable. For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals. After the authorized user approves or rejects the shipment, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approves or rejects the shipment in the *Decision By* field.

   An entry is also added in the *Approval Logs* section on the *Logs* tab. When a shipment cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.

   A workflow notification about the approval decision is triggered. In addition, an outbound event about the approval decision is also sent.

   Cancellation of the shipment triggers *Purchase Order Cancellation*, an outbound event to cancel the purchase order in *S/4HANA*. This purchase order is linked with the shipment in SAP Cell and Gene Therapy Orchestration.

9. On the *Documents* tab, upload or invalidate documents associated with the biospecimen shipment. For more information on how to upload documents, see Upload Documents [page 180].

10. On the *Logs* tab, you can view the document, e-signature, change, and approval logs related to the shipment. For example, the *Document Log* section displays the logs related to document upload and invalidation, *E-Signature Log* section displays the logs related to e-signatures, *Change Log* section displays the logs of all changes related to the shipment, and the *Approval Log* section displays details related to shipment approvals. For each approval or rejection done, you can see the name of the person who approved or rejected the shipment in the *Decision By* field.

Related Information

Create a Contact Person for an Organization [page 77]

6.9 Manage Outbound Logistics

Used by the Outbound Logistics Coordinator to manage outbound logistics for finished product (FS-FL) and intermediate product shipments by maintaining data relevant to logistics and for courier booking.

Context

You can use this application to manage outbound logistics, determine transportation lane, and for booking a courier.

Procedure

1. Go to the *Manage Outbound Logistics* app.
2. Set your filters and choose *Go*.
3. Select a specific shipment under *Product Shipments* to access detailed information. You can navigate to any of the following apps:
   - *Manage Orders*
   - *Order List*
   - *Order Overview*

   You can also choose the line item to view and manage the outbound logistics for the shipment.
4. Choose *Edit* to modify information.

Field/Tab	Description/Purpose
Shipment Status	View the shipment status.

Field/Tab	Description/Purpose
Product Administration Center	View and modify the center where the patient is infused with medicine.
Shipment Reason	Provide a reason for the shipment.
Shipment Cancellation Status	View the reason for cancellation of the shipment.
Reference ERP Order	Modify the ERP order number.
COI Confirmation Status	View the COI confirmation status.
Location	Modify the addresses in *From Location* and *To Location*.
Shipment Dates	View and modify the planned/actual pickup or delivery dates. You can also modify the actual COI confirmation date based on the events. The actual date cannot be in the future. The planned dates cannot be in the past.
Logistics	You can modify any of the fields as required.
Product Acceptance	You can modify the shipment confirmation details. The receipt details can only be viewed.
Documents	View any documents uploaded.
Logs	View document, e-signature, and change logs.
Product Batches	View the requested and allocated batches of material.

5. Choose *Determine Transportation Lane* to get the courier details, that is, primary contact person, courier ID, account number, and transportation lane for the shipment if this data is not already available in the *Logistics Details* section on the *Logistics* tab. If the data is available and you still choose *Determine Transportation Lane*, the system displays a warning message to confirm whether you want to overwrite the existing data and determine the courier details and transportation lane again. If you choose to proceed, the existing data is overwritten.
6. Choose *Book Courier* to book a new courier request.

   Following are the prerequisites to request a courier:

   - The schedule for the treatment order must be confirmed.
   - The shipment must contain information on the sender and receiver organizations, the contact person for each of these organizations, and the materials contained in the shipment.

   On selecting *Book Courier*, you will see general information about the courier, such as the ID, contact person, account number, quantity and so on. The planned pickup and delivery dates, the shipper information, and consignee for the courier are also shown. *Shipped Items* displays the materials allocated for shipment. If the manufactured materials have not yet been allocated for shipment, the requested materials are displayed.

   a. Under *Shipped Items*, the *Quantity* (based on the manufactured quantity of the allocated material), *Gross Weight*, and *Total Gross Weight* for each item is displayed. The total gross weight is calculated by multiplying the gross weight with the quantity. You can configure the type of quantity to be considered to calculate the total gross weight. The trigger point for the calculation of the total gross weight of the requested material is *Flow Version Confirmation*. The trigger point for the calculation of the total gross weight of the allocated material is *Material Allocation*. Refer to Business Rules to Configure Quantity Type for Shipment Weight Calculation in the *Administration Guide* for information on how to configure quantity. The total gross weight that is calculated here is then sent to the courier when sending a courier booking request.

> **Note**
>
> In case of *Requested Material*, the *Material Quantity* is set to one.

b. Provide the pickup and delivery instructions. Specify the number of shippers required and choose *Save*. If you do not specify any value, the system takes one as the default value for the number of shippers required.

   The courier booking request will now be placed, and the information you maintained will be sent to the courier system through the courier booking event.

   Based on the number of shipping containers requested, the courier will send shipper serial numbers and other information (temperature monitoring serial number, shipper tracking link). This information is seen under *Logistics* in the *Waybill Details* section.

7. On the *Business Partners* tab, you can view and maintain business partners for different business partner categories. You can add one or more business partners to any business partner category. However, it is mandatory for you to add at least one business partner to each of the following categories for finished product final leg shipments (FS-FL): Bill-To Party, Sold-To Party, and Goods Recipient (Ship-To Party). Similarly, for intermediate product shipents (IS), it is mandatory to add at least one business partner to each of the following categories: Bill-To Party, Sold-To Party, and Goods Recipient (Ship-To Party), Supplier, and Vendor.

   - To add or remove a business partner, choose *Edit*.
     - On the *Business Partners* tab, choose *Add*.
     - Select a business partner category.
     - Enter the business partner function.
     - Select the organization ID. Based on the selected organization ID, the location type and business partner ID are also selected.
     - Choose *Save*. This adds a business partner to the business partner category. To remove a business partner, select the row and choose *Remove*.

   > **Note**
   >
   > Prerequisites to add business partners to a business partner category:
   > - Create business partner roles for the category. For information on how to create business partners roles, see Configure Business Partner Roles [page 22].
   > - Associate business roles with relevant organization location types. For information on how to associate business roles with organization location types, see Create an Organization [page 78].

8. You can request for the cancellation of a finished product shipment (FS-FL) or an intermediate product shipment (IS), if required. To cancel a shipment, choose *Request for Cancellation*. You must have the necessary authorization to request for the cancellation of a shipment. The *Shipment Cancellation Status* changes to *Cancellation Requested*. The shipment cancellation request is logged on the *Cancellation Request Details* tab. You can configure the statuses to be displayed on the user interface. For more information, see , , and . To automatically trigger the shipment cancellation approval process, a workflow is configured. The configured workflow triggers a notification and initiates the cancellation approval in SAP Cell and Gene Therapy Orchestration. For each cancellation request, an approval entry is logged on the *Approval Details* tab. You can approve or reject a cancellation request if you have the required authorization.

   - Choose *Pending Approvals* to approve or reject a shipment cancellation request. On selecting *Approve* or *Reject*, you are prompted to select a reason code as applicable.

For information on how to configure reason codes, see Configure Reason Codes [page 43]. For information on the scenarios for which reason codes must be configured, see Reason Codes for Order and Shipment Approvals.
After the authorized user approves or rejects the shipment cancellation request, the approval status is logged on the *Approval Details* tab. You can see the name of the person who approves or rejects the request in the *Decision By* field.
An entry is also added in the *Approval Logs* section on the *Logs* tab. When a shipment cancellation request is approved, the *Shipment Cancellation Status* changes to *Approved* and the *Shipment Status* changes to *Cancelled*.
A workflow notification about the approval decision is triggered. An outbound event about the approval decision is also sent. For more information on the notifications generated during the cancellation process, see Configure Post Processing Framework Events.

> **Note**
>
> Cancellation of the finished product shipment (FS-FL) triggers a *Sales Order Cancellation* outbound event to cancel the sales order in *S/4HANA*. The sales order is linked with the finished product shipment in SAP Cell and Gene Therapy Orchestration.

> **Note**
>
> Cancellation of the intermediate product shipment (IS) triggers a *Stock Transport Order* outbound event in *S/4HANA*. The stock transport order is linked with the intermediate product shipment in SAP Cell and Gene Therapy Orchestration.

6.10 Manage Exceptions

View, create, and update exceptions.

Context

An exception occurs when there is a disruption in the normal process flow due to technical or business reasons. Examples of technical issues are validation failures, configuration errors, or other internal processing errors. Business errors occur when a process fails or is blocked, for example, due to the unacceptable quality of a finished product, or incorrect data such as a mismatch in patient attributes. Some exceptions require action while others are for information only.

You can use this app to monitor exceptions, create new exceptions, and assign exceptions to yourself or another user. You can get all the information you need from an exception to analyze and monitor the situation. The exception status is reset when it is resolved. Exceptions can be created manually or automatically.

The following exception filters are available as charts on the list page: *Start Date*, *Due Date*, *Priority*, and *Status*. Choose the *Compact Filters* button to switch to the text format. You can use the *Chart* or *Chart and Table* buttons on the list page to view the *Exception Analytics* chart for the filtered data.

In the exception analytics chart, the x-axis represents dimensions (*Settings* > *Dimensions*) such as exception source and message type, whereas the y-axis represents the exception count (*Settings*

Measures). By default, the list page displays a graph for exception source and message type. However, you can add additional filters using the *View By* button or change the dimensions using the *Settings* button.

Manually Created Exceptions

Follow the steps given below to create an exception.

1. In the *Manage Exceptions* app, choose *Create*.
2. Select the *Exception Type*.
   An exception can be of the following types:
   - *Technical* (for a coding error)
   - *Business* (for a failed delivery)
3. *Exception Source* is automatically updated based on the source of exception. Possible values are:
   - *AI Generated* – Exception was generated using the artificial intelligence system and sent to SAP Cell and Gene Therapy Orchestration via the Exception Creation event. For more information about the Exception Creation event, see Tasks and Exceptions on SAP Business Accelerator Hub.

     > **Note**
     >
     > For AI generated exceptions, you can view the AI recommendation in the *Exception Details* section, if available. Please exercise caution and verify the results/recommendations before accepting the AI recommendations.

   - *Externally Generated* – Exception was generated in an external system and sent to SAP Cell and Gene Therapy Orchestration via the Exception Creation event. For more information about the Exception Creation event, see Tasks and Exceptions on SAP Business Accelerator Hub.
   - *Internally Generated* – Exception was generated in SAP Cell and Gene Therapy Orchestration.
   - *Manual* – Exception was manually created by a user via the *Manage Exceptions* app in SAP Cell and Gene Therapy Orchestration.
   - *Rule Generated* – Exception was generated using the business rules capability within the SAP Build Process Automation service and sent to SAP Cell and Gene Therapy Orchestration via the Exception Creation event. For more information, see Use SAP Build Process Automation Service in the Administration Guide for SAP Cell and Gene Therapy Orchestration. For information about the Exception Creation event, see Tasks and Exceptions on SAP Business Accelerator Hub.
4. Set *Priority*.
   You can set the priority for the exception to *Low*, *Medium*, or *High*.
5. Set *Status*.
   You can set the status of the exception to *New*, *In Progress*, *On Hold*, *Resolved*, or *Cancelled*.
6. Select a *Due Date* for resolving the exception.
   This is the last date to resolve the exception. Ensure to select a date in the future.
7. Select the *Start Date* for the exception.
   Ensure to select a date before the due date.
8. Select the appropriate *Action Required*.
   Exceptions can be for information only and an action is not always required.
9. Select the *Reference Object* for which the exception is being created, such as an *Order*, *Shipment*, or *Processing Activity*.

10. Select the *Reference Object ID* for which the exception is being created. For example, if the reference object is a shipment, then select the shipment ID.
11. Select an *Assignee*. The assignee names listed are derived from the API, *User Registry Information*.
    To monitor the exception, you can assign the exception to yourself or to another user.
12. Enter the *Completion %*.
    You can enter a percentage to track the progress of the task. For example, 50.
13. Select the *Message Type*.
14. Enter the following information from the event:
    1. *Message Class*
    2. *Message Number*
15. Enter a *Summary*.
    You can enter a short summary of the exception not exceeding 250 characters.
16. Enter a *Description*.
    You can enter a long description of the exception not exceeding 1000 characters.
17. Optionally add a *Comment*.
    This is for information purposes only.
18. Optionally *Upload* relevant documents.
    You can upload, view, and invalidate documents. For more information, see Upload Documents [page 180].
19. Choose *Create*.

Result: A new exception is created and can be viewed in the list of all exceptions.

> ⓘ Note
>
> If required, you can edit the exception details. To do so, choose *Edit* and make the required changes.

Automatically Created Exceptions

These are the exceptions that are created by the system.

Blocked Disposition

An exception is automatically created when the disposition of any of the following is blocked at the batch or subunit level:

- Biospecimen Shipment Material
- Intermediate Product Shipment Material
- Finished Product Transit Leg Shipment Material
- Processing Activity Yield Material

ERP Document Request Failure

When a create, update, or cancellation request for an ERP document (purchase order, process order, sales order, stock transport order) fails in your ERP system, such as *S4/HANA*, an exception is raised in SAP Cell and Gene Therapy Orchestration.

> ⓘ Note
>
> You can modify an exception. To do so, choose *Edit* and make the required changes.

6.11 Manage Tasks

View, create, and edit a task.

Context

Using the *Manage Tasks* app, you can do the following:

- Create one or more tasks for a reference object using the reference object ID.
- Set the priority level of the task.
- Assign the task to yourself or another user.
- Monitor and report the progression of the task using the task status and completion percentage.
- Create a to-do list for a task.
- View the tasks assigned to the same reference object ID under *Related Tasks*.

Procedure

1. In the *Manage Tasks* app, choose *Create*.
2. Provide a short description of the task under *Summary*.

   You can enter up to 250 characters.
3. Select a category.

   Select *Manual Task* to enter information in all the fields manually.
4. Set the priority level of the task to either *Low*, *Medium*, or *High*.
5. Select a start date.

   You must select a date prior to the due date.
6. Select a due date for completing the task.

   This is the last date to complete the task. You must select a future date. Due date must follow the start date. In case the task is not completed by the due date, you will receive an alert message.
7. Set the status of the task.

   You can set the status to either *New*, *In Progress*, *On Hold*, *Resolved*, or *Cancelled*.
8. Select the reference object for which you are creating the task, such as a treatment order, shipment, or processing activity.
9. Select the reference object ID.

   For example, if the reference object is a shipment, select the shipment ID.
10. Enter the completion percentage.

    You can track and update the progress of the task by viewing and editing the completion percentage.
11. Select an assignee. The assignee names listed are derived from the API, *User Registry Information*.

