User Guide | PUBLIC
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User Guide for SAP Batch Release Hub for Life Sciences

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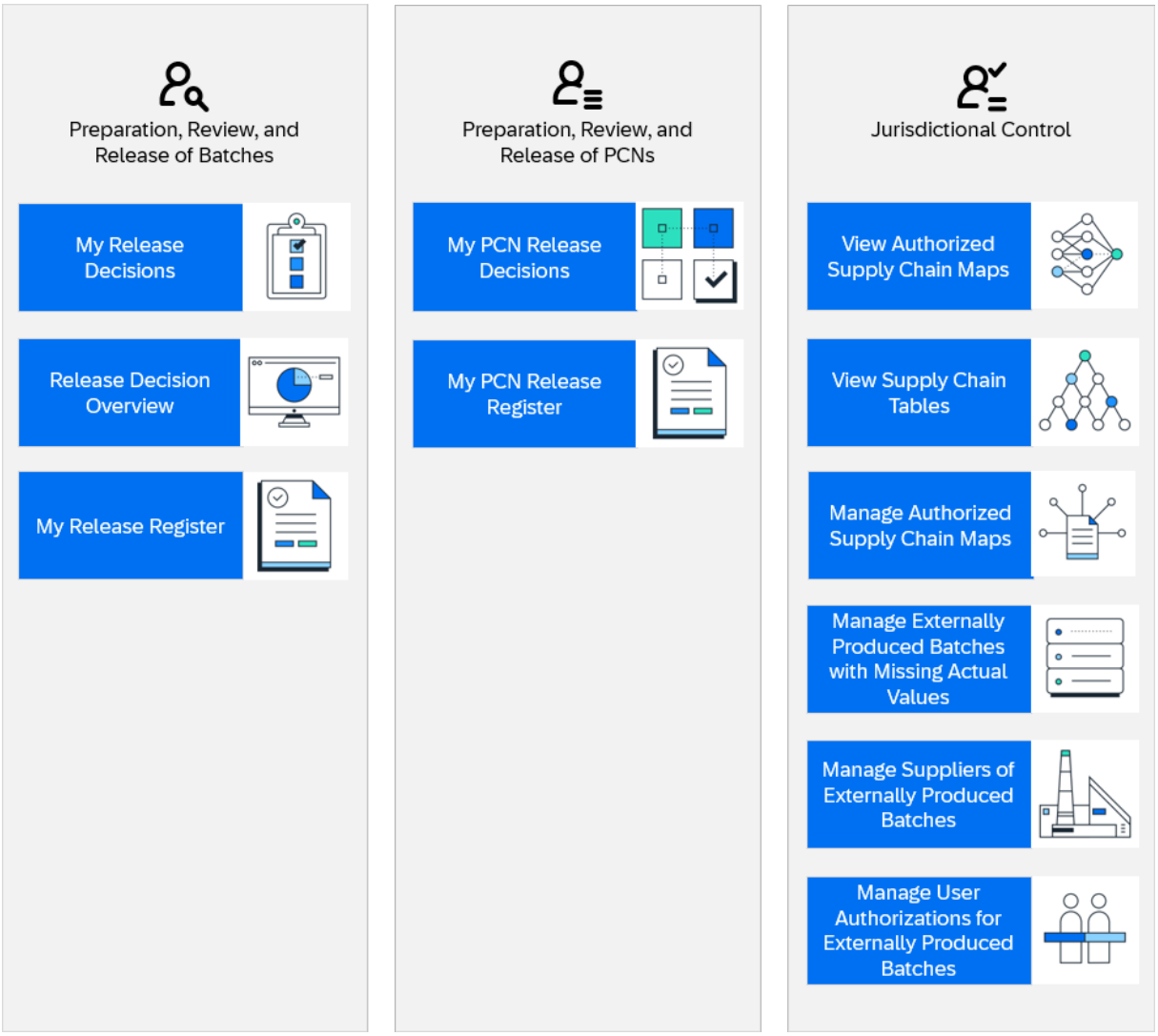
1 About This User Guide

This guide helps you with your daily tasks of preparing, reviewing, and making release decisions.

The image below summarizes the apps described in this guide.



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- [page 43]
- [page 44]
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- [page 42]
- Use this app to create and manage the authorized supply chain maps used for jurisdictional control. [page 43]
- Use this app to export a register of completed and confirmed PCN release decisions. [page 40]

The table below summarizes the purpose of each app:

App	Description
My Release Decisions	You use this app to prepare, review, and make release decisions for batches.
Release Decision Overview	You use this app to get an overview of your batch release decision workload and identify any urgent items.
My Release Register	You use this app to create a summary report of the release decisions made in one or more locations.
My PCN Release Decisions	You use this app to prepare, review, and make release decisions for packaging control numbers (PCN) used in clinical trials.
My PCN Release Register	You use this app to create a summary report of the PCN release decisions made in one or more locations.
View Authorized Supply Chain Maps	You use this app to view the authorized supply chain maps for your target materials in each relevant country or region.
View Supply Chain Tables	You use this app to view the supply chain tables for your target materials in each relevant country or region.
Manage Authorized Supply Chain Maps	You can use this app to create and manage the authorized supply chain maps used for jurisdictional control.
Manage Externally Produced Batches with Missing Actual Values	You use this app to manage externally produced batches and enter the actual values for their restriction drivers.
Manage Suppliers of Externally Produced Batches	You use this app to manage suppliers for batches that are produced externally by contract manufacturing organizations (CMOs).
Manage User Authorizations for Externally Produced Batches	You use this app to manage user authorizations for the *Manage Externally Produced Batches with Missing Actual Values* app.

> **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 the shellbar in the app.

Related Information

Working with In-App Help [page 55]

1.1 Document History

See what changes have been made to this document since it was first released.

> **Note**
>
> The latest version of this document is available on SAP Help Portal at https://help.sap.com/brh.

Date	Change
June 18, 2026	The following new topic has been added: • Output Management: Splitting of Large Reports (PDF Chunking) [page 105]: Explains how large release decision reports are split into separate PDFs

Date	Change
May 29, 2026	Updated version for release 2605 of SAP Batch Release Hub for Life Sciences. The following topics have been updated: • Reprocessing Release Decision Items [page 92]: Updated to explain the new options *Keep* and *Reset* • Working with Attachments [page 83]: Added a note about accessing additional information for attachments • Using SAP's Generative AI Copilot, Joule [page 194]: Added information about the white paper *Reap the Benefits of AI in GxP Environments with Joule* The following new topics have been added: • My PCN Release Register [page 40]: A new app • Reviewing Quality Deviations [page 74]: Information about reviewing quality deviations • Example: Automatic Deactivation of Outdated Deviations [page 75]: An example to illustrate how deactivation of deviations works • Example: Reprocessing Items with Manually Set Release Check Statuses [page 94]: An example to illustrate the new options *Keep* and *Reset* • Creating PCN Release Register Reports [page 136]: Information about how to use the new *My PCN Release Register* app
January 27, 2026	The following new section has been added: • Using SAP's Generative AI Copilot, Joule [page 194]: New section that describes the Joule capabilities in SAP Batch Release Hub for Life Sciences
January 19, 2026	The following topic has been updated: • Editing the Suitability of Countries/Regions in Release Decision Items [page 77]: Updated the information about the *Regulatory Suitability* field to reflect the new possible values introduced in Regular Change 2511.2.0