You can assign the task to yourself or another user to monitor.

12. View related tasks.

    You can see the list of related tasks that are assigned to the same reference object ID.

13. [Optional] Add a to-do list for the task.

    To add a to-do list:

    1. On the *To Do List* tab, choose *Create* to add an item.
    2. Enter a *Description*.
       You can enter up to 255 characters.

    If required, you can also copy the to-do list from an Excel sheet using the paste icon.

14. [Optional] Add a comment.

    This is for information purpose only.

15. [Optional] Upload relevant documents.
    1. On the *Documents* tab, choose *Upload.*
    2. Select the document to be uploaded.

Results

You can now view and edit the task assigned to you.

6.12 Clone Orders

You can clone treatment orders whenever there is a change in the attributes or flow of an order. When you clone an order, you have the option to copy all the parent order data or a part of it to the cloned order. The cloned order is referred to as a follow on order.

Context

Clone treatment orders when there is a:

- change in therapy due to which the order is reclassified. For example, when the therapy changes from commercial to clinical or vice-versa.
- change in flow version. For example, when the flow version steps of an order change due to new or changed processing activities or shipments.

> ⓘ Note
>
> Cloning can be done only when the Clone Order feature flag (ft_enable_order_clone) is enabled for a given tenant. For more information, see .

Execute the following steps to clone a treatment order to create a follow on order:

Procedure

1. Go to the *Manage Orders* app.
2. Choose *Go* in the filters section to view the list of orders. Alternatively, you can use the filter options to search for a specific order.

   For example, you can use the *COI ID* of an order to find the required order.
3. Open the required order to view details.
4. Choose *Clone Order*.
5. Select the reason type as *Reclassification* or *Flow Version Change* depending on the type of change in the treatment order.
6. Select the reason code from the dropdown. Optionally, enter the reason for cloning the order. Choose *Next Step* to navigate to the next screen. Choose *Previous Step* to navigate to the previous screen, if required.
7. If you select *Reclassification* as the reason for cloning in Step 5:
1. Select the therapy name from the dropdown.
2. The order type to which the order will be cloned is automatically selected in the *Order Type* dropdown. Choose *Next Step* to navigate to the next screen.
   The order type is determined on the basis of the therapy selected and country/region of the parent order. In addition, the order type must have been configured as a follow on order type for the parent order type. For more information, see Configure Order Types [page 72].
8. This screen displays the order entities (shipments and processing activities) and their status. Depending on the status of each shipment, the *To be Cloned* status for each is shown as *Yes* or *No*. Only shipments with status *Shipped* or *Delivered* are marked as *Yes* and will be copied to the follow on order. The processing activity that follows the shipment (selected for cloning) as per the flow version will also be copied to the follow on order. Choose *Next Step* to navigate to the next screen.
9. Select the attributes to be copied to the follow on order. Choose *Next Step* to navigate to the next screen.

   Attributes are the field groups that are a part of the order, shipments, and processing activity sections of the treatment order.

   You can deselect the attributes that are not to be copied to the follow on order. Attributes are determined by the copy control profile group associated with the follow on order type. If, however, the follow on order type is not associated with a copy control profile group, all the attributes of each section are shown. For more information, see Configure Order Types [page 72].
10. Review the information (reason, order entities, attributes) selected. To make changes to any section, choose *Edit*. This takes you to the relevant screen where you can make changes.
11. Choose *Clone*.
12. In the *E-signature* dialog, enter your password, select the reason code for cloning the order, and choose *Save*.

Results

This creates a follow on order of the parent order with the selected entities and attributes. The COI ID of the parent order is assigned to the follow on order. The system sets the parent order to inactive and you cannot perform any action on it. Further, you cannot modify the parent treatment order or its entities.

7 Managing the Manufacture of Finished Products

SAP Cell and Gene Therapy Orchestration provides apps that help facilitate the following activites:

- Manage biospecimen shipments [page 163]
- Manage processing activities [page 171]
- Manage finished product shipments [page 176]

You can manage these activites using the apps in the *Manufacturing* section of the solution.

> **Note**
>
> Transactional data once created or recieved in SAP Cell and Gene Therapy Orchestration, can neither be deleted nor deactivated.

> **Note**
>
> In the *Manufacturing* apps, any changes made to a record are stored in draft mode until the changes are saved. You can save, modify, or delete a draft record and can also exit the record without saving your data. A record in draft mode can be edited by another user after a system-defined timeout has elapsed.

7.1 Manage Biospecimen Shipments

You can do the following when managing a biospecimen shipment:

- Manage Incoming Biospecimen [page 163]
- Print Hangtag Labels [page 164]
- Confirm Shipment Receipt [page 165]
- Manage Biospecimen Disposition [page 166]

7.1.1 Manage Incoming Biospecimen

Review the details of the incoming biospecimen shipment.

You can use the *Manage Incoming Biospecimen* app to:

- Review and edit the purchase order number and batch numbers of the shipment. These numbers are used in the labels for the biospecimen shipment.

> **Note**
>
> You can only edit the batch numbers if batch management is enabled for the material in the *Plant Data* section of the *Manage Materials* app.

- Edit the expiration date of the batch.

  > **Note**
  >
  > After you edit the date, you must select the reason code and enter the reason for changing the date. The change in expiration date is then recorded in the *E-Signature Trail* trail section of a record.

- Print the Inbound Logistics Form (ILF), which includes the material and courier details.
- Upload and print the Biospecimen Data Form and Infectious Data Monitoring documents. To do this you navigate to the collection details page of the record, and upload the documents. For more information on uploading documents, see Upload Documents [page 180]

7.1.2 Print Hangtag Labels

Print the hangtag labels for a biospecimen shipment.

Context

You can print hangtag labels for a biospecimen shipment using the *Print Biospecimen Hangtag Label* app. With the app, you can print the labels for each subunit in a material batch.

> **Note**
>
> To view and print the labels, you will be redirected to the data and document integration for SAP Cell and Gene Therapy Orchestration.

Procedure

1. In the *Print Biospecimen Hangtag Labels* app, open the record for your shipment

   Use the *COI ID* to locate the record for your order.
2. In the *Label Documents* section, select the labels you want to print.

   The *Label Documents* section displays the label uploaded for each subunit. The hyperlink to view the label is only available after you print the label.

   The *Document Name* includes the label type, Chain of Identity (COI) ID, material number, batch number, subunit ID, document status, and version.

   If the label has not been printed, the *Document Status* is *Not Printed*.

3. Choose *Generate* to print the labels.

   > **Note**
   >
   > You will be redirected to your data and document integration to view the label.

   The *Document Status* is updated to *In Process*. You won't be able to reprint or invalidate the label when the status is *In Process*.
4. In the *Document Viewer* screen, choose the print icon to print all the labels.

Results

In the *Print Biospecimen Hangtag Labels* app, the *Document Status* of the subunits is updated to *Printed*. You can now choose the hyperlink under *Document Name* to view the label.

Next Steps

If required, you can reprint the labels. To do this, choose *Reprint* and to provide the reason code and enter a reason for reprinting the label. The *Document Status* is then updated to *Reprinted*.

You can also invalidate the label. The document status changes to *Invalidated*, but you can print the label again if required.

7.1.3 Confirm Shipment Receipt

Confirm receipt and chain of identity (COI) details of biospecimen shipments.

Context

After you receive the biospecimen shipment, record its receipt using the *Confirm Biospecimen Receipt* app. With the app, you can also confirm the the chain of identity details of the received shipment.

Procedure

1. Go to the *Confirm Biospecimen Receipt* app, and open the record for your order.

   Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.

3. In the *Biospecimen Materials* section, choose the material line item to view batch and subunit details.
4. Select the *Received* checkbox to confirm the receipt of the batches and subunits.

   For non-serialized materials, confirm the receipt of batches. For serialized materials, confirm the receipt of each subunit.
5. In the *Receipt Confirmation* section, confirm the chain of identity details of the shipment.
6. Select the *Actual COI Confirmation Date*.
7. Confirm your changes and click *Apply*, then click *Save*.

7.1.4 Manage Biospecimen Disposition

Manage the disposition of the biospecimen based on your quality checks.

Context

After you confirm the shipment receipt, you can disposition the biospecimen based on your quality checks. To do this, set a batch or disposition status using the *Manage Biospecimen Disposition* app.

Only the batches or subunits with statuses *Unrestricted* or *Released with Restrictions* can be used for further processing.

Procedure

1. In the *Manage Biospecimen Disposition* app, open the record for your shipment

   Use the *COI ID* locate the record for your order.
2. Choose *Edit*.
3. In the *Biospecimen Batch* section, set a *Batch Status*.
   - *Unrestricted* or *Released with Restrictions* if the batch can be used for processing.
   - *Blocked* if the batch can't be used for processing.

   When you select a batch status, all the subunits in the batch are updated with the same status. You can still change the disposition status of the subunits.

   > **Note**
   >
   > If the material isn't batch managed, then the status is *Unrestricted* and can't be edited.
4. If required, set a *Disposition Status* for the subunits in each batch.

   > **Note**
   >
   > Ensure that at least one subunit has the same status as the batch.

5. Confirm your changes and choose *Apply*, and then choose *Save*.

7.2 Manage Intermediate Product Shipments

Managing intermediate product shipments involves the following activities:

- Allocate Batches to Intermediate Product Shipments [page 167]
- Confirm Intermediate Product Shipment Pickup [page 168]
- Confirm Intermediate Product Shipment Receipt [page 169]
- Manage Intermediate Product Disposition [page 170]

7.2.1 Allocate Batches to Intermediate Product Shipments

Allocate batches to intermediate product shipment and specify the planned delivery date of the shipment.

Context

After completing the disposition of the processed material, you can specify the batches to be shipped using the *Allocate Batches to Intermediate Product Shipment* app. With this app, you can also specify the planned delivery date of the shipment.

> ⓘ Note
>
> You can allocate batches for shipment only if the flow version is confirmed.

Procedure

1. In the *Allocate Batches to Intermediate Product Shipments* app, open the record for your shipment. Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. In the *Shipment Details* section, you can view the pickup and delivery location for the shipment.
4. In the *Items to Ship* section, add the batches to be shipped.

   You can only view the batches with a subunit inventory status *Available to Ship*.

   The inventory status is determined by the batch or disposition status assigned in the *Manage Product Disposition* app. Only the batches with an *Unrestricted Use* or *Released with Restrictions* status have the inventory status set to *Available to Ship*.

   After you add the batches, the inventory status of the batch changes to *Allocated for Shipping*.

> **Note**
>
> You can remove an allocated batch if the pickup has not been done. Select the batch and choose *Remove Allocated Batches*.

5. Under *Items to Ship*, you can view the requested and allocated material. To view the details of a given allocated batch, choose the line item. If the batch has not been shipped and delivered, you can change the assigned shipper serial number using the dropdown. The shipper serial number can be changed at the batch and subunit levels.
6. In the *Shipping Details* section, you can view the planned pick up dates for the shipment.
7. Enter the planned delivery date for the shipment.
8. Confirm your changes and choose *Apply*, and then choose *Save*.

> **Note**
>
> Once the intermediate product shipment batch or subunit has been picked up for shipment, you will not be able to edit the batch.

7.2.2 Confirm Intermediate Product Shipment Pickup

Confirm the pickup date and shipping conditions of the intermediate product shipment.

Context

You can confirm the pickup date and shipping conditions of the intermediate product shipment, using the *Confirm Intermediate Product Pickup* app.

Procedure

1. In the *Confirm Intermediate Product Pickup* app, open the record for your shipment.

   Use the *COI ID* to locate the record for your order.
2. Click *Edit*.
3. On the *Logistics* tab, you can view the courier and waybill details for the intermediate product shipment.
4. On the *Items to Ship* tab, you can view the requested and allocated material. To view the details of a given allocated batch, navigate using the right arrow at the end of the row. If the batch has not been shipped and delivered, you can change the assigned shipper serial number using the dropdown.

> **Note**
>
> The shipper serial number can be changed at the batch and subunit levels

5. On the *Shipment Dates* tab, you can view the planned pick up and delivery dates for the shipment.
6. Enter the *Actual Pickup Date* of the shipment.

   > **Note**
   >
   > The actual pickup date must not be in the future

7. On the *Shipment Confirmation* tab, confirm the shipping conditions.
8. On the *Documents* tab, upload or invalidate documents associated with the intermediate shipment.
9. Confirm your changes and click *Apply*, and then click *Save*.

7.2.3 Confirm Intermediate Product Shipment Receipt

Confirm receipt and chain of identity (COI) details of intermediate product shipments.

Context

Record the receipt of the intermediate product shipment after you receive the shipment at the plant using the *Confirm Intermediate Product Receipt* app. With the app, you can also confirm the the chain of identity details of the received shipment.

Procedure

1. Go to the *Confirm Intermediate Product Receipt* app, and open the record for your order.

   Use the *COI ID* or *Intermediate Product Shipment* ID to locate the record for your order.
2. Choose *Edit*.
3. On the *Intermediate Product Materials* tab, you can see the allocated material batches. Choose the batch line item to view details of the batch and subunits.
4. Select the *Received* checkbox to confirm the receipt of the batch if the material is non-serialized. For serialized material, select the *Received* checkbox of each subunit to confirm its receipt. When you select the *Received* checkbox of all the subunits of a batch, the receipt confirmation status of the batch is automatically updated.

   For non-serialized materials, you must confirm the receipt of the batches. For serialized materials, you must confirm the receipt of each subunit.
5. On the *Receipt Confirmation* tab, confirm whether the shipping conditions and chain of identity details meet the required specifications.
6. Select the *Actual COI Confirmation Date*.
7. Confirm your changes and choose *Apply*, then choose *Save*.

7.2.4 Manage Intermediate Product Disposition

Manage disposition of intermediate products based on your quality checks.

Context

After you confirm the shipment receipt, disposition the intermediate products based on your quality checks. To do this, set a batch or disposition status using the *Manage Intermediate Product Disposition* app.

> **Note**
>
> To disposition intermediate products:
>
> - Shipment must have been received at the plant. The shipment is marked as *Received* in the *Confirm Intermediate Product Receipt* app.
> - The *Actual Chain of Identity (COI) Confirmation Date* must have been specified.
> - Receipt confirmation must be complete. This means that the shipping conditions and the COI confirmation are as per specifications. The receipt confirmation is given in the *Confirm Intermediate Product Receipt* app.

Only the batches or subunits with the status *Unrestricted Use* or *Released with Restrictions* can be used for further processing.

Procedure

1. In the *Manage Intermediate Product Disposition* app, open the record for your shipment.

   Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. On the *Intermediate Product Materials* tab, set the *Batch Status* as one of the following:
   - *Unrestricted Use* or *Released with Restrictions* if the batch can be used for processing.
   - *Quality Inspection*
   - *Blocked* if the batch can't be used for processing.

   When you select a batch status, all the subunits in the batch are updated with the same disposition status. You can still change the disposition status of the subunits.

   > **Note**
   >
   > If the material isn't batch managed, then the status is set to *Unrestricted Use* and the status cannot be changed.
4. If required, set a *Disposition Status* for each subunit of the batch. Choose the batch line item to view batch and subunit details.

> **Note**
>
> Ensure that at least one subunit has the same status as the batch.

5. Confirm your changes and choose *Apply*, then choose *Save*.

7.3 Manage Processing Activities

You can do the following when managing a processing activity:

- Manage Process Order Batch Details [page 171]
- Report Processing Start [page 172]
- Print Finished Product Labels [page 173]
- Report Processing Completion [page 174]
- Manage Product Disposition [page 175]

7.3.1 Manage Process Order Batch Details

Manage the details of the batches to be manufactured.

Context

For a scheduled processing activity, you can enter the batch and subunit details of the batches to be manufactured. You can add these details in the *Manage Process Orders* app.

The batch and subunit details are used in the labels for the finished product.

Procedure

1. In the *Manage Process Orders* app, open the record for your processing activity.

   You can use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. Enter the process order number.
4. In the *Process Order Batches (Yield)* section, enter the batch numbers for each batch to be manufactured.

> **Note**
>
> The number of batches displayed under *Process Order Batches (Yield)* are determined by the maximum number of batches configured for the material. This configuration is made in the *Plant Data* section of the *Manage Materials* app.

5. Open the batch records, and provide information for the subunit, if not already shown.
    - *Subunit Type*
    - *Subunit Qualifier*
    - *Subunit ID*

    The subunit information is shown here if you have configured it while creating material in the *Manage Materials* app. Depending on the *Subunit ID* mode of configuration (Auto Generate or Batch), *Subunit ID* is assigned a serial number or the material batch number.
6. Confirm your changes and choose *Apply*, then choose *Save*.

7.3.2 Report Processing Start

Specify the processing start details, which includes the actual processing start date, formulation date, and the materials used for processing.

Context

You can update the actual processing start date and formulation date using the *Report Processing Start* app. You can also specify the materials (biospecimen and intermediate product) that are used for processing the yield.

Procedure

1. In the *Report Processing Start* app, open the record for your processing activity.

    Use the *COI ID* to locate the record for your order.
2. Click *Edit*.
3. Select the actual processing start date and the formulation date. The formulation date must be after the actual processing start date.
4. On the *Process Order Components* tab, add the materials that are used for processing. Choose *Add* to select the materials to be added.

    You can only view materials with consumption status *Not Consumed* or *Partially Consumed*.

    The consumptions status of a material is determined by the batch or disposition status assigned to it during dispositioning. Only batches with *Unrestricted Use* or *Released with Restrictions* status have a consumption status of *Not Consumed*.

    After you add the materials, the consumption status of the batch changes to *Consumed* or *Partially Consumed* depending on whether the entire batch was used. For each material added, you can see the source or the type (biospecimen or intermediate product) of the material.

    > ⓘ Note
    >
    > In scenarios where the flow version consists of a coproduct, that is, a processing activity yields a main material and coproducts, and the coproduct needs to be consumed in the subsequent processing

activity in the same plant, you can view and add the yield material from the relevant processing activity for consumption. In scenarios where a material from a processing activity is consumed by another processing activity, you can only add the materials for which the *Inventory Status* is *Available to Ship*.

You can also remove the material added. Select the material and choose *Remove*.

5. Confirm your changes and choose *Apply*, then choose *Save*.

7.3.3 Print Finished Product Labels

Print the labels for the product to be manufactured.

Context

You can print labels for the product to be manufactured using the *Print Finished Product/Secondary Packaging Label* app. With the app, you can print the following labels for each subunit:

- Finished Product Label
- Secondary Packaging Label
- Finished Product Shortened Label

> **Note**
>
> - To view and print the labels, you will be redirected to the data and document integration for SAP Cell and Gene Therapy Orchestration.
> - A label type must be mapped to a therapy for donor identification during label generation for Finished Product, Secondary Packaging, and Finished Product Short Label.

Procedure

1. In the *Print Finished Product/Secondary Packaging Label* app, open the record for your shipment

   Use the *COI ID* to locate the record for your order.
2. Select the labels you want to print in the *Print Labels* section.

   The *Print Labels* section displays the label uploaded for each subunit. The hyperlink to view the label is only available after your print the label.

   The *Document Name* includes the label type, Chain of Identity (COI) ID, material number, batch number, subunit ID, document status, and version.

   If the label has not been printed, the *Document Status* is *Not Printed*.

> **Note**
>
> The subunit is only displayed if the batch expiration date is populated in the *Manage Process Order Batches* app.

3. Click *Generate* to print the labels.

> **Note**
>
> You will be redirected to your data and document integration to view the label.

The *Document Status* is updated to *In Process*. You won't be able to print, reprint, or invalidate the label when the status is *In Process*.

4. In the *Document Viewer* screen, click the print icon to print all the labels.

Results

In the *Print Finished Product/Secondary Packaging Label* app, the *Document Status* of the subunits is updated to *Printed*. You can now click the hyperlink under *Document Name* to view the label.

Next Steps

If required, you can reprint the labels. To do this, click *Reprint* and to provide the reason code and enter a reason for reprinting the label. The *Document Status* is then updated to *Reprinted*.

You can also invalidate the label. The document status changes to *Invalidated*, but the label can be printed again if required.

7.3.4 Report Processing Completion

Record the details of the manufactured batches.

Context

After the manufacturing is done, you can record the processing end date in the *Report Processing Completion and Yield* app. With this app, you can also specify the batches that were produced and the subunit quantity produced for each batch.

Only the batches with the subunit marked as produced will be available for disposition and shipment.

Procedure

1. In the *Report Processing Completion and Yield* app, open the record for your processing activity.

   Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. Select the processing end date.
4. In the *Process Order Batches (Yield)* section, provide the following information for the manufactured batches:
   - Confirm whether the subunit has been produced.
   - Specify the produced subunit quantity.
5. Confirm your changes, choose *Apply*, then choose *Save*.

7.3.5 Manage Product Disposition

Manage disposition of manufactured batches.

Context

After you have recorded the details of a manufactured batch, disposition the batch based on your quality checks. To do this, assign a disposition status to the manufactured product using the *Manage Product Disposition* app.

Only batches with status *Unrestricted Use* or *Released with Restrictions* can be allocated for shipment.

Procedure

1. In the *Manage Product Disposition* app, open the record for your processing activity.

   Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. On the *Product Batches* tab, set the batch status. Choose the batch line item to view batch and subunit details. Specify the disposition status at the subunit level for serialized material. For non-serialized material, specify the batch status at the material level.
   - *Unrestricted Use* or *Released with Restrictions* if the batch can be shipped.
   - *Blocked* if the batch can't be shipped.

> **Note**
>
> The *Disposition Status* of the subunits is automatically updated when you set the *Batch Status*. If the material is not batch managed, then the *Batch Status* is set to *Unrestricted Use* and the status cannot be changed.

4. Confirm your changes, choose *Apply*, then choose *Save*.
5. Choose *Close Process Order* after completing the disposition of the product batches, ensuring that the processing status is already marked as *Completed* and all relevant documents are uploaded for the processing activity.

7.3.6 Process Order Components

Specifies the components used for processing.

Context

You can update the components used for processing using the *Manage Processing Activities* app. You can also specify the components that are used for processing the yield.

Procedure

1. In the *Manage Processing Activities* app, open the record for your processing activity. Use the *COI ID* to locate the record for your order.
2. Choose the specific entry.
3. In the *Process Order Batches (Components)* section, add the materials that are used for processing. Choose *Add* to select the materials to be added.

   You can only view materials with consumption status, as *Not Consumed* or *Partially Consumed*.

   The consumption status of the material is determined by the batch or disposition status assigned to it during dispositioning. Only batches with an *Unrestricted Use* or *Released with Restrictions* status have a consumption status of *Not Consumed*.
4. After you add the materials, the consumption status of the batch changes to *Consumed* or *Partially Consumed* depending on whether the entire batch was used. For each material added, you can see the source or the type (biospecimen or intermediate product) of the material.
5. You can also remove the material added. Select the material and choose *Remove*.
6. Choose *Confirm* to confirm the changes and save.

7.4 Manage Finished Product Shipment

You can do the following when managing a finished product shipment:

- Allocate Batches to Shipment [page 177]
- Confirm Shipment Pickup [page 179]

7.4.1 Allocate Batches to Shipment

Allocate batches to be shipped and specify the planned delivery date of the shipment.

Context

After completing the disposition of the manufactured product, you can specify the batches to be shipped using the *Allocate Batches to Finished Product Shipment* app. With this app, you can also specify the planned delivery date of the shipment.

> **Note**
>
> You can allocate batches for shipment only if the flow version is confirmed.

Procedure

1. In the *Allocate Batches to Finished Product Shipment* app, open the record for your shipment.

   Use the *COI ID* to locate the record for your order.
2. Choose *Edit*.
3. On the *Items to Ship* tab, add the batches to be shipped. Choose *Allocate Batches*.

   You can only view batches with inventory status *Available to Ship*.

   The inventory status is determined by the batch or disposition status assigned in the *Manage Product Disposition* app. Only batches with *Unrestricted Use* or *Released with Restrictions* status have the inventory status *Available to Ship*.

   After you allocate batches, the inventory status of the batch changes to *Allocated for Shipping*.

   > **Note**
   >
   > You can remove an allocated batch if the pickup has not been done. Select the batch and choose *Remove Allocated Batches*.
4. On the *Items to Ship* tab, you can view the requested and allocated batches. To view the details of a given allocated batch, choose the batch line item. If the shipment has not been shipped and delivered, you can change the assigned shipper serial number using the dropdown. The shipper serial number can be changed at the batch and subunit levels.
5. Enter the planned delivery date for the shipment.
6. Confirm your changes and choose *Apply*, then choose *Save*.

7.4.1.1 Generate COI Certificate (Allocate Batches to Finished Product Shipment)

Generate, view, save, and print COI certificates using the *Allocate Batches to Finished Product Shipment* app.

Context

A chain of identity (COI) certificate contains information about the patient, biospecimen, and product. You can generate COI certificates for finished product final leg shipments (FS-FL) at shipment and batch levels. SAP CGTO prefills all the required information to generate the COI certificate.

You can use the *Allocate Batches to Finished Product Shipment* app to generate COI certificates at batch level. COI certificate generation is enabled only for allocated batches of FS-FL shipments that are associated with an active order.

To generate COI certificates at shipment level, you can use the *Manage Orders* and *Manage Shipments - Finished Product* apps. For more information, see Generate COI Certificate (Manage Orders) [page 131] and Generate COI Certificate (Manage Shipments - Finished Product) [page 181].

Generating a COI certificate requires a template that is customized for your requirements. The details displayed in the COI certificate depend on the COI certificate template configuration. For more information, see Configure COI Certificate Templates [page 225].

Follow the steps given below to generate COI certificate at batch level using the *Allocate Batches to Finished Product Shipment* app.

Procedure

1. Go to the *Allocate Batches to Finished Product Shipment* app.
2. Choose *Go* in the filters section to view the list of finished product shipments. You can also use the filter options to search for a specific shipment. For example, use the *COI ID* or *Finished Product Shipment* ID to find the required finished product final leg shipment (FS-FL).
3. Open the required shipment and navigate to the *Items to Ship* section.
4. Open the allocated batch item for which you wish to generate the COI certificate.
5. In the *Documents* tab, choose *Generate COI Certificate*.

   > **Note**
   >
   > The *Generate COI Certificate* button is enabled only for allocated batches of FS-FL shipments that are associated with an active order.

6. In the *E-Signature* window, enter the required details and choose *Save*.

   You can use the *Comments* field in the *E-Signature* window to add information related to the finished product. The comments you enter in this field will be updated in the *Additional Comments* section of the COI Certificate.

7. You will be redirected to Data and Document Integration for SAP Cell and Gene Therapy to view the document.

   You can also print or save the COI certificate using the respective buttons.

   In the *Documents* tab, you can view the certificate generated and saved last. To view the certificates saved earlier, go to *Logs* > *Document Log* in the *Mange Shipments - Finished Product* app.

7.4.2 Confirm Shipment Pickup

Confirm the pickup date and shipping conditions of finished product shipments.

Context

You can confirm the actual pickup date and shipping conditions of the finished product shipment, using the *Confirm Finished Product Pickup* app.

Procedure

1. In the *Confirm Finished Product Pickup* app, open the record for your shipment.

   Use the *COI ID* to locate the record for your order.
2. Click *Edit*.
3. On the *Items to Ship* tab, you can view the requested and allocated material. To view the details of a given allocated batch, choose the batch line item. If the shipment has not been shipped and delivered, you can change the assigned shipper serial number using the dropdown. The shipper serial number can be changed at the batch and subunit levels.
4. On the *Shipment Dates* tab, specify the *Actual Pickup Date* of the shipment. The actual pickup date must not be a future date.
5. Confirm the shipping conditions on the *Shipment Confirmation* tab.
6. Confirm your changes and choose *Apply*, then choose *Save*.

7.5 Upload Documents

Upload documents using SAP Cell and Gene Therapy Orchestration

Context

You can upload or invalidate documents in the *Manage Orders* or *Manufacturing Management* apps.

These documents can be specific to an order, shipment, processing activity, batch, or collection. For example, if you upload the document for a shipment in the *Manage Incoming Biospecimen* app, the document will be displayed in the other *Manufacturing Management* apps for the same shipment.

> **Note**
>
> To view or upload documents, you will be redirected to data and document integration for SAP Cell and Gene Therapy Orchestration.

Procedure

1. Open the record for your order in the *Manage Order* or any of the manufacturing apps.

   Use the *COI ID* to locate the record for your order.
2. Go to the *Documents* section, and click *Upload*.
   - To upload documents for an order, shipment, or processing activity, go to the *Documents* section of the record.
   - To upload documents for a batch, open the record for a batch and go to the *Documents* section.
   - To upload documents for a collection, click the collection number, and go to the *Documents* section.

   > **Note**
   >
   > You will be redirected to your data and document integration to upload the document.
3. On the *Document Upload* screen, select the document type. Only document types that are defined as both *Active* and *Allowed for Upload* in the *Configure Document Types* app are available for selection from the dropdown.

   The document type determines what the document is used for, and is configured in the same app.
4. Browse to the document in your system, select it, and choose *Upload*.