Date	Change
November 28, 2025	Updated version for release 2511 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • Manage Authorized Supply Chain Maps [page 43]: A new app • View Authorized Supply Chain Map Signature Log [page 54]: A new app • Documentation of the Supply Chain [page 138]: New section that includes information about using the new *Manage Authorized Supply Chain Maps* app The following topics have been updated: • Business Rule [page 19]: Updated to reflect that business rules remain active for release decision items configured for automated batch release • Processing Status [page 23]: Updated to include the new processing status *Released Externally* • Apps for SAP Batch Release Hub for Life Sciences [page 33]: Added new apps to the diagram (*Manage Authorized Supply Chain Maps* and *View Authorized Supply Chain Map Signature Log*) • Finding the Software Release Version [page 56]: Updated to reflect that the major release is now shown in the format YYMM • Life Cycle of Batch Release Decision Items [page 59]: Added information about the new processing status *Released Externally* • Setting Batch Release Decisions [page 87]: Added information about release decision certificates • Viewing Authorized Supply Chain Maps [page 159]: Updated to explain that authorized supply chain maps can be created by API or in the *Manage Authorized Supply Chain Maps* app. • Entering Missing Actual Values of Restriction Drivers [page 169]: Updated to reflect that the actual values of CMO batches cannot be edited in the *My Release Decisions* app • Editing the Suitability of Countries/Regions in Release Decision Items [page 77]: Added information about the new *Regulatory Suitability* field • Glossary [page 199]: Added the term "serialization commissioning check"

Date	Change
July 29, 2025	The following new topic has been added: • Finding the Software Release Version [page 56]: Explains how to find the software release version in the tenant you are working in
July 25, 2025	The following topic has been updated: • Evaluations of Multiple Specifications [page 80]: Adjusted to reflect that the *Analytical Suitability* column is always displayed in the *Countries/Regions* and *Customers* sections.
July 16, 2025	The following topic has been updated: • Prerequisites for Working on PCN Release Decisions: Added information about the Batch Where-Used List function

Date	Change
June 27, 2025	Updated version for release 2506 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • View Supply Chain Tables [page 42]: A new app • Evaluations of Multiple Specifications [page 80]: A new feature in the *My Release Decisions* app • Setting Up Additional Batch Characteristics: A new feature in the *My Release Decisions* app • Integration with SAP Extended Warehouse Management: A new feature for managing the batch release quantity on handling unit level • Viewing Supply Chain Tables [page 161]: Information about how to use the new app • Reevaluation of the Jurisdictional Control Check [page 175]: A new feature in the jurisdictional control check The following topics have been updated: • About This User Guide [page 6]: Added the new *View Supply Chain Tables* app • Apps for SAP Batch Release Hub for Life Sciences [page 33]: Added the new *View Supply Chain Tables* app • Working with Attachments [page 83]: Added information about setting attachments as inactive • Completing Custom Release Checks [page 85]: Updated to reflect the user experience enhancements • Reprocessing Release Decision Items [page 92]: Added information about the mandatory comment • Regenerating Release Decision Items [page 97]: Added information about the mandatory comment • SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 189]: Updated to describe the new settings *Enable Comparison* and *Attributes for Comparison* • Generating AI-Based Proposals for SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 192]: Updated to reflect the user experience enhancements • Glossary [page 199]: Added the term "supply chain table"
April 8, 2025	The following new topic has been added: • Final System Checks Before Setting the Release Decision [page 90]

Date	Change
February 20, 2025	The following section has been updated: • Working with Externally Produced Batches [page 177]: Added information about the new *Enable Processing of Externally Produced Batches* setting

Date	Change
November 29, 2024	Updated version for release 2411 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • Manage Externally Produced Batches with Missing Actual Values [page 43]: A new app • Manage Suppliers of Externally Produced Batches [page 44]: A new app • Manage User Authorizations for Externally Produced Batches [page 45]: A new app • Editing the Suitability of Customers in Release Decision Items [page 79]: A new feature in the *My Release Decisions* app • Checking if Items Were Regenerated or Reprocessed [page 99]: Added step-by-step instructions • Assigning PCN Release Decision Items for Processing [page 113]: A new feature in the *My PCN Release Decisions* app • Prioritizing PCN Release Decision Items [page 114]: A new feature in the *My PCN Release Decisions* app • Reprocessing PCN Release Decision Items [page 130]: A new feature in the *My PCN Release Decisions* app • Regenerating PCN Release Decision Items [page 131]: A new feature in the *My PCN Release Decisions* app • Changing the Release Type of PCN Release Decision Items [page 133]: A new feature in the *My PCN Release Decisions* app • Checking if Items Were Regenerated or Reprocessed [page 134]: A new feature in the *My PCN Release Decisions* app • Canceling PCN Release Decision Items [page 135]: A new feature in the *My PCN Release Decisions* app • Entering Missing Actual Values of Restriction Drivers [page 169]: A new feature in the jurisdictional control check in the *My Release Decisions* app • Editing the Status of Manual Restriction Drivers [page 171]: A new feature in the jurisdictional control check in the *My Release Decisions* app • Editing the Suitability of Batches [page 173]: A new feature in the jurisdictional control check in the *My Release Decisions* app • Working with Externally Produced Batches [page 177]: A new section that describes how to use the new *Manage*

Date	Change
	Batches with Missing Actual Values for Restriction Drivers app • AI in SAP Batch Release Hub for Life Sciences [page 188]: A new section that describes the AI-enhanced custom release check The following topics have been updated: • About This User Guide [page 6]: Added the new apps described in this guide • Apps for SAP Batch Release Hub for Life Sciences [page 33]: Added the new apps in this release • Adjusting the Stock Postings for Release Decision Items [page 81]: Added information about fixed stock postings
June 28, 2024	Updated version for release 2406 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • Authorized Supply Chain Map [page 18]: A new important concept • Restriction Driver [page 32]: A new important concept • My PCN Release Decisions [page 39]: A new app • View Authorized Supply Chain Maps [page 41]: A new app • View PCN Signature Log [page 53]: A new app • PCN Release Decisions [page 108]: A new section that describes how to use the *My PCN Release Decisions* app • Jurisdictional Control [page 138]: A new section that describes how to work with the *View Authorized Supply Chain Maps* app
November 30, 2023	Updated version for release 2311 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • My Release Register [page 39] • Creating Release Register Reports [page 106] • Creating Release Decision Reports [page 103] The following topics have been updated: • Apps for SAP Batch Release Hub for Life Sciences [page 33]: Added information about the *My Release Register* app.

Date	Change
June 30, 2023	Updated version release 2306 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • View User Responsibilities [page 49] The following topics have been updated: • About SAP Batch Release Hub for Life Sciences [page 17]: Updated the architecture diagram to show the Industry Solution for Life Sciences add-on (ISLS). • Apps for SAP Batch Release Hub for Life Sciences [page 33]: Added information about the new *View User Responsibilities* app.
December 1, 2022	Updated version for release 2212 of SAP Batch Release Hub for Life Sciences. The following new topics have been added: • Release Decision Overview [page 38] • Transport Configuration Settings [page 50] • Managing Your Batch Release Decisions [page 65] • Batch Release Decision Items for Clinical Trials [page 102] • Viewing the Release Process Flow for a Batch [page 70] • Canceling Release Decision Items [page 100]
June 30, 2022	First release

2 About SAP Batch Release Hub for Life Sciences

SAP Batch Release Hub for Life Sciences is your central point of access to the information necessary for making fast and accurate release decisions in the pharmaceutical industry.