   You can only upload PDFs and the latest Microsoft Word file types.

Results

The link to view the document is displayed in the *Documents* section. You will be redirected to your data and document integration to view the uploaded document.

> **Note**
>
> In the *Manufacturing Management* apps, you can view all the documents uploaded for a shipment, processing activity, batch, or collection in the *Document Logs* section of a record.

Related Information

Configure Document Types [page 52]

7.6 Generate COI Certificate (Manage Shipments - Finished Product)

Generate, view, save, and print COI certificates using the *Manage Shipments - Finished Product* app.

Context

A chain of identity (COI) certificate contains information about the patient, biospecimen, and product. You can generate COI certificates for finished product final leg shipments (FS-FL) at shipment and batch levels. For shipments, the COI certificates can be generated irrespective of whether the batch is allocated or not. SAP CGTO prefills all the required information to generate the COI certificate.

You can use the *Manage Shipments - Finished Product* and *Manage Orders* apps to generate COI certificates at shipment level. If there are multiple batches, all the batch details will be added to the *Product Information* section of the COI certificate. COI certificate generation is enabled only for FS-FL shipments of active orders. For information about generating COI certificate through *Manage Orders* app, see Generate COI Certificate (Manage Orders) [page 131].

To generate COI certificates at batch level, you can use the *Allocate Batches to Finished Product Shipment* app. For more information, see Generate COI Certificate (Allocate Batches to Finished Product Shipment) [page 178].

Generating a COI certificate requires a template that is customized for your requirements. The details displayed in the COI certificate depend on the COI certificate template configuration. For more information, see Configure COI Certificate Templates [page 225].

Follow the steps given below to generate COI certificate at shipment level using the *Manage Shipments - Finished Product* app.

Procedure

1. Go to the *Manage Shipments - Finished Product* app.
2. Choose *Go* in the filters section to view the list of shipments. You can also use the filter options to search for a specific shipment. For example, use the *Shipment ID* to find the required finished product final leg shipment (FS-FL).
3. Open the required shipment and navigate to the *Documents* tab and choose *Generate Certificate*.

   > **Note**
   >
   > The *Generate Certificate* button is enabled only for FS-FL shipments of active orders.

4. In the *E-Signature* window, enter the required details and choose *Save*.

   You can use the *Comments* field in the *E-Signature* window to add information related to the finished product. The comments you enter in this field will be updated in the *Additional Comments* section of the COI Certificate.
5. You will be redirected to Data and Document Integration for SAP Cell and Gene Therapy to view the document.

   You can also print or save the COI certificate using the respective buttons.

   In the *Documents* tab, you can view the certificate generated and saved last. To view the certificates saved earlier, go to *Logs* > *Document Log*.

8 Chain of Custody and Chain of Identity

SAP Cell and Gene Therapy Orchestration provides apps that allow you to:

- Configure rules for generating a COI ID [page 183].
- Monitor the events generated for a COI ID. [page 196]
- Monitor the Chain of Custody (COC) of a material in a treatment order. [page 221]

8.1 Configure COI Generation Rules

View, create, and deactivate COI generation rules.

Context

With the *Configure COI Generation Rules* app, you can configure rules to specify the following parameters of the COI ID:

- The character limit of the COI ID.
- The pattern of the COI ID:
  - **Sequential**: To configure a sequential pattern, you must provide the starting and ending sequence number. When the ID is generated, the number is incremented by one from the starting sequence number.
  - **Random**: To configure a random pattern, you must specify the number and type of characters to be used in the ID. For example, if you select 11 positions as the character limit, you must also define the character or position type for each position. The supported position types are *Fixed*, *Numeric* and *Alphanumeric*. You can also specify the characters that should not be used in the COI ID in the *Exclusion Criteria* section.

    > ⓘ Note
    >
    > Numeric and alphanumeric values are non editable.

Procedure

1. In the *Configure COI Generation Rules* app, choose *Create*.
2. Enter a unique COI ID rule.

   You can enter up to 10 characters.

3. Select an ID limit character.

   You can select a predefined character from the drop-down.
4. Select a COI ID Pattern.

   You can select a predefined COI ID pattern from the drop-down.

1. If you choose random COI ID pattern, then:
   1. Select the position type. In the *ID Character Position Mapping*, you can select for each character a character type from the drop-down. If the character is fixed, you can enter the value.
   2. [Optional] Create exclusion criteria. You can enter the values that you want to exclude in the COI ID.
2. If you choose sequential COI ID pattern, then:
   1. Enter a starting sequential number
   2. Enter a ending sequential number
5. Choose the default rule.

   Indicates that the COI ID generation rule created is the default rule.

Results

The created COI ID generation rule can be used to generate the COI ID.

8.2 Configure COC Event Profiles

Learn how to configure field control for the *Monitor Chain of Custody (COC)* app.

Procedure

1. Go to the *Configure COC Event Profiles* app.
2. Click *Create*.
3. Provide a *Profile ID*.
4. Click *Continue*.
5. Provide a *Description*.
6. Under the *Events* section, there is a list of attributes listed. Against each attribute, check the box to enable visibility of that attribute for the user. The following table contains a list of possible attributes that can be configured for field control or visibility in COC profiles.

Event	Business Object	Attributes
Order Creation – COC	TreatmentOrder	• Treatment Order Number • Treatment Reference Order • Treatment Center • Externally Changed On • Externally Changed By • Treatment Therapy • Treatment Protocol ID
Biospecimen Ready for Collection	Shipment	• Shipment ID • Reference Shipment ID • Externally Changed On • Externally Changed By • Shipment Pickup Location ID • Collection Center
Biospecimen Handover to Courier	Shipment	• Reference Shipment ID • Shipment ID • Externally Changed By • Shipment Courier ID • Actual Shipment Pickup Date • Externally Changed On
Biospecimen Material Subunit Receipt Verification	MaterialSubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Shipment Processing Site (Subunit) • Shipment Subunit Received • Externally Changed On • Actual COI Confirmation Date of Shipment (Subunit)
Biospecimen Material Batch Receipt Verification	ShipmentMaterial	• Material Batch Number • Shipment Material Received • Externally Changed On • Shipment Processing Site (Batch) • Externally Changed By • Actual COI Confirmation Date of Shipment (Batch)
Intermediate Product Shipment Handover to Courier	Shipment	• Shipment ID • Externally Changed By • Externally Changed On • Shipment Courier ID • Actual Shipment Pickup Date

Event	Business Object	Attributes
Intermediate Product Material Batch Receipt at Processing Plant	ShipmentMaterial	• Shipment Material Received • Material Batch Number • Actual COI Confirmation Date of Shipment (Batch) • Externally Changed By • Shipment Processing Site (Batch) • Externally Changed On
Intermediate Product Material Subunit Receipt at Processing Plant	MaterialSubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Actual COI Confirmation Date of Shipment (Subunit) • Shipment Subunit Received • Shipment Processing Site (Subunit) • Externally Changed On
Finished Product Transit Leg Shipment Handover to Courier	Shipment	• Shipment ID • Externally Changed On • Actual Shipment Pickup Date • Shipment Courier ID • Externally Changed By
Finished Product Transit Leg Material Batch Receipt at Designated Location	ShipmentMaterial	• Material Batch Number • Shipment Material Received • Externally Changed On • Actual COI Confirmation Date of Shipment (Batch) • Externally Changed By • Shipment Processing Site (Batch)
Finished Product Transit Leg Material Subunit Receipt at Designated Location	MaterialSubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Actual COI Confirmation Date of Shipment (Subunit) • Externally Changed By • Shipment Subunit Received • Shipment Processing Site (Subunit)

Event	Business Object	Attributes
Finished Product Handover to Courier	Shipment	• Shipment ID • Reference Shipment ID • Shipment Courier ID • Externally Changed By • Externally Changed On • Actual Shipment Pickup Date • Shipment Pickup Location ID
Finished Product Receipt – COC	Shipment	• Shipment Receipt Approved At • Shipment Treatment Center ID • Externally Changed By • Externally Changed On

7. Click *Save*.

Related Information

Configure Profile Groups [page 70]

8.3 Configure COI Event Profiles

Learn how to configure field control for the *Monitor Chain of Identity (COI)* app.

Procedure

1. Go to the *Configure COI Event Profiles* app.
2. Click *Create*.
3. Provide a *Profile ID*.
4. Click *Continue*.
5. Provide a *Description*.
6. Under the *Events* section, there is a list of attributes listed. Against each attribute, check the box to enable visibility of that attribute for the user. The following table contains a list of possible attributes that can be configured for field control or visibility in COI profiles.
   Attributes for Treatment Order Profile

Event	Business Object	Attributes
COI Creation	COI ID	• COI Patient Therapy Number • COI Therapy • Externally Requested On • Is COI ID External • Externally Requested By
Order Creation – COI	Treatment Order	• Patient Information • Treatment Order Number • Treatment Reference Order • Externally Changed By • Clinical Trial Subject ID • Treatment Protocol ID • Treatment Center • Treatment Therapy • Treatment Patient ID • Treatment Overall Status • Externally Changed On

Attributes for Biospecimen Shipment Profile

Event	Business Object	Attributes
Biospecimen Shipment	Shipment	• Shipment Courier Details • Shipment ID • Reference Shipment ID • Externally Changed On • Collection Center • Externally Changed By • Shipment Status • Shipment Courier ID
Biospecimen Collection	Shipment Collection	• Shipment Collection ID • Shipment Reference Collection ID • Shipment Collection Qualifier Value • Externally Changed By • Shipment Collection Qualifier ID • Externally Changed On
Biospecimen Collection Material Batch	Shipment Material	• Shipment Material ID • Material Batch Number • Shipment Material Item ID • Shipment Material Group • Externally Changed On • Externally Changed By • Shipment Material Type

Event	Business Object	Attributes
Biospecimen Material Usage Decision	Release Decision Material	• Material ID • Batch Number • Usage Decision Code • Usage Decision Text • Decision Set By • Decision Set On
Biospecimen Material Batch Receipt	Shipment Material	• Material Batch Number • Shipment Material Received • Shipment Material ID • Shipment Material Item ID • Externally Changed On • Externally Changed By
Biospecimen Material Batch Disposition	Shipment Material	• Shipment Material Item ID • Shipment Material ID • Material Batch Number • Batch Status • Externally Changed By • Externally Changed On
Biospecimen Material Batch Consumption	Shipment Material	• Material Batch Number • Shipment Material Item ID • Consumption Status • Shipment Material ID • Externally Changed On • Externally Changed By
Biospecimen Collection Material Subunit	Material SubUnit	• Shipment Subunit ID • Shipment Reference Subunit ID • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number • Externally Changed By
Biospecimen Material Subunit Receipt	Material SubUnit	• Shipment Subunit ID • Shipment Reference Subunit ID • Shipment Subunit Received • Externally Changed By • Externally Changed On
Biospecimen Material Subunit Disposition	Material SubUnit	• Disposition Status • Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By

Event	Business Object	Attributes
Biospecimen Material Subunit Consumption	Material SubUnit	• Shipment Subunit ID • Consumption Status • Shipment Reference Subunit ID • Externally Changed By • Externally Changed On

Attributes for Processing/Manufacturing Profile

Event	Business Object	Attributes
Creation of Processing Activity	Processing Activity Details	• Processing Activity ID • Processing Activity Status
Start of Processing	Processing Activity Details	• Processing Activity ID • Actual Start Date of Process Order • Externally Changed By • Processing Plant • Process Order ID • Externally Changed On
Start of Processing – Biospecimen or Intermediate Product Material Batch	Processing Activity Material Item	• Process Order Material ID • Process Order Batch Number • Processing Activity Material Item • Externally Changed By • Externally Changed On
Start of Processing – Biospecimen or Intermediate Product Material Subunit	Processing Activity Material SubUnit	• Process Order Reference Subunit ID • Process Order Subunit ID • Processing Activity Material Subunit • Externally Changed On • Externally Changed By
Production End	Processing Activity Details	• Processing Activity ID • Actual End Date of Process Order • Externally Changed By • Process Order ID • Processing Terminated Prematurely • Processing Plant • Externally Changed On

Event	Business Object	Attributes
Production End – Finished Product or Intermediate Product Material Batch	Processing Activity Material Item	• Batch Genealogy Information • Process Order Batch Number • Process Order Material ID • Externally Changed By • Process Order Expiration Date • Process Order Material Group • Process Order Material Type • Externally Changed On • Processing Date
Yield Product Usage Decision	Release Decision Material	• Material ID • Batch Number • Decision Set By • Usage Decision Code • Usage Decision Text • Decision Set On
Production End – Finished Product or Intermediate Product Material Subunit	Processing Activity Material SubUnit	• Process Order Subunit ID • Process Order Reference Subunit ID • Process Order Subunit Produced • Externally Changed By • Externally Changed On
Finished Product or Intermediate Product Material Batch Disposition	Processing Activity Material Item	• Batch Status • Process Order Material ID • Process Order Batch Number • Externally Changed By • Externally Changed On
Finished Product or Intermediate Product Material Subunit Disposition	Processing Activity Material SubUnit	• Process Order Subunit ID • Disposition Status • Process Order Reference Subunit ID • Externally Changed On • Externally Changed By

Attributes for Intermediate Product Shipment Profile

Event	Business Object	Details Recorded
Intermediate Product Shipment	Shipment	• Shipment Courier Details • Shipment ID • Shipment Courier ID • Externally Changed By • Externally Changed On • Collection Center • Shipment Status

Event	Business Object	Details Recorded
Intermediate Product Shipment – Material Batch Allocation	Shipment Material	• Material Batch Number • Shipment Material ID • Shipment Material Item ID • Shipment Material Type • Externally Changed By • Shipment Material Group • Externally Changed On
Intermediate Product Shipment – Material Subunit Allocation	Material SubUnit	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed By • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number
Intermediate Product Shipment – Post Goods Issue – Material Batch	Shipment Material	• Material Batch Number • Shipment Material ID • Externally Changed By • Externally Changed On • Shipment Material Group • Shipment Material Type
Intermediate Product Shipment – Post Goods Issue – Material Subunit	Material SubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By
Intermediate Product Shipment – Material Batch Receipt	Shipment Material	• Shipment Material ID • Shipment Material Received • Material Batch Number • Shipment Material Item ID • Externally Changed On • Externally Changed By
Intermediate Product Shipment – Material Subunit Receipt	Material SubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Shipment Subunit Received • Externally Changed By • Externally Changed On
Intermediate Product Shipment – Material Batch Disposition	Shipment Material	• Shipment Material Item ID • Material Batch Number • Batch Status • Shipment Material ID • Externally Changed By • Externally Changed On

Event	Business Object	Details Recorded
Intermediate Product Usage Decision	Release Decision Material	• Material ID • Batch Number • Usage Decision Code • Decision Set By • Usage Decision Text • Decision Set On
Intermediate Product Shipment – Material Subunit Disposition	Material SubUni	• Shipment Subunit ID • Disposition Status • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By
Intermediate Product Shipment – Material Batch Consumption	Shipment Material	• Material Batch Number • Shipment Material ID • Consumption Status • Shipment Material Item ID • Externally Changed By • Externally Changed On
Intermediate Product Shipment – Material Subunit Consumption	Material SubUnit	• Consumption Status • Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By

Attributes for Finished Product Profile

Event	Business Object	Details Recorded
Finished Product Transit Leg Shipment	Shipment	• Shipment Courier Details • Shipment ID • Externally Changed On • Externally Changed By • Shipment Status • Shipment Courier ID • Collection Center
Finished Product Transit Leg Shipment – Material Batch Allocation	Shipment Material	• Shipment Material ID • Shipment Material Item ID • Material Batch Number • Shipment Material Type • Externally Changed On • Shipment Material Group • Externally Changed By

Event	Business Object	Details Recorded
Finished Product Transit Leg Shipment – Material Subunit Allocation	Material SubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number
Finished Product Transit Leg Shipment – Post Goods Issue – Material Batch	Shipment Material	• Shipment Material ID • Material Batch Number • Externally Changed On • Shipment Material Type • Shipment Material Group • Externally Changed By
Finished Product Transit Leg Shipment – Post Goods Issue – Material Subunit	Material SubUnit	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By
Finished Product Transit Leg Shipment – Material Batch Receipt	Shipment Material	• Shipment Material Item ID • Material Batch Number • Shipment Material Received • Shipment Material ID • Externally Changed By • Externally Changed On
Finished Product Transit Leg Shipment – Material Subunit Receipt	Material SubUnit	• Shipment Subunit ID • Shipment Subunit Received • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By
Finished Product Transit Leg Shipment – Material Batch Disposition	Shipment Material	• Shipment Material Item ID • Batch Status • Material Batch Number • Shipment Material ID • Externally Changed On • Externally Changed By
Finished Product Usage Decision	Release Decision Material	• Batch Number • Material ID • Decision Set By • Decision Set On • Usage Decision Text • Usage Decision Code

Event	Business Object	Details Recorded
Finished Product Transit Leg Shipment – Material Subunit Disposition	Material SubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Disposition Status • Externally Changed On • Externally Changed By
Finished Product Shipment	Shipment	• Shipment Courier Details • Actual Shipment Pickup Date • Shipment ID • Reference Shipment ID • Shipment Status • Externally Changed On • Shipment Courier ID • Externally Changed By
Finished Product Final Leg Shipment Batch Allocation	Shipment Material	• Material Batch Number • Shipment Material ID • Shipment Material Type • Externally Changed By • Shipment Material Group • Externally Changed On
Finished Product Final Leg Shipment Subunit Allocation	Material SubUnit	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Shipment Subunit Qualifier • Externally Changed By
Finished Product Final Leg Shipment Post Goods Issued – Batch	Shipment Material	• Shipment Material ID • Material Batch Number • Externally Changed By • Externally Changed On • Shipment Material Type • Shipment Material Group
Finished Product Final Leg Shipment Post Goods Issued – Subunit	Material SubUnit	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By
Finished Product Delivery	Shipment	• Delivery Approved By • Delivery Verified By • Delivery Approved At • Delivery Verified At

Event	Business Object	Details Recorded
Finished Product Receipt – COI	Shipment	• Shipment Receipt Approved At • Shipment Receipt Verified By • Shipment Receipt Verified At • Shipment Receipt Approved By • Shipment Treatment Center ID • Finished Product Review Status

7. Click *Save*.

Related Information

Configure Profile Groups [page 70]

8.4 Monitor Chain of Identity (COI)

Chain of Identity (COI) is the permanent, unequivocal, and transparent association of a donor's unique identifiers to their tissue or cells (raw material), and the resulting drug product, for the entire process from order through manufacturing to treatment and post treatment monitoring.

With the *Monitor Chain of Identity (COI)* app, you can monitor the events generated for a COI ID, from its creation to the receipt of the finished product with which the COI ID is associated. To view the events generated for a COI ID, select a COI ID from the dropdown and choose *Go*. You can then access the information from both a graphical and tabular view.

In the *Graphical View*, the events are displayed under the following groupings: *Treatment Order*, *Biospecimen Shipment*, *Processing/Manufacturing*, or *Finished Product*. You can expand the groups to view the events generated for a business object.

For more configuration information, see the Administration Guide under Manage Chain of Identity Events.

The tables below list the events generated along with their details. The information on when the events are generated and displayed in the *Monitor Chain of Identity (COI)* app is also given in the tables.

> **Note**
>
> The event details displayed in this application are based on the COI event profile configuration. For more information on configuring COI event profiles, see Configure COI Event Profiles [page 187].

Treatment Order

Event	Business Object	Group	When is the event triggered?	Details Recorded
COI Creation	COI ID	Treatment Order	• When a COI ID is created in SAP Cell and Gene Therapy Orchestration. • When the COI Patient Therapy Number and/or COI Therapy are updated while creating a treatment order.	• COI Patient Therapy Number • COI Therapy • Externally Requested On • Is COI ID External • Externally Requested By
Order Creation – COI	Treatment Order	Treatment Order	• When the treatment order is created via an inbound event or via the *Manage Orders* app. • When the Treatment Reference Order, Clinical Trial Subject ID, Treatment Protocol ID, Treatment Center, Treatment Therapy, Treatment Patient ID, and/or Treatment Overall Status are updated.	• Patient Information • Treatment Order Number • Treatment Reference Order • Externally Changed By • Clinical Trial Subject ID • Treatment Protocol ID • Treatment Center • Treatment Therapy • Treatment Patient ID • Treatment Overall Status • Externally Changed On

Biospecimen Shipment

Event	Business Object	Group	When is the event triggered?	Details Recorded
Biospecimen Shipment	Shipment	Biospecimen Shipment	• When a biospecimen shipment is created via an inbound event or via the *Manage Orders* app. • When the Shipment Courier Details, Reference Shipment ID, Collection Center, Shipment Status,and/or Shipment Courier ID are updated.	• Shipment Courier Details • Shipment ID • Reference Shipment ID • Externally Changed On • Collection Center • Externally Changed By • Shipment Status • Shipment Courier ID
Biospecimen Collection	Shipment Collection	Biospecimen Shipment	• When a collection is created for a biospecimen shipment via an inbound event. • When the Shipment Reference Collection ID, Shipment Collection Qualifier Value, and/or Shipment Collection Qualifier ID are updated.	• Shipment Collection ID • Shipment Reference Collection ID • Shipment Collection Qualifier Value • Externally Changed By • Shipment Collection Qualifier ID • Externally Changed On
Biospecimen Collection Material Batch	Shipment Material	Biospecimen Shipment	• When the collection details are created for a material in the biospecimen shipment via an inbound event. • When the Shipment Material ID, Material Batch Number, Shipment Material Group, and/or Shipment Material Type are updated.	• Shipment Material ID • Material Batch Number • Shipment Material Item ID • Shipment Material Group • Externally Changed On • Externally Changed By • Shipment Material Type

Event	Business Object	Group	When is the event triggered?	Details Recorded
Biospecimen Material Usage Decision	Release Decision Material	Biospecimen Shipment	When the usage decision is created in the *Manage Shipments - Biospecimen* app via an inbound event.	• Material ID • Batch Number • Usage Decision Code • Usage Decision Text • Decision Set By • Decision Set On
Biospecimen Material Batch Receipt	Shipment Material	Biospecimen Shipment	When the material in a biospecimen shipment is marked as received for a non-serialized material in the *Confirm Biospecimen Receipt* app or the *Manage Shipments - Biospecimen* app or via an inbound event.	• Material Batch Number • Shipment Material Received • Shipment Material ID • Shipment Material Item ID • Externally Changed On • Externally Changed By
Biospecimen Material Batch Disposition	Shipment Material	Biospecimen Shipment	When the batch status of a biospecimen shipment material is changed for a non-serialized material via the *Manage Shipments - Biospecimen* app or the *Manage Biospecimen Disposition* app or via an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Shipment Material Item ID • Shipment Material ID • Material Batch Number • Batch Status • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Biospecimen Material Batch Consumption	Shipment Material	Biospecimen Shipment	When the consumption status of shipment material is changed via the *Manage Processing Activities* app or the *Report Processing Start* app or via an inbound event. **Note** This event is not triggered for the status change from blank to Not Consumed.	• Material Batch Number • Shipment Material Item ID • Consumption Status • Shipment Material ID • Externally Changed On • Externally Changed By
Biospecimen Collection Material Subunit	Material SubUnit	Biospecimen Shipment	• When a subunit is created for a material in the biospecimen shipment via an inbound event. • When the Shipment Reference Subunit ID, Shipment Reference Subunit ID, and/or Subunit Batch Number are updated.	• Shipment Subunit ID • Shipment Reference Subunit ID • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number • Externally Changed By
Biospecimen Material Subunit Receipt	Material SubUnit	Biospecimen Shipment	When the subunit in the biospecimen shipment is marked as received for a serialized material in the *Confirm Biospecimen Receipt* app or the *Manage Shipment - Biospecimen* app or via an inbound event.	• Shipment Subunit ID • Shipment Reference Subunit ID • Shipment Subunit Received • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Biospecimen Material Subunit Disposition	Material SubUnit	Biospecimen Shipment	When the disposition status of the subunit is changed for a serialized material via the *Manage Shipments - Biospecimen* app or the *Manage Biospecimen Disposition* app or an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Disposition Status • Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By
Biospecimen Material Subunit Consumption	Material SubUnit	Biospecimen Shipment	When the consumption status of shipment material subunit is changed via the *Manage Processing Activities* app or the *Report Processing Start* app or via an inbound event. **Note** This event is not triggered for the status change from blank to Not Consumed.	• Shipment Subunit ID • Consumption Status • Shipment Reference Subunit ID • Externally Changed By • Externally Changed On

Processing/Manufacturing

Event	Business Object	Group	When is the event triggered?	Details Recorded
Creation of Processing Activity	Processing Activity Details	Processing/Manufacturing	• When a processing activity is created after the flow version confirmation. • When a processing activity is manually created via the *Manage Orders* app after the flow version confirmation.	• Processing Activity ID • Processing Activity Status
Start of Processing	Processing Activity Details	Processing/Manufacturing	When the start date of the processing activity is confirmed in the *Report Processing Start* app or the *Manage Processing Activities* app or via an inbound event.	• Processing Activity ID • Actual Start Date of Process Order • Externally Changed By • Processing Plant • Process Order ID • Externally Changed On
Start of Processing – Biospecimen or Intermediate Product Material Batch	Processing Activity Material Item	Processing/Manufacturing	When the material batch from the biospecimen or intermediate product shipment is specified as consumed or partially consumed in the *Report Processing Start* app or in the *Manage Processing Activities* app or via an inbound event.	• Process Order Material ID • Process Order Batch Number • Processing Activity Material Item • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Start of Processing – Biospecimen or Intermediate Product Material Subunit	Processing Activity Material SubUnit	Processing/Manufacturing	When the material subunit from the biospecimen or intermediate product shipment is specified as consumed for a serialized material in the *Report Processing Start* app or in the *Manage Processing Activities* app or via an inbound event.	• Process Order Reference Subunit ID • Process Order Subunit ID • Processing Activity Material Subunit • Externally Changed On • Externally Changed By
Production End	Processing Activity Details	Processing/Manufacturing	When the actual processing end date is updated in the *Report Processing Completion and Yield* app or the *Manage Processing Activities* app or via an inbound event.	• Processing Activity ID • Actual End Date of Process Order • Externally Changed By • Process Order ID • Processing Terminated Prematurely • Processing Plant • Externally Changed On
Production End – Finished Product or Intermediate Product Material Batch	Processing Activity Material Item	Processing/Manufacturing	When the yield material is marked as produced in the *Report Processing Completion and Yield* app or the *Manage Processing Activities* app or via an inbound event.	• Batch Genealogy Information • Process Order Batch Number • Process Order Material ID • Externally Changed By • Process Order Expiration Date • Process Order Material Group • Process Order Material Type • Externally Changed On • Processing Date

Event	Business Object	Group	When is the event triggered?	Details Recorded
Yield Product Usage Decision	Release Decision Material	Processing/Manufacturing	When the usage decision is created in the *Manage Processing Activities* app via an inbound event.	• Material ID • Batch Number • Decision Set By • Usage Decision Code • Usage Decision Text • Decision Set On
Production End – Finished Product or Intermediate Product Material Subunit	Processing Activity Material SubUnit	Processing/Manufacturing	When the yield material subunit is marked as produced in the *Report Processing Completion and Yield* app or the *Manage Processing Activities* app or via an inbound event.	• Process Order Subunit ID • Process Order Reference Subunit ID • Process Order Subunit Produced • Externally Changed By • Externally Changed On
Finished Product or Intermediate Product Material Batch Disposition	Processing Activity Material Item	Processing/Manufacturing	When the batch status of the yield material is updated for a non-serialized material via the *Manage Processing Activities* app or the *Manage Product Disposition* app or an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection	• Batch Status • Process Order Material ID • Process Order Batch Number • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product or Intermediate Product Material Subunit Disposition	Processing Activity Material SubUnit	Processing/Manufacturing	When the disposition status of the yield material subunit is changed for a serialized material via the *Manage Processing Activities* app or the *Manage Product Disposition* app or an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection	• Process Order Subunit ID • Disposition Status • Process Order Reference Subunit ID • Externally Changed On • Externally Changed By

Intermediate Product Shipment

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment	Shipment	Intermediate Product Shipment	When the intermediate product shipment is created after the flow version confirmation.	• Shipment Courier Details • Shipment ID • Shipment Courier ID • Externally Changed By • Externally Changed On • Collection Center • Shipment Status