SAP Batch Release Hub for Life Sciences provides you with the information you need to prepare, review, and make compliant release decisions. By centralizing the relevant data from diverse source systems in one place, the solution helps you manage the complexity of the release decision process and detect any deviations early in the process.

Key Benefits

- End-to-end view of the release process
- Increased compliance by reducing manual effort and the potential for human error
- Increased efficiency of tasks related to the preparation and review of release decisions
- Transparency of release check results and any deviations that need to be addressed
- Standardization of the release process across quality departments
- Preconfigured content to help you get started immediately
- Extensive configuration options to adjust the release process to your needs
- Role-based applications that provide an intuitive and personalized user experience

Integration Options

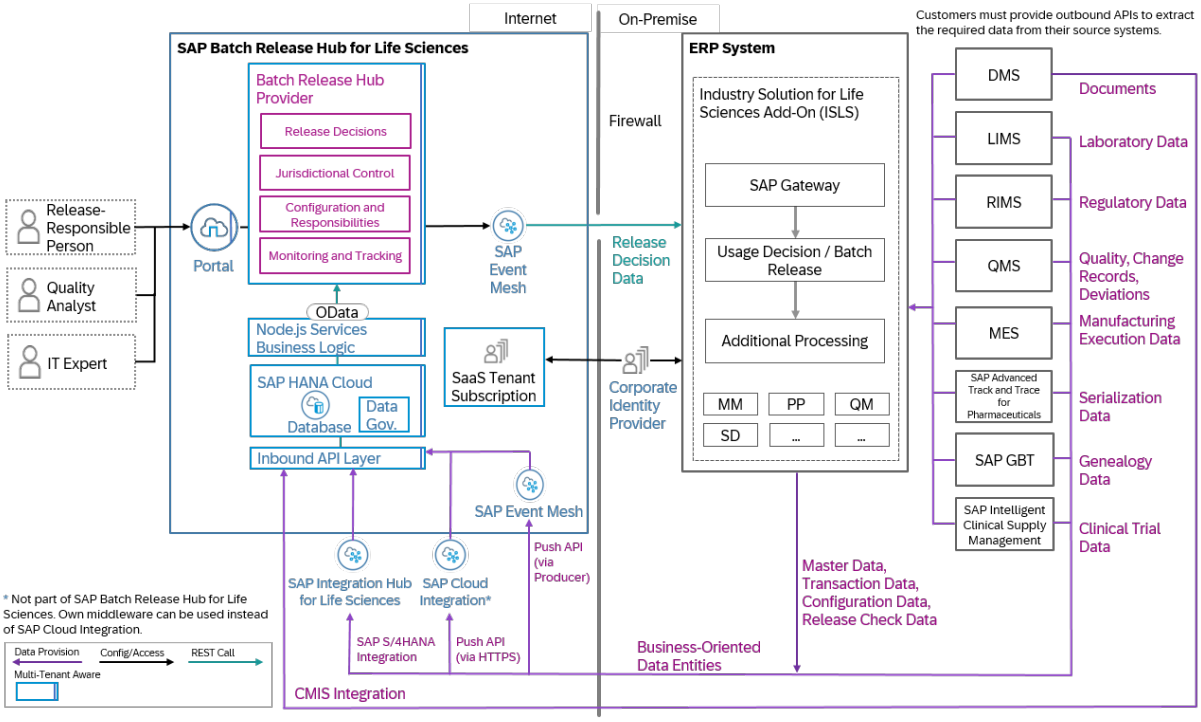
Depending on your business needs, SAP Batch Release Hub for Life Sciences can be integrated with a variety of source systems such as follows:

- SAP S/4HANA
- SAP Advanced Track and Trace for Pharmaceuticals
- Laboratory information management system (LIMS)
- Regulatory information management system (RIMS)
- Quality management system (QMS)
- Manufacturing execution system (MES)
- SAP Global Batch Traceability (SAP GBT)
- SAP Intelligent Clinical Supply Management

> ⓘ Note
>
> Customers need to implement outbound application programming interfaces (APIs) to extract the required data from their source systems.

> → Tip
>
> We recommend that you use OData APIs as your method of communication for inbound data.

The following diagram gives you an overview of the high-level architecture of SAP Batch Release Hub for Life Sciences:



2.1 Important Concepts

Get to know the key concepts used in SAP Batch Release Hub for Life Sciences.

2.1.1 Authorized Supply Chain Map

Authorized supply chain maps are used to document the activities in your supply chain that are relevant for regulatory control.

An authorized supply chain map is defined for a target material, which is the final material in the specification of the supply chain, and for a country or region. Usually, the material is a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company. The map documents the restriction driver attributes that are relevant for jurisdictional control at each processing step. To comply with health authority regulations, the actual values of the restriction driver attributes must match the authorized reference values.

You can view your company's authorized supply chain maps in the *View Authorized Supply Chain Maps* app.

Supply Chain Map Node

An authorized supply chain map consists of nodes that represent a material at a particular processing step. In the tabular view, each row in the table corresponds to a supply chain map node. In the graphical view, each supply chain map node is represented by an icon. The nodes flow from left to right, and there are connectors between the nodes to illustrate the flow of the processing steps.

Each node is used to document the authorized reference values of the restriction driver attributes for a material at a processing step. In the jurisdictional control check, the authorized reference values of the restriction driver attributes are compared to the actual values to evaluate the compliance of a batch.

Related Information

View Authorized Supply Chain Maps [page 41]
Restriction Driver [page 32]

2.1.2 Business Rule

Business rules allow you to automate decision making. If a business rule is assigned to a release check, the data that's received from the source system is evaluated against the business logic encapsulated in the rule to determine the release check status.

Business rules are run at the following times:

- Whenever new data is received from the relevant source systems and the corresponding release decision items have not yet been completed
- Whenever a country/region is added to a release decision item manually, the business rule for the regulatory data check is rerun
- Whenever a release decision is set
  This is a "safety net" that ensures the release check statuses calculated by the business rules are up to date at the point of the release decision. If there is no change to the release check statuses, the release decision is processed and completed. If there is a change to a release check status or if the automated calculation fails due to a deleted business rule project, the release decision process is stopped, and the status of the release decision item is returned to *In Progress*.

Once the business rule run is completed, the corresponding release check status and release check messages are shown in the appropriate app: *My Release Decisions* for batch release decision items or *My PCN Release Decisions* for PCN release decision items.

Business rules are included in rule projects and defined in the *Manage Business Rules* app. SAP delivers a set of preconfigured rules. As a business administrator or configuration expert, you can create your own rules.

> ⚠ Caution
>
> Avoid making changes in the preconfigured content. In case of an update, any changes you've made in the preconfigured content are overwritten along with all existing versions. If you want to change the SAP standard business rules, make a copy of the project. For more information, see Creating Custom Business Rules for Release Checks.

Business Rule Status

If a release decision item has not been worked on or changed for 30 days, the system automatically deactivates its business rules. This is to prioritize the release decision items that are being worked on more frequently and ensure they are processed as quickly and efficiently as possible. You can reactivate the business rules by choosing *Activate Business Rule* on the release decision details page.

> **Note**
>
> The business rules always remain active for release decision items that are configured for automated batch release. This ensures that the release check statuses are always up to date when a batch is released automatically.

The following business rule statuses are possible:

Business Rule Status	What it Means
Active	Each time new data is received for this release decision item, the business rules are run to update the release check statuses based on the latest information.
Inactive	This release decision item has not been worked on or changed for 30 days, and the system has automatically deactivated the business rules. The release check statuses for this release decision item could be out of date. To update the release check statuses based on the latest information, choose *Activate Business Rule* on the release decision details page. **Note** The business rules always remain active for release decision items that are configured for automated batch release.
Completed	The processing of this release decision item has been completed and it is no longer necessary to run the business rules to update the release check statuses. The data for the release decision item is "frozen".

Related Information

Setting Up Business Rules
Preconfigured Business Rules
Manage Business Rules [page 47]

2.1.3 Location

Locations are used to to reflect the organizational structure and responsibilities within a quality department.

You can structure locations flexibly to meet your business needs.

At minimum, a location corresponds to a plant or a customer in your supply chain. If you need additional granularity, you can use organizational areas. Organizational areas enable you to distinguish between activities at the same location, such as production areas, storage locations, or work centers. In a quality department, you can then assign user responsibilities at the level of the defined organizational areas. You can also use location types to provide additional information about the activities in a location, for example, whether it's a distribution center or a warehouse.

You can configure organizational areas and location types in the *Manage Release Configurations* app. You assign locations to quality departments in the *Manage Quality Departments* app.

Related Information

Setting Up Quality Departments

2.1.4 Method of Release Type Determination

The method of release type determination controls how the relevant release types for a batch are determined for the creation of release decision items in the *My Release Decisions* app.

When setting up SAP Batch Release Hub for Life Sciences, you specify the *Determination Method* in the *Manage Release Configurations* app under *Make General Settings* > *Release Type Determination*. You can choose between the following options:

Determination Method	What It Does
Release Process Flow	If you use this option, you can assign a sequence of release types to a combination of location, procurement type, and optionally, an inspection type, material type, material group, or material. You can also specify that the release process flow is used only for reevaluating the jurisdictional control check. A release process flow includes a set of release types in a specific processing sequence. Each step in a release process flow leads to the creation of a worklist item in the *My Release Decisions* app. This means that one release decision item is created in the worklist per release type.

Determination Method	What It Does
Inspection Type	If you use this option, you can assign one release type to a combination of inspection type, location, procurement type, and, optionally, material type, material group, or material. Before you can create an assignment, you must make the relevant inspection types available in the *Manage Release Configurations* app. You can either do this manually or import the inspection types from your source system (for example, SAP S/4HANA).

These determination methods are mutually exclusive. You can use only one of them for release type determination.

> **Note**
>
> The PCN release decision items displayed in the *My PCN Release Decisions* app are not affected by this *Determination Method* setting. The relevant release types for the creation of PCN release decision items are always determined based on PCN release process flows.

Related Information

Release Type [page 31]
Release Decision Item [page 29]
Making General Settings
Configuration of Release Type Determination

2.1.5 Organizational Area

Organizational areas can be used as an additional differentiating factor for defining the locations in a quality department.

Optionally, you can use organizational areas to structure locations in quality departments. Organizational areas enable you to distinguish between activities at the same location, such as production areas, storage locations, or work centers. In a quality department, you can then assign user responsibilities at the level of the defined organizational areas.

Organizational areas are defined in the *Manage Release Configurations* app. Once you have defined your organizational areas, you can add them to locations in the *Manage Quality Departments* app.

Related Information

Setting Up Quality Departments

2.1.6 Processing Status

The processing status is an attribute that indicates the current stage of processing for a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Processing Status in the My Release Decisions App

Here's an overview of the possible values for the processing status of a release decision item in the *My Release Decisions* app:

Processing Status	What It Means
New	Processing of the item has not yet started.
In Progress	Processing of the item has started. For example, the item has been assigned to a responsible person.
Release in Progress	A release decision has been set for the item and the system is performing the following steps in the background: • Creating a snapshot of all the data for the release decision item • Rerunning the business rules for the release checks • Freezing all the data for the release decision item • Sending the release decision details to the source system
Completed	A release decision has been set for the item. The item can no longer be changed. The decision has not yet been confirmed in the source system.
Confirmed	Follow-on processing is completed and the release decision is confirmed in the source system.
Obsolete	The item was manually regenerated, invalidated due to changes in the configuration, or canceled through a release decision trigger. When an item is made obsolete due to manual regeneration or configuration changes, a new item is created with the latest configuration settings. Obsolete items can no longer be changed.
Canceled	The item was manually set to canceled by a responsible person. Only new and in progress items can be set to canceled. Canceled items can no longer be changed.

Processing Status	What It Means
Regeneration in Progress	The item was manually regenerated by a responsible person. The system is in the process of creating a new item with the latest configuration settings. When the regeneration has completed, this item will be set to the processing status *Obsolete*.
Released Externally	The batch was released in the source system, outside of SAP Batch Release Hub for Life Sciences, and has been closed automatically. Only new and in progress items are closed automatically. Items that have been released externally can no longer be changed, but they can be regenerated if necessary.

PCN Processing Status in the My PCN Release Decisions App

Here's an overview of the possible values for the processing status of a PCN release decision item in the *My PCN Release Decisions* app:

PCN Processing Status	What It Means
New	Processing of the item has not yet started.
In Progress	Processing of the item has started. A user has made a manual change. For example, an attachment has been uploaded or a release check status has been changed.
Release in Progress	A PCN release decision has been set for the item and the system is performing the following steps in the background: • Creating a snapshot of all the data for the PCN release decision item • Rerunning the business rules for the release checks • Freezing all the data for the PCN release decision item • Sending the PCN release decision details to the source system
Completed	The PCN release decision has been set and the background processing has completed. The item can no longer be changed. The decision has not yet been confirmed in the source system for the PCN.
Confirmed	Follow-on processing in the source system has been completed and all the assigned batch release decision items have been confirmed. Once all the assigned batch release decision items have been confirmed, the status of the PCN release decision item is set to *Confirmed*.

PCN Processing Status	What It Means
Obsolete	The item was manually regenerated by a responsible person. When an item is regenerated, a new item is created with the latest configuration settings. Obsolete items can no longer be changed.
Canceled	The item was manually set to canceled by a responsible person. Only new and in progress items can be set to canceled. Canceled items can no longer be changed.
Regeneration in Progress	The item was manually regenerated by a responsible person. The system is in the process of creating a new item with the latest configuration settings. When the regeneration has completed, this item will be set to the processing status *Obsolete*.

Related Information

Release Decision [page 27]
Release Decision Item [page 29]

2.1.7 Quality Department

You use quality departments to manage the users, locations, and responsibilities relevant for the processing of release decisions in your organization.

When you set up a quality department in the *Manage Quality Departments* app, you assign users and locations. You can then create user responsibilities for users at specific locations. These settings form the basis for building an individual worklist for each user working with the *My Release Decisions* app and the *My PCN Release Decisions* app.