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Material Batch Allocation	Shipment Material	Intermediate Product Shipment	• When the yield batch is allocated to the intermediate product shipment via the *Manage Shipments - Intermediate Product* app or the *Allocate Batches to Intermediate Product Shipments* app or via an inbound event. • When the yield batch is deallocated from the intermediate product shipment via the *Manage Shipments - Intermediate Product* app or the *Allocate Batches to Intermediate Product Shipments* app or via an inbound event.	• Material Batch Number • Shipment Material ID • Shipment Material Item ID • Shipment Material Type • Externally Changed By • Shipment Material Group • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Material Subunit Allocation	Material SubUnit	Intermediate Product Shipment	• When the yield batch subunit is allocated to intermediate product shipment via the *Manage Shipments - Intermediate Product* app or the *Allocate Batches to Intermediate Product Shipments* app or via an inbound event. • When the yield batch subunit is deallocated from the intermediate product shipment via the *Manage Shipments - Intermediate Product* app or the *Allocate Batches to Intermediate Product Shipments* app or via an inbound event.	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed By • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Post Goods Issue – Material Batch	Shipment Material	Intermediate Product Shipment	• When the goods issue is posted for the material batch for a non-serialized material via the *Manage Shipments - Intermediate Product* app or *Confirm Intermediate Product Pickup* app or an inbound event. • When the goods issue is reversed for the material batch for a non-serialized material via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Pickup* app or an inbound event.	• Material Batch Number • Shipment Material ID • Externally Changed By • Externally Changed On • Shipment Material Group • Shipment Material Type

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Post Goods Issue – Material Subunit	Material SubUnit	Intermediate Product Shipment	• When the goods issue is posted for the material subunit for a serialized material via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Pickup* app or an inbound event. • When the goods issue is reversed for the material subinit for a serialized material via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Pickup* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Material Batch Receipt	Shipment Material	Intermediate Product Shipment	• When the good receipt is posted for the material batch via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event. • When the good receipt is reversed for the material batch via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event.	• Shipment Material ID • Shipment Material Received • Material Batch Number • Shipment Material Item ID • Externally Changed On • Externally Changed By
Intermediate Product Shipment – Material Subunit Receipt	Material SubUnit	Intermediate Product Shipment	• When the good receipt is posted for the material subunit via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event. • When the good receipt is reversed for the material subunit via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Shipment Subunit Received • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Material Batch Disposition	Shipment Material	Intermediate Product Shipment	When the batch status of intermediate product shipment material is changed for a non-serialized material via the *Manage Shipment - Intermediate Product* app or the *Manage Intermediate Product Disposition* app or an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Shipment Material Item ID • Material Batch Number • Batch Status • Shipment Material ID • Externally Changed By • Externally Changed On
Intermediate Product Usage Decision	Release Decision Material	Intermediate Product Shipment	When the usage decision is created in the *Manage Shipments - Intermediate Product* app via an inbound event.	• Material ID • Batch Number • Usage Decision Code • Decision Set By • Usage Decision Text • Decision Set On
Intermediate Product Shipment – Material Subunit Disposition	Material SubUnit	Intermediate Product Shipment	When the disposition status of intermediate product material subunit is changed for a serialized material via the *Manage Shipment - Intermediate Product* app or the *Manage Intermediate Product Disposition* app or via an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Shipment Subunit ID • Disposition Status • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Intermediate Product Shipment – Material Batch Consumption	Shipment Material	Intermediate Product Shipment	When the consumption status of intermediate product shipment material is changed via the *Manage Processing Activities* app or the *Report Processing Start* app or via an inbound event. **Note** This event is not triggered for the status change from blank to Not Consumed.	• Material Batch Number • Shipment Material ID • Consumption Status • Shipment Material Item ID • Externally Changed By • Externally Changed On
Intermediate Product Shipment – Material Subunit Consumption	Material SubUnit	Intermediate Product Shipment	When the consumption status of intermediate product material subunit is changed via the *Manage Processing Activities* app or the *Report Processing Start* app or via an inbound event. **Note** This event is not triggered for the status change from blank to Not Consumed.	• Consumption Status • Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By

Finished Product

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment	Shipment	Finished Product	When the finished product transit leg shipment is created after the flow version confirmation.	• Shipment Courier Details • Shipment ID • Externally Changed On • Externally Changed By • Shipment Status • Shipment Courier ID • Collection Center
Finished Product Transit Leg Shipment – Material Batch Allocation	Shipment Material	Finished Product	When the yield batch is allocated to the finished product transit leg shipment via the *Manage Shipments - Finished Product* app or an inbound event. When the yield batch is deallocated from the finished product transit leg shipment via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Material ID • Shipment Material Item ID • Material Batch Number • Shipment Material Type • Externally Changed On • Shipment Material Group • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment – Material Subunit Allocation	Material SubUnit	Finished Product	When the yield batch subunit is allocated to the finished product transit leg shipment via the *Manage Shipments - Finished Product* app or an inbound event. When the yield batch subunit is deallocated from the finished product transit leg shipment via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Shipment Subunit Qualifier • Externally Changed On • Subunit Batch Number
Finished Product Transit Leg Shipment – Post Goods Issue – Material Batch	Shipment Material	Finished Product	When the goods issue is posted for the finished product transit leg shipment material batch for a non-serialized material via the *Manage Shipments - Finished Product* app or an inbound event. When the goods issue is reversed for the finished product transit leg shipment material batch for a non-serialized material via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Material ID • Material Batch Number • Externally Changed On • Shipment Material Type • Shipment Material Group • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment – Post Goods Issue – Material Subunit	Material SubUnit	Finished Product	When the goods issue is posted for the finished product transit leg shipment material subunit for a serialized material via the *Manage Shipments - Finished Product* app or an inbound event. When the goods issue is reversed for the finished product transit leg shipment material subunit for a serialized material via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By
Finished Product Transit Leg Shipment – Material Batch Receipt	Shipment Material	Finished Product	When the good receipt is posted for the finished product transit leg shipment material batch via the *Manage Shipments - Finished Product* app or an inbound event. When the good receipt is reversed for the finished product transit leg shipment material batch via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Material Item ID • Material Batch Number • Shipment Material Received • Shipment Material ID • Externally Changed By • Externally Changed On

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment – Material Subunit Receipt	Material SubUnit	Finished Product	When the good receipt is posted for the finished product transit leg shipment material subunit via the *Manage Shipments - Finished Product* app or an inbound event. When the good receipt is reversed for the finished product transit leg shipment material subunit via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Subunit ID • Shipment Subunit Received • Shipment Reference Subunit ID • Externally Changed On • Externally Changed By
Finished Product Transit Leg Shipment – Material Batch Disposition	Shipment Material	Finished Product	When the batch status of finished product transit leg shipment material is changed for a non-serialized material via an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Shipment Material Item ID • Batch Status • Material Batch Number • Shipment Material ID • Externally Changed On • Externally Changed By
Finished Product Usage Decision	Release Decision Material	Finished Product	When the usage decision is created in the *Manage Shipments - Finished Product* app via an inbound event.	• Batch Number • Material ID • Decision Set By • Decision Set On • Usage Decision Text • Usage Decision Code

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment – Material Subunit Disposition	Material SubUnit	Finished Product	When the disposition status of finished product transit leg shipment material subunit is changed for a serialized material via an inbound event. **Note** This event is not triggered for the initial status change from blank to Quality Inspection.	• Shipment Reference Subunit ID • Shipment Subunit ID • Disposition Status • Externally Changed On • Externally Changed By
Finished Product Shipment	Shipment	Finished Product	• When the finished product shipment is created. • When the Shipment Courier Details, Actual Shipment Pickup Date, Reference Shipment ID, and/or Shipment Status attributes are updated.	• Shipment Courier Details • Actual Shipment Pickup Date • Shipment ID • Reference Shipment ID • Shipment Status • Externally Changed On • Shipment Courier ID • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Final Leg Shipment Batch Allocation	Shipment Material	Finished Product	When the yield batch is allocated to the finished product final leg shipment via the *Manage Shipments - Finished Product* app, or the *Allocate Batches to Finished Product Shipment* app or an inbound event. When the yield batch is deallocated from the finished product final leg shipment via the *Manage Shipments - Finished Product* app or the *Allocate Batches to Finished Product Shipment* app or an inbound event.	• Material Batch Number • Shipment Material ID • Shipment Material Type • Externally Changed By • Shipment Material Group • Externally Changed On
Finished Product Final Leg Shipment Subunit Allocation	Material SubUnit	Finished Product	When the yield batch subunit is allocated to the finished product final leg shipment via the *Manage Shipments - Finished Product* app or the *Allocate Batches to Finished Product Shipment* app or an inbound event. When the yield batch subunit is deallocated from the finished product final leg shipment via the *Manage Shipments - Finished Product* app or the *Allocate Batches to Finished Product Shipment* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Shipment Subunit Qualifier • Externally Changed By

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Final Leg Shipment Post Goods Issued – Batch	Shipment Material	Finished Product	When the goods issue is posted for the finished product final leg shipment material batch for a non-serialized material via the *Manage Shipments - Finished Product* app or the *Confirm Finished Product Pickup* app or an inbound event. When the goods issue is reversed for the finished product final leg shipment material batch for a non-serialized material via the *Manage Shipments - Finished Product* app or the *Confirm Finished Product Pickup* app or an inbound event.	• Shipment Material ID • Material Batch Number • Externally Changed By • Externally Changed On • Shipment Material Type • Shipment Material Group

Event	Business Object	Group	When is the event triggered?	Details Recorded
Finished Product Final Leg Shipment Post Goods Issued – Subunit	Material SubUnit	Finished Product	When the goods issue is posted for the finished product final leg shipment material subunit for a serialized material via the *Manage Shipments - Finished Product* app or the *Confirm Finished Product Pickup* app or an inbound event. When the goods issue is reversed for the finished product final leg shipment material subunit for a serialized material via the *Manage Shipments - Finished Product* app or the *Confirm Finished Product Pickup* app or an inbound event.	• Shipment Subunit ID • Shipment Reference Subunit ID • Externally Changed On • Shipment Actual Pickup Date • Externally Changed By
Finished Product Delivery	Shipment	Finished Product	When the Delivery Approved By, Delivery Verified By, Delivery Approved At, and/or Delivery Verified At attributes are updated via an inbound event or the *Manage Shipments - Finished Product* app.	• Delivery Approved By • Delivery Verified By • Delivery Approved At • Delivery Verified At
Finished Product Receipt – COI	Shipment	Finished Product	When the Shipment Receipt Approved At, Shipment Receipt Verified By, Shipment Receipt Verified At, Shipment Receipt Approved By, and/or Finished Product Review Status attributes are updated via an inbound event or the *Manage Shipments - Finished Product* app.	• Shipment Receipt Approved At • Shipment Receipt Verified By • Shipment Receipt Verified At • Shipment Receipt Approved By • Shipment Treatment Center ID • Finished Product Review Status

8.5 Monitor Chain of Custody (COC)

Monitor the chain of custody of a material in the treatment order.

Chain of Custody (COC) is the permanent capture of data related to who handled the collection or product or both, what actions were performed, the location, date, and time of the actions from the start of tissue or cell collection through product administration.

With the *Monitor Chain of Custody (COC)* app, you can track the Chain of Custody (COC) of a material for a specific Chain of Identity (COI) ID. When the custody of a material changes, an event is generated and displayed in the graphical or tabular view in the app. In the graphical view, you can see an interactive diagram of the change of custody of a material from treatment order creation to the finished product receipt.

The tables below list the events generated along with the details recorded with each change of custody. It also lists when the event is generated and displayed in the *Monitor Chain of Custody (COC)* app.

> **Note**
>
> The event details displayed in this application are based on the COC event profile configuration. For more information on configuring COC event profiles, see Configure COC Event Profiles [page 184].

Event	Business Object	When is the event triggered?	Details Recorded
Order Creation – COC	TreatmentOrder	When the treatment order is created. When the Treatment Reference Order, Treatment Protocol ID, Treatment Center, and/or Treatment Therapy are updated.	• Treatment Order Number • Treatment Reference Order • Treatment Center • Externally Changed On • Externally Changed By • Treatment Therapy • Treatment Protocol ID
Biospecimen Ready for Collection	Shipment	• When a biospecimen shipment is created in the *Manage Shipments - Biospecimen* app via an inbound event. • When a biospecimen shipment is created manually via the *Manage Orders* app. • When the Reference Shipment ID, Shipment Pickup Location ID, and/or Collection Center are updated.	• Shipment ID • Reference Shipment ID • Externally Changed On • Externally Changed By • Shipment Pickup Location ID • Collection Center

Event	Business Object	When is the event triggered?	Details Recorded
Biospecimen Handover to Courier	Shipment	• When the Actual Shipment Pickup Date is updated via an inboud event or the *Manage Shipment - Biospecimen* app. • When the Reference Shipment ID and/or Shipment Courier ID are updated in the *Manage Shipment - Biospecimen* app or via an inbound event.	• Reference Shipment ID • Shipment ID • Externally Changed By • Shipment Courier ID • Actual Shipment Pickup Date • Externally Changed On
Biospecimen Material Subunit Receipt Verification	MaterialSubUnit	When the subunit in the biospecimen shipment is marked as received for a serialized material in the *Confirm Biospecimen Receipt* app or the *Manage Shipment - Biospecimen* app or via an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Shipment Processing Site (Subunit) • Shipment Subunit Received • Externally Changed On • Actual COI Confirmation Date of Shipment (Subunit)
Biospecimen Material Batch Receipt Verification	ShipmentMaterial	When the material in a biospecimen shipment is marked as received for a non-serialized material in the *Confirm Biospecimen Receipt* app or the *Manage Shipments - Biospecimen* app or via an inbound event.	• Material Batch Number • Shipment Material Received • Externally Changed On • Shipment Processing Site (Batch) • Externally Changed By • Actual COI Confirmation Date of Shipment (Batch)

Event	Business Object	When is the event triggered?	Details Recorded
Intermediate Product Shipment Handover to Courier	Shipment	• When the Actual Shipment Pickup Date is updated via an inboud event or the *Manage Shipment - Intermediate Product* app or the *Confirm Intermediate Product Pickup* app. • When the Shipment Courier ID is updated in *Manage Shipment - Intermediate Product* app or via an inbound event.	• Shipment ID • Externally Changed By • Externally Changed On • Shipment Courier ID • Actual Shipment Pickup Date
Intermediate Product Material Batch Receipt at Processing Plant	ShipmentMaterial	When the good receipt is posted for the material batch via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event. When the good receipt is reversed for the material batch via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event.	• Shipment Material Received • Material Batch Number • Actual COI Confirmation Date of Shipment (Batch) • Externally Changed By • Shipment Processing Site (Batch) • Externally Changed On
Intermediate Product Material Subunit Receipt at Processing Plant	MaterialSubUnit	When the good receipt is posted for the material subunit via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event. When the good receipt is reversed for the material subunit via the *Manage Shipments - Intermediate Product* app or the *Confirm Intermediate Product Receipt* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed By • Actual COI Confirmation Date of Shipment (Subunit) • Shipment Subunit Received • Shipment Processing Site (Subunit) • Externally Changed On

Event	Business Object	When is the event triggered?	Details Recorded
Finished Product Transit Leg Shipment Handover to Courier	Shipment	When the Actual Shipment Pickup Date is updated via an inboud event or the *Manage Shipment - Finished Product* app. When the Shipment Courier ID is updated in *Manage Shipment - Finished Product* app or via an inbound event.	• Shipment ID • Externally Changed On • Actual Shipment Pickup Date • Shipment Courier ID • Externally Changed By
Finished Product Transit Leg Material Batch Receipt at Designated Location	ShipmentMaterial	When the good receipt is posted for the material batch via the *Manage Shipments - Finished Product* app or an inbound event. When the good receipt is reversed for the material batch via the *Manage Shipments - Finished Product* app or an inbound event.	• Material Batch Number • Shipment Material Received • Externally Changed On • Actual COI Confirmation Date of Shipment (Batch) • Externally Changed By • Shipment Processing Site (Batch)
Finished Product Transit Leg Material Subunit Receipt at Designated Location	MaterialSubUnit	When the good receipt is posted for the material subunit via the *Manage Shipments - Finished Product* app or an inbound event. When the good receipt is reversed for the material subunit via the *Manage Shipments - Finished Product* app or an inbound event.	• Shipment Reference Subunit ID • Shipment Subunit ID • Externally Changed On • Actual COI Confirmation Date of Shipment (Subunit) • Externally Changed By • Shipment Subunit Received • Shipment Processing Site (Subunit)
Finished Product Handover to Courier	Shipment	When the Actual Shipment Pickup Date is updated via the *Manage Shipments - Finished Product* app, the *Confirm Finished Product Pickup* app or an inbound event.	• Shipment ID • Reference Shipment ID • Shipment Courier ID • Externally Changed By • Externally Changed On • Actual Shipment Pickup Date • Shipment Pickup Location ID

Event	Business Object	When is the event triggered?	Details Recorded
Finished Product Receipt – COC	Shipment	When the Shipment Receipt Approved At attribute is updated via an inbound event or the *Manage Shipments - Finished Product* app.	• Shipment Receipt Approved At • Shipment Treatment Center ID • Externally Changed By • Externally Changed On

8.6 Configure COI Certificate Templates

View, create, edit, activate, and deactivate COI Certificate Templates.