Note the following about making assignments in a quality department:

- Each user in a quality department has a business role that provides authorization for a specific release activity in the *My Release Decisions* app and the *My PCN Release Decisions* app. For example, a user authorized for release review can display release decision items and details but can't make any changes. A user can have only one business role in a quality department, but the user can have a different business role in another quality department.
- The assigned locations define the plants or customers that are relevant for release decision processing in a quality department. You use locations to reflect the organizational structure of your supply chain. You can use organizational areas to distinguish between activities at the same locations, such as production areas, storage locations, or work centers.

- For a combination of user and location, you create a responsibility to specify the release types, material types, and material groups that the user is in charge of.
  The responsibilities determine which release decision items appear in the user's worklist in the *My Release Decisions* app and the *My PCN Release Decisions* app. The assigned business role determines what a user is authorized to do with the items.

  > **Note**
  >
  > Material types and material groups are not relevant for the *My PCN Release Decisions* app, as each PCN has a number of assigned batches that can have different materials. When defining responsibilities for the *My PCN Release Decisions* app, ensure that the material type and material group are set to *All*.

- Optionally, you can set an expiry date for a user in a quality department. When the expiry date is reached, the user can no longer access release decisions for the quality department in the *My Release Decisions* app and the *My PCN Release Decisions* app. You can use this option to deactivate a user, for example, if a user changes department or leaves the company.

Related Information

Configuring User Responsibility Templates
Setting Up Quality Departments

2.1.8 Release Check

Release checks cover the specifications, characteristics, or attributes relevant for a certain release type.

Each release check is based on a release check type, which determines the check's basic attributes. In addition, a release check can be assigned a business rule. In this case, the system evaluates the data received from the source system against the business logic encapsulated in the rule to determine the release check status.

Here are some important concepts related to release checks:

Release Check Type

The release check type controls which attributes are shown for a release check in the *My Release Decisions* app and the *My PCN Release Decisions* app.

Release Check Status

The release check status controls whether a release decision item can be released without restrictions, released with a comment, or can't be released at all. If a business rule is assigned to the release check, the status is set automatically. If no business rule is assigned to the release check, the status must be set by a user in the *My Release Decisions* app or the *My PCN Release Decisions* app. Depending on how a release check is configured, an automatically determined status can also be changed manually in the *My Release Decisions* app or the *My PCN Release Decisions* app. In the *My PCN Release Decisions* app, the release check status is aggregated for all the batches assigned to the packaging control number (PCN).

You can enable the automatic reset of a release check status that has been set by a user. When this option is enabled, the release check status is reset when new release check data is received from the source system or when a user manually changes the release check data. If the automatic reset is not enabled, then once a status is changed manually, it is no longer updated automatically, and the manual status change takes precedence over any automatic status changes.

Release Check Message

Release check messages are relevant for release checks that have a business rule assigned. The messages are generated automatically during a business rule run and are shown in the release check details in the *My Release Decisions* app or the *My PCN Release Decisions* app. Release check messages provide more information about the outcome of a release check, thus helping you to understand if a release check ended with an error or warning.

Preconfigured Release Checks

SAP provides a set of preconfigured release checks that you can use to get started quickly. You can also configure your own release checks in the *Manage Release Configurations* app.

Related Information

Business Rule [page 19]

Configuration of Release Checks
Preconfigured Release Checks

2.1.9 Release Decision

A release decision is an activity that entails the finalizing action in the processing of a release decision item.

Setting a release decision is the final step in the processing of a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app. As a release-responsible person, you set the release decision once you've made sure that all release checks relevant for the release type have been completed.

SAP Batch Release Hub for Life Sciences provides a set of preconfigured release decisions that you can use as they are or you can configure own release decisions to reflect your own processes. You can configure your release decisions in the *Manage Release Configurations* app.

What happens when you set a release decision?

When you set a release decision, the processing status of the item initially changes to *Release in Progress* while the system performs the following steps:

- Creates a snapshot of all the data for the release decision item
- Reruns the business rules for the release checks
- Freezes all the data for the release decision item
- Sends the release decision details to the source system

When these steps have completed, the processing status of the release decision item changes to *Completed*. Once a release decision is set, you can no longer change the release decision item in the *My Release Decisions*

app or the *My PCN Release Decisions* app, and the item is no longer updated with information from the source system. Once the required follow-on processing is completed in the source system, a confirmation is sent back to SAP Batch Release Hub for Life Sciences. The processing status of the release decision item changes to *Confirmed* in the *My Release Decisions* app or the *My PCN Release Decisions* app, and the release decision item details are updated with the relevant confirmation data, such as the confirmed quality batch status and the confirmed usage decision.

Can a release decision be changed?

Once you've set a release decision for an item in your worklist, the item can no longer be changed. However, depending on how the release decision is configured at your company, you can trigger the creation of a new item for reprocessing the same details in the *My Release Decisions* app or the *My PCN Release Decisions* app. This is required if you want to set a new release decision, for example, if important business data changed in the source system or if the initial release decision was a preliminary one.

When you trigger the creation of a new item for reprocessing, the app creates a copy of the original item. The new item is updated with the latest information from the source system and the relevant release checks are triggered again.

The following information is updated:

Information	What Happens to the Information
Release check statuses that were set by the system	Release check statuses are updated based on the latest available business data.
Release check statuses that were set manually	The statuses of manually set release checks are updated depending on the option you select when reprocessing: • *Keep*: Manually set release check statuses are copied to the new item, unless the system-calculated status is different to the one that applied when the original release decision was set. • *Reset*: All manually set release check statuses are reset. **Note** Custom release checks are an exception: the statuses of custom release checks are always kept because there's no inbound data for custom release checks.
Regulatory attribute valuations	Manual changes are reset.
Person responsible assigned to the item	The assignment is reset.
Countries/regions suitable for release	Manual changes are reset.
Stock postings	Manual changes are reset.
Confirmation from the source system	Confirmation data is cleared.

The following information is copied from the original item and remains unchanged:

- Key data, such as material, batch, location, release type, and release decision trigger
- Prioritized due date
- Statuses of release checks that do not allow an automated reset
- Statuses of custom release checks
- Comments
- Attachments

Related Information

Release Decision Item [page 29]
Final System Checks Before Setting the Release Decision [page 90]

2.1.10 Release Decision Item

A release decision item is a worklist item that represents a release decision to be made for a batch or a packaging control number (PCN).

Release Decision Items in the My Release Decisions App

As a release-responsible person or quality analyst, the *My Release Decisions* app provides you with an up-to-date worklist for preparing and setting release decisions for batches. Each entry in the worklist corresponds to a release decision item. A release decision item represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.

Release decision items are created automatically based on the data received from the connected source systems and the available configuration settings. If a batch is associated with multiple materials, locations, release types, or release decision triggers, the worklist includes multiple release decision items for the same batch.

PCN Release Decision Items in the My PCN Release Decisions App

A PCN groups batches that must be processed together for the purposes of a clinical trial. As a release-responsible person or quality analyst, the *My PCN Release Decisions* app provides you with an up-to-date worklist for preparing and setting release decisions for PCNs. Each entry in the worklist corresponds to a PCN release decision item. A PCN release decision item represents a release decision to be made for a combination of PCN, PCN version, location, release type, and PCN release decision trigger.