Context

Generating a COI certificate requires a configurable template that is customized or your requirements. The *Configure COI Certificate Templates* app allows you to create and maintain templates for COI certificates.

Procedure

1. In the *Configure COI Certificate Templates* app, choose *Create*.
2. Enter a unique ID for the template and choose *Continue*.

   You can enter up to 40 characters.
3. Enter a description.

   You can enter up to 250 characters.
4. Use *Title Line 1* and *Title Line 2* to enter the certificate title text.

   You can enter up to 50 characters with spaces.
5. Choose *Upload* to add a logo from your PC or local storage that you want to be printed on the certificate.

   The image you select must be in .png format and it cannot exceed 1MB.
6. On the *Details* tab, select the sections you want to print on the COI certificate.

   The available options are:
   - Patient Information
   - Biospecimen Information
   - Product Information
7. Choose *Create*.

Results

The COI certificate template is created and available for use in generating a COI certificate.

Related Information

Configure Profile Groups [page 70]

8.7 Configure External Attributes

View, configure, edit, activate, and deactivate external event attributes.

Context

With this app, you can configure and manage external event attributes. You can also view the CGTO attributes available in the system.

To view the CGTO attributes, go to the *CGTO Attributes* tab and then choose *Go* in the filters section. You can view and configure the external event attributes from the *External Attributes* tab.

You can use the CGTO attributes and the external attributes configured in this application to configure external events. For more information, see Configure External Events [page 227].

Procedure

1. In the *Configure External Attributes* application, choose *Create*.
2. Enter a unique ID for the attribute.
3. Enter the attribute name and description.
4. Choose *Create*.
    - The status of an attribute is automatically set to *Active* when you create an attribute.
    - You can use the *Edit* option to update the attribute name and description.

8.8 Configure External Events

View, configure, edit, activate, and deactivate external events.

Context

With this app, you can register external Chain of Identity (COI) and Chain of Custody (COC) events and manage the attributes associated with these external events. The system validates the registered external events based on this configuration. This ensures that all the required attributes are present and processed correctly.

This feature enables efficient processing of COI / COC events received from external systems and supports the generation of traceability reports to comply with regulatory requirements.

> **Note**
>
> You must register external COI / COC events in this application if you want to include their details in the COI / COC traceability report.

> **Note**
>
> You can use the *Configure Event Attributes* application to configure external event attributes. For more information, see Configure Event Attributes [page 226].

Procedure

1. In the *Configure External Events* application, choose *Create*.
2. Enter a unique ID for the event in the *Event Type* field.
3. Enter the event name and description.
4. Select the business object for which the event is configured. Possible values are:
   - COI ID
   - Material SubUnit
   - Processing Activity Details
   - Processing Activity Material Item
   - Processing Activity Material SubUnit
   - Release Decision Material
   - Shipment
   - Shipment Collection
   - Shipment Material
   - Treatment Order
5. Select the event category. Possible values are:
   - Chain of Identity (COI)

- Chain of Custody (COC)

6. Now, you can add the attributes associated with the event. To add an attribute,
   a. Choose *Create* in the *Attributes* section.
   b. Select the required attribute in the *Attribute* column.

      In the *Select: Attribute* window, you can view the CGTO attributes and the external attributes configured via the *Configure Event Attributes* application.
   c. Then, select the *Is Mandatory* checkbox if the attribute is mandatory for the selected event.

      The status of an attribute is automatically set to *Active* when you add an attribute.
7. Choose *Create*.

   Once the event is configured, you cannot delete the listed attributes. You can either activate or deactivate the listed attributes, as applicable.

   You can use the *Edit* option to add attributes and update the event name, description, and the *Is Mandatory* checkbox for the listed attributes.

9 System Administration

You can use the tiles in the *System Administration* section on the feature landing page to set up and maintain basic settings and functions in the system.

You can do the following:

- View Change Logs [page 229]
- Manage Cloud ALM Registration [page 231]
- Monitor Business Events [page 231]
- Monitor Chain of Identity (COI) [page 196]
- Configure Cloud Services [page 232]

9.1 View Change Logs

Change logs are business logs used to track changes made in the system.

Change logs are provided for each business entity within an application. You can use the *View Change Logs* app to view the logs for all entities. You can also view change logs from within the entity records in the respective apps. For example, you can view the change logs for biospecimen shipments in the *Manage Shipments - Biospecimen* app.

Consider an example where a user changes the consumption status of a shipment material subunit. In this example, the change logs will show the following key information:

Column Name	Description	Example
COI ID	COI ID of the treatment order of the shipment	LUO230097
Root Entity	Name and business ID of the root entity	Shipment (18663)
Entity	Name of the entity changed	Material Subunit
Attribute	Attribute changed	Subunit Consumption Status
Action	Type of change (Update, Create, Delete)	Update
Old Value	Value before the action	Unusable
New Value	New value	Not Consumed
Changed On	Date of change	Jan 8, 2025, 4:07:00 PM
Changed By	ID of the user who made the change	Abc@sap.com

In the above example, the root entity (Shipment) is different from the entity (Material Subunit). There may be instances where there is no difference between the root entity and entity. For example, if you change the *Modified At* date of a shipment, the root entity (Shipment) and the entity are the same (Shipment). The change logs will show the following key information:

Column Name	Description	Example
COI ID	COI ID of the treatment order of the shipment.	LUO230097
Root Entity	Name and business ID of the root entity	Shipment (18663)
Entity	Name of the entity changed	Shipment
Attribute	Attribute changed	Modified At
Action	Type of change (Update, Create, Delete)	Update
Old Value	Value before the action	2024-12-20 10:58:21.686000000
New Value	New value	2024-12-20 11:00:18.974000000
Changed On	Date of change	Jan 8, 2025, 4:07:00 PM
Changed By	ID of the user who made the change	Abc@sap.com

> **Note**
>
> To view the ID of an entity, choose *Settings* and select the *ID* column. This displays the *ID* column. The value in the *ID* column may still display the UUID and not the business ID of the entity. For example, if you change the *Subunit Type* of a subunit, the change log displays the UUID of the subunit, not the business ID in the *ID* column.

There are 7 apps where a combination of existing fields are used to create a business ID to uniquely identify a record. For example, in the *Configure Entity Status Profile* app, the combination of the following fields is used to create a business ID for each record:

- *Status Profile Object*
- *Object Type*
- *Status Type*

For example, **ApproveShipment_Z1_BS** is a business ID created by the concatenation of **Field1_Field2_Field3**. The business ID is assigned a value when saving a record. The value of the business ID is shown for each record in the app. To disable changes to the business ID of these apps, the fields that are used to create a business ID are disabled in each app and a back-end validation is done to restrict an update to these fields.

The business ID is shown in the *Root Entity* column.

The apps where a combination of fields is used to define a business ID are given below:

- Configure Reason Codes
- Configure Entity Status Profiles
- Configure Number Ranges
- Configure Rules
- Map Label Template to Therapy, Country/Region, and Material
- Manage Organization-Location-Therapy Rules
- Destination

> **Note**
>
> Change logs are sorted chronologically and cannot be deleted or changed.

For more information and technical prerequisites see, Change Logs.

9.2 Manage Cloud ALM Registration

Learn how to manage registering the subscriber tenant with SAP Cloud ALM.

SAP Cloud ALM is an application lifecycle management (ALM) tool. External inbound and outbound events can be pushed to SAP Cloud ALM for monitoring.

Manage Cloud ALM Registration app enables you to manage the registration of the subscriber tenant with SAP Cloud ALM. The tenant to be monitored by Integration Monitoring Service must be registered with SAP Cloud ALM for integration monitoring.

Upon registration, the integration monitoring data is pushed to SAP Cloud ALM. The registered tenant is visible in **Integration & Exception Monitoring** application in SAP Cloud ALM.

> ⓘ Note
>
> - Creating destination for SAP Cloud ALM in SAP BTP subscriber subaccount is a prerequisite for registration
> - Only one active entry can be maintained in the system

For more information, see the Administration Guide under Connection to SAP Cloud Application Lifecycle Management (CALM).

9.3 Monitor Business Events

Learn all about the *Monitor Business Events* app.

An event is an action generated or triggered by a system or user when processes are executed in the system. It notifies a consumer that an object has changed.

With the *Monitor Business Events* app, you can view and monitor the business events consumed (inbound) and published (outbound) by SAP Cell and Gene Therapy Orchestration.

As an administrator, you can use this application to monitor and retrigger inbound business events for applicable scenarios. Only the following inbound events can be retriggered:

- Events that ended with the following errors:

Error Code	Description
ES004	Action failed due to technical or functional reasons.
ES005	Backend service is down.

- Events that have been in status *Processing* or *Transformed* for more than 15 minutes. You must check the *Created At* field and retrigger the event as required.

Select an event on the *Business Event* screen to view the event details and status logs. You can also view business logs which capture external synchronous API calls. These logs are generated when you view or upload documents, generate or validate labels, view patient details, and book couriers.

> **Note**
>
> Only the business events generated over the last three months are displayed by default. Use the *Period* filter to view the events generated earlier.

The outbound events triggered by post processing events can be tracked in *Monitor Business Events* app using the PPF event ID. Using this PPF event ID, you can search and relate to the specific outbound event. In the *Manage Biospecimen Shipments*, *Manage Finished Product Shipments*, *Manage Orders*, and *Manage Processing Activity* apps, there is a *PPF* tab which lists all the PPF events.

Procedure

Execute these steps to find the corresponding business event:

1. Launch any of the *Manage Biospecimen Shipments*, *Manage Finished Product Shipments*, *Manage Orders*, and *Manage Processing Activity* apps.
2. Search for any of the orders, activities, or shipments using the search criteria.
3. Click on the specific order, activity, or shipment to view detailed information.
4. Click *PPF Events* tab.
5. Copy the PPF event ID in the column *ID* against the specific entry corresponding to the business event. Using this PPF event ID you can search for the specific correlation ID.
6. Navigate to the *Monitor Business Events* app.
7. Search for the business event using the search criteria.
8. In the *Actions* column, against the specific business event, choose the *Action* dropdown, and then choose *View Request Payload*.
9. In the *Request Payload* dialog, spot the *Correlation ID*. This is how you can map or connect a PPF event to an outbound event.

For more information, see SAP Events Integration Framework Guide in the Administration Guide for SAP Cell and Gene Therapy Orchestration.

9.4 Configure Cloud Services

Learn about built-in support functions that are available with SAP Cell and Gene Therapy Orchestration.

Built-In Support tool is integrated with SAP Cell and Gene Therapy Orchestration to enable support functions like incident creation, expert chat, and access to the knowledge base. To enable the support functionalities available in Built-In Support, the External ID and the Main URL of the subscriber tenant must be configured in this application.

> **Note**
>
> Only one active entry can be maintained in the system.

For information on technical prerequisites required for configuration, see the Administration Guide under Configure Cloud Services.

9.5 Manage Transports

Manage transporting of configuration data.

The *Manage Transports* application is used for managing the transfer of configuration data to destination systems within your landscape. Outgoing transport requests facilitate the movement of configuration data from source tenant to one or more destination tenants. This feature not only allows for the migration of configuration records but also enables updates to previously transported configuration records, ensuring the system remains updated with the latest changes.

The application provides flexibility to use both full transport requests that contain all the configuration data for the transport, and custom transport requests that allow the selective transportation of specific entities or enhancements tailored to meet unique business requirements.

The following functions are available when working with transport requests:

- Create and manage full transpor requests [page 233]
- Create and manage custom transport requests [page 233]
- Create transport templates
- Copy templates and update
- Export configuration data
- Import configuration data

9.5.1 Create Transport Request

You can transport the configuration data by creating outgoing transport requests for the destination systems in your landscape.

- Create full transport request
- Create custom transport request
- Create custom transport request from template

> **Note**
>
> The entities supported in transport requests are:
>
> - Sales Organizations
> - Distribution Channels
> - Divisions
> - Sales Areas
> - Plants
> - Order Types

- Business Partner Roles
- Address Types
- Therapy Categories
- Therapy Types
- Material Types
- Material Groups
- Material Type and Material Group Combinations
- Purchasing Organizations
- Indications
- EAN Categories
- Temperature Condition Codes
- Transportation Group for Materials
- Packaging Product Type for Materials
- Transportation Lane Rules
- Reason Codes
- Change Reasons
- Status Profiles
- User Statuses
- Document Types
- Organization Location Types
- Location Rules
- Post-Processing Events
- Field Control Profiles
- Milestones
- Label Types
- Material – Biospecimen
- Material – Finished Product
- Flow Section Types
- Profile Groups

To create a full transport request

1. Go to the *Manage Transports* app.
2. Choose *Create*.
3. Enter a description in *Transport Description* for easy identification.
4. Select the *Source* as *Full Transport*.
5. Choose *Continue*.
   The status will now indicate as *In Progress*.
6. From the top right corner, select *Create Transport Request*.
7. In the *E-Signature* dialog, enter your password.
8. Choose the appropriate reason in *Reason Code for E-Signature* .
9. Optionally, you can add a comment in *Comments*.
10. Click *Save*
    The status will now be updated to *Created*.