PCN release decision items are created automatically based on the data received from the connected source systems and the available configuration settings. If a PCN is associated with multiple locations, release types, or PCN release decision triggers, the worklist includes multiple release decision items for the same PCN.

Reprocessing and Regenerating Release Decision Items

Authorized users have the following options to manually create release decision items in the *My Release Decisions* app and the *My PCN Release Decisions* app:

- Reprocess a completed or confirmed release decision item
  Reprocessing creates a copy of the selected item. Reprocessing is required, for example, if the initial release decision was a preliminary one or if new business information requires the original decision to be revised.
- Regenerate a new, in progress, or canceled release decision item
  Regenerating marks the selected item as obsolete and creates a new one. Regenerating an item is required if you want to change the release type or if the configuration has changed.

> **Note**
>
> Your assigned business role determines the actions that you're allowed to do. The availability of some actions also depends on configuration.

Related Information

Processing Status [page 23]
Release Decision [page 27]
Release Decision Trigger [page 30]

2.1.11 Release Decision Trigger

A release decision trigger represents an event that leads to the creation of a new release decision item for a batch or a packaging control number (PCN).

Certain events necessitate a release decision for a batch or a PCN. If a batch or a PCN is associated with multiple release decision triggers, you'll find multiple release decision items in your worklist in the *My Release Decisions* app or the *My PCN Release Decisions* app. For example, when there are different inspection lots for the same batch (one inspection lot per trigger) or different versions of a PCN (one version per trigger). In addition, depending on your configuration, one release decision trigger can lead to the creation of multiple release decision items.

Here are some important concepts related to release decision triggers:

Release Decision Trigger Type

The release decision trigger type reflects the type of event that led to the creation of a release decision item.

For a batch, the possible release decision trigger types are as follows:

- Goods Receipt (GR)
- Goods Issue (GI)
- Creation of an Inspection Lot (IL)
- Reevaluation (RE)

For a PCN, the following standard release decision trigger types are provided, but you can configure more in your source system if required:

- Internal Manufacturing (IM)
- External Manufacturing (EM)
- Relabeling (RL)
- Rework (RW)
- PCN Technically Completed or Closed (TC)
- Stock Transport (ST)

Release Decision Trigger ID

The release decision trigger ID comes from the source system and depends on the release decision trigger type. For example, it could be a goods receipt item ID, a goods issue item ID, or an inspection lot ID.

Related Information

Release Decision Item [page 29]
Configuration of Release Type Determination

2.1.12 Release Type

The release type is an attribute that defines the quality and compliance requirements for the release of a batch or a packaging control number (PCN).

Depending on your business processes, your release decisions could pertain to different scenarios such as technical release for internal production, technical release for external procurement, market release, and distribution release. Based on the release type, the release decision items in the *My Release Decisions* app and the PCN release decision items in the *My PCN Release Decisions* app have different data characteristics and therefore include different release checks and different possible release decisions.

SAP Batch Release Hub for Life Sciences provides a set of preconfigured release types that you can use as they are, or you can configure own release types to reflect your release decision processes. You can configure your release types in the *Manage Release Configurations* app.

Related Information

Configuration of Release Types
Preconfigured Release Types

2.1.13 Restriction Driver

A restriction driver consists of one or more attributes of the supply chain that are subject to regulatory control. Restriction driver attributes and their authorized reference values are documented in authorized supply chain maps that are used for jurisdictional control in the batch release process.

You configure your restriction drivers in the *Manage Release Configurations* app. For each restriction driver, you define the attributes that are subject to regulatory control. You also define the processing steps that are relevant for jurisdictional control such as procurement, manufacturing, or packaging. Finally, you assign processing steps and material types to the restriction drivers, which defines a master set of restriction drivers that can be used for a certain node in the authorized supply chain map. In the jurisdictional control check, the authorized reference values of the restriction driver attributes are compared to their actual values to determine compliance.

Below are some examples of restriction drivers and their authorized reference values:

Restriction Driver	Option	Restriction Driver Attribute	Comparison Operator	Authorized Value
Manufacturing Site	1	Business Partner	Equal to	Acme Manufacturing
Testing	1	Business Partner	Equal to	ABC Testing
		Testing Type	Equal to	All tests
		Retest Interval	Less than or equal to	1 month
	2	Business Partner	Equal to	XYZ Testing
		Testing Type	Equal to	All tests
		Retest Interval	Less than or equal to	1 month
Shelf Life	1	Shelf Life	More than	12 months
Specification	1	Specification Number	Equal to	SPEC09872314
		Specification Version	Equal to	3.0

You can view the restriction drivers and their authorized reference values for a target material and country or region in the *View Authorized Supply Chain Maps* app.

Manual Restriction Drivers

Some restriction drivers consist of unstructured data that cannot be evaluated automatically by the system, and these restriction drivers need to be reviewed manually in the jurisdictional control check in the *My Release Decisions* app. You can specify that a restriction driver requires manual evaluation in your configuration settings.

Related Information

Authorized Supply Chain Map [page 18]
Manage Release Configurations [page 46]

2.1.14 Tenant

An onboarded SAP Batch Release Hub for Life Sciences subaccount is known as a "tenant".

SAP BTP supports a multitenancy software architecture in which each tenant has separate data and separate identity and access management. Tenants can share the same technical resources.

Related Information

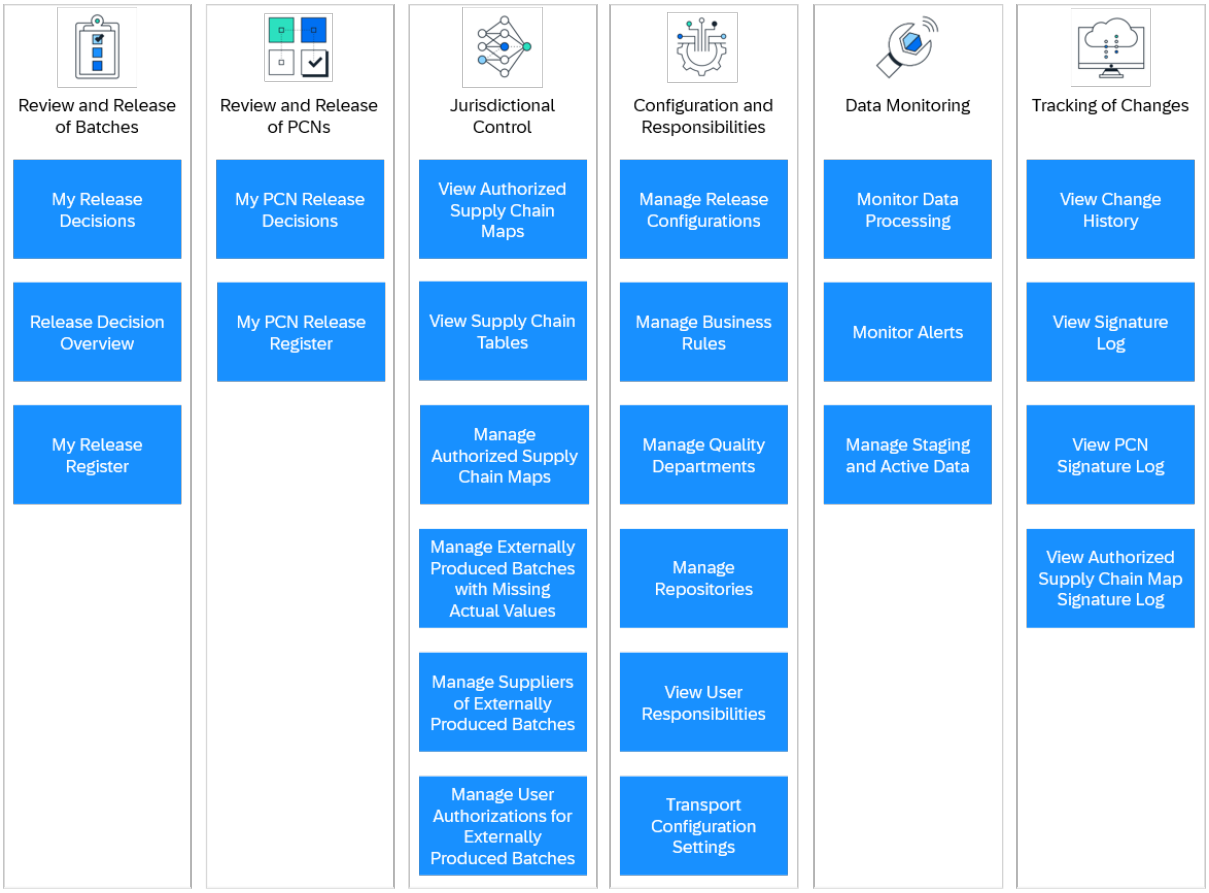
Isolation and Multitenancy

2.2 Apps for SAP Batch Release Hub for Life Sciences

Get an overview of the apps provided for SAP Batch Release Hub for Life Sciences.

The interactive diagram below summarizes typical tasks and the apps provided to complete them.

Hover over each area for a description. Click the highlighted areas for more information.



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- [page 43]
- [page 44]
- [page 45]
- [page 42]
- Create and manage the authorized supply chain maps used for jurisdictional control. [page 43]
- Check who approved or published an authorized supply chain map. [page 54]
- Create and export a register of completed and confirmed PCN release decisions. [page 40]

Task	Typical Activities
Preparation, review, and release of batches	• Review the details of a release decision item for a batch including the release check results • Set the status of a release check • Change the suitability of countries/regions • Review the urgency of release decisions and prioritize processing accordingly • Assign a release decision item to yourself or a colleague for processing • Set release decisions for batches • Revise release decisions by reprocessing worklist items • Regenerate a release decision item to reflect configuration changes • Cancel release decision items that are no longer required • Create a register of completed and confirmed release decisions and export the register to a PDF file
Preparation, review, and release of packaging control numbers (PCNs)	• Review the details of a release decision item for a PCN including the assigned batches and the release check results • Set the status of a release check • Change the suitability of countries/regions • Review the urgency of PCN release decisions and prioritize processing accordingly • Assign a PCN release decision item to yourself or a colleague for processing • Set release decisions for PCNs • Revise PCN release decisions by reprocessing worklist items • Regenerate a PCN release decision item to reflect configuration changes • Cancel PCN release decision items that are no longer required • Create a register of completed and confirmed PCN release decisions and export it

Task	Typical Activities
Jurisdictional control	• Create the authorized supply chain maps used for jurisdictional control • View the authorized supply chain maps for materials, including the applicable restriction drivers and their authorized reference values • View the supply chain tables for materials, including additional processing steps regardless of whether they are relevant for jurisdictional control or not • Manage externally produced batches and enter the actual values for their restriction drivers • Manage the suppliers of batches that are produced externally by contract manufacturing organizations (CMOs) • Manage the user authorizations for the *Manage Externally Produced Batches with Missing Actual Values* app
Configuration and responsibilities	• Set up and manage quality departments, including business roles and responsibilities • Adjust configuration settings according to business needs • Copy configuration settings from a source tenant to a target tenant • Create business rules for automating release checks • Connect repositories for document management • View the responsibilities assigned to the users in your quality departments
Data monitoring	• Monitor data processing • Monitor alerts for events that occur during the life cycle of a data record • Monitor data exchange with connected systems
Tracking of changes	• Review changes made across all apps • Review the signature log for batch release decisions • Review the signature log for PCN release decisions • Review the signature log for authorized supply chain maps

2.2.1 My Release Decisions

With this app, you prepare and manage the release decisions for which you are responsible.

Key Features

You can use this app to do the following:

- Filter for specific attributes to show the release decision items that you're interested in
- Create your own views to personalize the filters and information shown in your release decision worklist
- Assign release decision items for processing
- Set a prioritized due date for release decision items to indicate the urgency of a release decision
- View detailed information for the batch associated with a release decision item
- View the results of the relevant release checks for a release decision item and, if applicable, change the release check status
- View deviations for release decision items
- Add suitable countries/regions and change the suitability of countries/regions
- Change stock posting types for batch quantities or handling units
- View existing comments and create new ones
- Upload attachments
- Set release decisions for release decision items
- Reprocess completed or confirmed release decision items to set a new release decision
- Regenerate new, in progress, or canceled release decision items to change the release type and reflect any changes in configuration
- Cancel release decision items that are no longer required

> **Note**
>
> Your assigned business role determines the actions that you're allowed to do. The availability of some actions also depends on configuration.

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]
Release Decision Item [page 29]

2.2.2 Release Decision Overview

With this app, you can prioritize and manage your release decision workload.

Key Features

This app provides an insight into the status and urgency of your release decision items so that you can prioritize the items that need your attention the most. The app displays a dashboard of various cards showing the following key metrics:

- A donut chart categorizing your release decision items as on time, urgent, and overdue
- The number of release decision items that are ready for release
- The number of release decision items that have open deviations
- A prioritized list of the release decision items that require manual intervention
- A prioritized list of the release decision items that are urgent and overdue
- A prioritized list of the release decision items that have pending and non-compliant release checks
- A bar chart showing the number of release decisions completed in the past days

From each card, you can navigate to the *My Release Decisions* app to process the release decision items. The worklist in the *My Release Decisions* app is automatically filtered to display only the relevant release decision items.

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]
Release Decision Item [page 29]

2.2.3 My Release Register

With this app, you can create a register of completed and confirmed release decisions and then export the register to a PDF file.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find the completed and confirmed release decisions that you're interested in Several filters are available. At minimum, you must select at least one *Batch Location*. Note that you can choose only from the locations and the quality departments that you are assigned to.
- Export the release register to a PDF report
  The release register report is suitable for audit purposes. In addition to the list of completed and confirmed release decisions, the report includes the name of the person who created the report, the date and time that the report was created, and the list of applied filters.

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]
Creating Release Register Reports [page 106]

2.2.4 My PCN Release Decisions

With this app, you prepare and manage the PCN release decisions for which you are responsible.