To create a custom transport request

1. Go to the *Manage Transports* app.
2. Choose *Create*.
3. Enter a descriptive *Transport Description* for easy identification.
4. Select the *Source* as *Custom Transport*.
5. Choose *Continue*.
   The status will now indicate *In Progress*.
6. In the *Items* section, click *Select Records*.
7. Choose the entity or entities and record(s) to add them to the transport and click *Select*.
8. Click *Reset* to clear the selected records.
9. From the top right corner, select *Create Transport Request*.
10. In the *E-Signature* dialog, enter your password.
11. Choose the appropriate reason in *Reason Code for E-Signature* .
12. Optionally, you can add a comment in *Comments*.
13. Click *Save*
    The status will now be updated to *Created*.

To create a custom transport request from template

1. Go to the *Manage Transports* app.
2. Choose *Create*.
3. Enter a description in *Transport Description* for easy identification.
4. Select the *Source* as *Use Template*.
5. From the *Select Template* dropdown, choose the template from which you want to create a new transport request.

   > **Note**
   >
   > Only templates with *Active* status will be available in the list.

6. Choose *Continue*.
   The status will now indicate as *In Progress*.
7. In the *Items* section, click *Select Records*.
8. Choose the entity or entities and record(s) available in the selected template to them to the transport, and click *Select*.
9. Click *Reset* to clear the selected records.
10. Click *Save* to selected records.
11. From the top right corner, select *Create Transport Request* to create a custom transport request using the chosen template and selected entities and records.
12. In the *E-Signature* dialog, enter your password.
13. Choose the appropriate reason in *Reason Code for E-Signature* .
14. Optionally, you can add a comment in *Comments*.
15. Click *Save*
    The status will now be updated to *Created*.

> **Note**
>
> Transport requests for full transports and custom transports are created in *SAP Cloud Transport Management*. To import the transport requests into your destination tenant, you must follow the procedure described in Import Transport Requests.

9.5.2 Create Transport Templates

This feature allows you to create, duplicate, and utilize custom transport templates. It provides flexibility and efficiency for configuring tailored configuration entities and associated records.

Context

You can define a transport template with selected configuration entities and related records for a specific therapy or country. The templates can be further reused to streamline the process of creating transport requests for similar therapies or countries, optimizing time and efficiency.

Procedure

1. Go to the *Manage Transports* app.
2. Click *Create*.
3. Enter the template ID, template description, and select multiple configuration entities with multiple records.
4. Click *Reset* to clear the selected records.
5. Click *Save* to save the template, after providing an e-Signature.

   If the template ID already exists, you will receive an error message. The template will be in *Inactive* status once it is saved.
6. Click *Activate* to activate the template. Once in *Active* status, you can deactivate the template.
7. If you choose to *Activate* or *Deactivate*, add the *Activation/Deactivation Reason*.

   > **Note**
   >
   > The template cannot be used directly to create the transport request.
8. Click *Copy* to duplicate the template.

   Provide a new name for the duplicated template. You can provide a new template name.

   > **Note**
   >
   > - The duplicated template will include the selected configuration entities and records from the original template.

- You can create a copy of an active and inactive template.

Next Steps: The created transport template can be used to create transport request [page 233].

9.5.3 Export Configuration Data

Learn how to export configuration data in SAP Cell and Gene Therapy Orchestration.

With the *Manage Transports* app, you can export your configuration data from your SAP Cell and Gene Therapy Orchestration instance to one or more tenants. You can create an outgoing transport request which allows you to export all the data from the configuration apps.

> **Note**
>
> Configuration entities created with the following apps are not transported:
>
> - *Configure Number Ranges*
> - *Configure COI Generation Rules*
> - *Configure Cloud Services*
> - *Configure Rules*
> - *Configure Destinations*
> - *Configure Entity Status Profiles*
> - All *Master Data* apps

> **Note**
>
> Sub entity data created with the following apps is not transported. This data must be created manually in the target system once a transport has been imported.
>
> - Reason codes in the *Configure Change Reasons* app
> - Reason codes in the *Configure Reason Codes* app
> - Events in the *Configure Post Processing Events* app
> - Shipment profiles, document profiles, and processing activity profiles in the *Configure Profile Groups* app
> - Attributes in the *Configure Field Control Profiles* app

To export configuration data using the *Manage Transports* app.

1. In the *Outgoing Transports* tab, choose *Create*.
2. Provide a description stating the purpose of the outgoing request and choose *Next*.
3. Provide the *E-Signature* details, and then choose *Save*.

Result: The outgoing transport request is created and can be viewed in the *Outgoing Transports* tab.

9.5.4 Import Configuration Data

Learn how to import configuration data to another tenant.

The data exported can be imported to a new tenant. It is also referred here as the destination tenant. To import the configuration data to the destination tenant, go to the *Transport Nodes* tab of your Cloud Management Dashboard and select the target transport node.

> ⓘ Note
>
> For more information on how to import configuration data, see the documentation for SAP Cloud Transport Management under Import Transport Requests.

After the data is successfully imported, you can log in to the SAP Cell and Gene Therapy Orchestration instance (destination tenant) where the configuration data was imported. In the *Incoming Transports* tab of the *Manage Transports* app, you can confirm or verify the details of the imported transport request such as the source node and transport description.

Re-importing Configuration Data

In case the imported configuration data undergoes some change in the destination tenant, then it needs to be restored to the previous version of the exported data. In order to accomplish this, the transport request must be reset and marked as repeatable. This enables the transport request to be imported again.

> ⓘ Note
>
> The retention period for the transport request is 30 days.

Follow these steps:

1. Follow the steps in the documentation for SAP Cloud Transport Management under Reset Transport Requests.
2. Navigate to the *Import Queue*.
3. Ensure the same transport request is selected.
4. To import the configuration data again, follow the steps in the documentation for SAP Cloud Transport Management under Import Transport Requests.

Result: The transport request along with the configuration data is imported into the new tenant.

> ⓘ Note
>
> In case the transport request creates a new record in the destination tenant, then the old record is not deleted. Both of them are retained. If needed, you can manually mark this record as inactive by clicking the *Deactivate* button in SAP Cell and Gene Therapy Orchestration application.

There is certain configuration data which is not transported through the transport request. This data is from the non-transportable configuration entities. For example, Number Range. In order to edit this non-transportable entities in the destination tenant, assign new authorization role `CGT_NonTransportable_ConfigAdmin_Write_Srv` to the user.

> **Note**
>
> It is recommended to assign `CGT_ConfigAdmin_Read_Srv` and `CGT_NonTransportable_ConfigAdmin_Write_Srv` authorization roles to users in the production system. With these roles, the user can modify only the non-transportable configuration entities and not the other entities.

> **Note**
>
> For more information on storage capacity for files uploaded to SAP Cloud Transport Management service, see Background Information: Storage Capacity.

9.5.5 View Transport Logs

The transport change logs display the history of all changes related to the tenant. For example, a change log is created when a configuration entity is successfully imported into the target tenant. The entity records on target tenant are either created or updated due to changes in configuration entities from the source tenant..

Each transport log captures and displays the following information:

- User and time when the change was completed
- New and old values of the changed attributes including description of the change
- The type of change, whether the entity has been created or modified
- The reason for the change including reason code, reason text and type, for each updated field in the entity

10 Glossary

The following table lists terms that are essential for working with SAP Cell and Gene Therapy Orchestration:

Term	Definition
Biospecimen	A sample of material, such as blood or tissue from a human patient that is used for manufacturing the finished product.
Biospecimen Disposition	A process to approve received biospecimen material as fit for use in manufacturing.
Biospecimen Hangtag Label	A label used for identifying and managing biospecimen shipments. The label includes details such as the Chain of Identity (COI) ID, material number, batch number, subunit ID, document status, and version.
Business Partner Roles	Business partner roles describe the role a business partner could take. Examples are vendor or customer.
Chain of Custody ID	The permanent capture of data related to who handled the collection or product or both, actions taken, and the location/date/time of the actions from the start of tissue/cell collection through product administration.
Chain of Identity (COI) ID	The permanent, unequivocal, and transparent association of a patient's unique identifiers to their biospecimen tissue or cells (raw material), and the resulting drug product, for the entire process from the treatment order through drug manufacturing to treatment and post-treatment monitoring.
Clinical Randomization	A process of assigning patients to groups that receive different treatments.
COI Certificate	A chain of identity (COI) certificate contains information of the patient, biospecimen, and product.
Collection ID	A unique identifier for the biospecimen collected from a patient.
Consumption Status	Consumption status indicates the extent to which a biospecimen material or shipment batch has been processed. Only batches with a disposition status of "Unrestricted Use" or "Released With Restrictions Use" can be processed. Depending on the quantity of the material or batch processed, the consumption status for it changes to "Partially Consumed" or "Consumed".

Term	Definition
Contract Development and Manufacturing Organization (CDMO)	A company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing.
Contract Manufacturer Organization (CMO)	A supply chain partner that manufactures products in the name of a market authorization holder or brand owner. A CMO does not own and sell the products in the market, but only produces them.
Copy Control Profile	A profile configured to copy complete or partial treatment order, shipment, and processing activity data during order cloning.
Courier	A third-party logistics provider that serves to transport material from one location to another.
Courier Account Number	Sponsor's customer number at the courier. This will be the account number against which the sponsor will be billed.
Distribution Channel	A channel through which saleable materials or services reach customers. Distribution channels include wholesale, retail, and direct sales. You can assign a distribution channel to one or more sales organizations.
Document Type	Type of document, for example, a confidential PHI (protected health information) or PII (personally identifiable information) document.
EAN	A standard to encode product numbers and is made of either 8 or 13 digits (EAN-8 and EAN-13). These barcodes are product identification numbers used worldwide for marking products sold at retail points of sale. EAN is required for the export of shipment materials and is used to identify articles at the point of sales using a barcode. You can configure different types of EANs such as in-store or perishable EANs.
Field Control Profile	A profile configured to control the display of fields and field groups displayed in a treatment order record. You use field control profiles to control the display of information related to the treatment order, which includes information on shipments, patient, labels, and processing activities.
Finished Product	A therapeutic product synthesized from a patient's or donor's biospecimen, which is ready to be used for treating the patient.
Finished Product Final Leg Shipment	Last leg of a finished product shipment from the final transit location to its delivery location.
Finished Product Transit Leg Shipment	Intermediate leg of a finished product shipment to a transit location.
Finished Product Disposition	A quality check done to approve finished product material as fit for shipment.

Term	Definition
Flow Definition	Flow definition defines the logistical supply chain steps from collecting biospecimen to delivery of the final product.
Finished Product Label	A label that provides information about a packaged finished product. See *Finished Product Shortened Label*, *Secodary Packing Label*.
Secondary Packaging Label	A label for the packaging of a finished product. See *Finished Product Label*.
Finished Product Shortened Label	A label with a summarized version of information on the finished product label. See *Finished Product Label*.
Flow Node	A step in the supply chain. It could be the pickup or delivery of shipment, the actual shipment, or the processing plant node.
Flow Section Type	Defines the details of a specific flow step throughout the supply chain.
Flow Version	Flow version describes how treatment orders will be processed through the supply chain defining the different steps.
Good X Practice	A collection of quality guidelines and regulations (such as GMP and GLP) created to ensure that bio/pharmaceutical products are safe, meet their intended use, and adhere to quality processes during manufacturing, control, storage, and distribution.
Indication	A sign, condition, or circumstance that makes a particular course of treatment or procedure advisable.
Intermediate Product Shipment	Shipment of a semi-finished product from one processing plant to another processing plant.
Inventory Status	Refers to the current state of a batch in terms of its availability for shipment. Only batches with an inventory status of "Available to Ship" can be allocated for shipment. On allocation for shipment, the status changes to "Allocated for Shipment" and when the batch is shipped and out for delivery, the status is changed to "Shipped". Users can configure the statuses.
Location Rule	A rule to determine the location type for an organization.
Location Type	Categorization and grouping of locations based on business or technical purposes.
Material Group	A group of materials with common attributes.
Material Type	A group of materials with the same basic attributes such as raw materials, semifinished products, or finished products.

Term	Definition
Organization Location Type	An organization location type identifies the function an organization could play in different situations, for example, it could be a pickup location or a drop-off location.
Post-Processing Events	Events generated by the post-processing framework in a given business context, for example, *Update_Shipment_Logistics* is an outbound event, which is triggered whenever the biospecimen shipment logistics information (courier details) is added or updated.
Processing Activity	An activity to process biospecimen material or semi-finished product.
Processing Node	A specific step within a process flow where processing activities are carried out.
Process Order	A manufacturing order used in process manufacturing.
Profile Group	A group of control profiles (field control profiles or copy control profiles).
Protected Health Information	Information that includes all individually identifiable health details including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or to provide healthcare services or healthcare coverage.
Purchasing Organization	An organizational unit in logistics that structures the company according to its purchasing requirements. A purchasing organization is responsible for purchasing materials and services.
Reason Code	Code associated with a reason. Users must select a reason to save certain changes made in the system.
Reference Order	Unique and anonymized patient therapy number received from the treatment center.
Rules	Rules used to initiate workflows or trigger business rules whenever an entity is changed.
Sales Area	An organizational unit in logistics that structures the companyaccording to its sales requirements.A sales organization is responsible for selling materials and services.
Sales Organization	An organizational unit in logistics that structures the company according to its sales requirements.A sales organization is responsible for selling materials and services.
Status Profile	A series of user statuses logically grouped together in a single profile. Used to mark and track transition changes.
Subunit	A constituent of material, it can be a certain quantity of biospecimen or finished product.

Term	Definition
Therapy Category	A group of therapy types.
Therapy Type	A categorization and grouping of medical treatments for impairment, injury, disease, or disorder.
Transportation Group	An ID that groups the important attributes related to the transportationof a product. Every product is assigned to a transportation group.
Transportation Lane	A relationship between two locations, two transportation zones or a combination of locations and zones that expresses the direct reachability of the locations, or of all locations within the zones for a specific means of transport.
Exception	An exception occurs when there is a disruption in the normal process flow due to technical or business reasons.
Yield	The resultant output of a processing activity.

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