Key Features

You can use this app to do the following:

- Filter for specific attributes to show the PCN release decision items that you're interested in
- Create your own views to personalize the filters and information shown in your PCN release decision worklist

- Assign PCN release decision items for processing
- Set a prioritized due date for PCN release decision items to indicate the urgency of a PCN release decision
- View detailed information for the batches assigned to a PCN release decision item
- View the results of the relevant release checks for a PCN release decision item and, if applicable, change the release check status
- Change the suitability of countries/regions
- Upload attachments
- Set PCN release decisions
- Reprocess completed or confirmed PCN release decision items to set a new release decision
- Regenerate new, in progress, or canceled PCN release decision items to change the release type and reflect any changes in configuration

> **Note**
>
> Your assigned business role determines the actions that you're allowed to do. The availability of some actions also depends on configuration.

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]
Release Decision Item [page 29]

2.2.5 My PCN Release Register

With this app, you can create a register of completed and confirmed PCN release decisions and then export the register to a spreadsheet.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find the completed and confirmed PCN release decisions that you're interested in
  Several filters are available. At minimum, you must select at least one *Release Responsible Location*. Note that you can choose only from the locations and the quality departments that you are assigned to.

- Export the PCN release register
  The PCN release register report can be exported to a spreadsheet, which shows the list of completed and confirmed PCN release decisions.

Supported Device Types

- Desktop

2.2.6 View Authorized Supply Chain Maps

With this app, you can view the authorized supply chain maps for your target materials in each relevant country or region.

The target material is usually a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company. For example, it could be a sellable brite stock material. Each target material can have a different map for each relevant country or region. Each map has multiple materials included in it.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find the authorized supply chain maps that you're interested in
  You can filter by target material, country/region, and included material. An included material is a component material that is included at a processing step in the supply chain map.
- Create your own views to personalize the filters and information shown in the list of authorized supply chain maps
- View the authorized supply chain map for a target material and particular country or region in either a graphical view or a tabular view
- View the applicable restriction drivers and their authorized reference values for each node in the authorized supply chain map

Supported Device Types

- Desktop

Related Information

Authorized Supply Chain Map [page 18]

2.2.7 View Supply Chain Tables

With this app, you can view the supply chain tables for your target materials in each relevant country or region.

A supply chain table documents the end-to-end supply chain activities related to a specific pharmaceutical material and its destination country/region. It outlines manufacturing, testing, and distribution steps, along with relevant control attributes. While it supports traceability and Qualified Person (QP) certification, it is maintained for documentation purposes only and is not directly used for jurisdictional control checks during batch release decisions.

The target material of a supply chain table is usually the final material in the specification of the supply chain, but it could also be a step before the finished good if the final production and logistics are done outside the company. For example, it could be a sellable brite stock material. A target material can have a different supply chain table for each relevant country or region. Each supply chain table has multiple materials included in it.

The *View Supply Chain Tables* app is similar to the *View Authorized Supply Chain Maps* app. The key difference is that supply chain tables are for documentation purposes only while authorized supply chain maps are used for jurisdictional control checks during batch release decisions. For a particular target material and country/region, you may see more processing steps and restriction drivers in the *View Supply Chain Tables* app than in the *View Authorized Supply Chain Maps* app.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find the supply chain tables that you're interested in
  You can filter by target material, country/region, and included material. An included material is a component material that is included at a processing step in the supply chain table.
- Create your own views to personalize the filters and information shown in the list of supply chain tables
- View the supply chain table for a target material and particular country or region in either a graphical view or a tabular view
- View the applicable restriction drivers and their authorized reference values for each relevant node in the supply chain table
- Identify which restriction drivers are relevant for jurisdictional control with an icon in the graphical view and in a separate column in the table view

Supported Device Types

- Desktop

2.2.8 Manage Authorized Supply Chain Maps

With this app, you can create and manage the authorized supply chain maps that are used in the jurisdictional control process.

You can create an authorized supply chain map for a target material and a specific country or region. The target material is usually a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company. For example, it could be a sellable brite stock material. Each target material can have a different map for each relevant country or region. Each map has multiple materials included in it.

Key Features

You can use this app to do the following:

- Create a new authorized supply chain map from scratch
- Create a new authorized supply chain map by copying an existing authorized supply chain map
- Create a new version of a published authorized supply chain map
- Set a new authorized supply chain map as ready for review
- Assign an authorized supply chain map to a colleague
- Review an authorized supply chain map and either approve or reject it
- Set an authorized supply chain map as obsolete
- Publish an approved authorized supply chain map

Supported Device Types

- Desktop

2.2.9 Manage Externally Produced Batches with Missing Actual Values

With this app, you can manage externally produced batches and enter missing actual values for restriction drivers.

When batches are externally manufactured or packaged by contract manufacturing organizations (CMOs), their actual values cannot be received in the usual way through a system integration. In this scenario, the actual values need to be entered manually, so that they can be used in the jurisdictional control check. In the jurisdictional control check, the actual values of a batch are compared against the authorized reference values of the restriction driver attributes.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find batches that you're interested in
- Create your own views to personalize the filters and information shown in your worklist
- Assign a batch to yourself or another user for processing
- Set a batch to the status completed
- Set a batch to the status canceled
- Regenerate a batch to apply the latest configuration settings or to process a batch that was previously canceled
- Add and remove component batches
- Enter the actual values of the restriction driver attributes of each batch and its component batches
- Upload attachments
- View existing comments and create new ones

Supported Device Types

- Desktop

Related Information

Restriction Driver [page 32]

2.2.10 Manage Suppliers of Externally Produced Batches

With this app, you can manage the suppliers of batches that are produced externally by contract manufacturing organizations (CMOs).

CMO suppliers are relevant for batches in the *Manage Externally Produced Batches with Missing Actual Values* app. You can manage the user authorizations for the *Manage Externally Produced Batches with Missing Actual Values* app by assigning CMO suppliers and locations (CMO plants) to users in the *Manage User Authorizations for Externally Produced Batches* app.

Key Features

You can use this app to do the following:

- Filter for specific attributes to find suppliers that you're interested in

- Create your own views to personalize the filters and information shown in your worklist
- Create a new supplier
- Edit the details of an existing supplier
- Set a supplier as inactive

Supported Device Types

- Desktop

2.2.11 Manage User Authorizations for Externally Produced Batches

With this app, you can manage user authorizations for the *Manage Externally Produced Batches with Missing Actual Values* app.

You use this app to authorize existing users to enter missing actual values for batches produced externally by contract manufacturing organizations (CMOs). You can assign authorization for a supplier and/or a batch location (a CMO plant).

Key Features

You can use this app to do the following:

- Filter for specific attributes to find the user authorizations that you're interested in
- Create your own views to personalize the filters and information shown in your worklist
- Create a new user authorization by assigning suppliers and/or batch locations to a user
- Edit the details of an existing user authorization
- Set a user authorization as inactive

Supported Device Types

- Desktop

2.2.12 Manage Release Configurations

With this app, you can set up and configure the processing of release decisions for batches and packaging control numbers (PCN).

Key Features

You can use this app to do the following:

- Make basic settings such as the method of release type determination, document management settings, and general settings for release checks
- Configure release checks, release check statuses, release check messages, and deviation statuses
- Configure quality batch statuses, usage decisions, stock posting types, and release decisions
- Configure release types and specify which release checks must be completed and which release decisions can be set for a release type
- Specify how release types are determined for batches, using release process flows or inspection types
- Specify PCN release process flows for determining the release types for PCN release decision items
- Create business roles, material types, location types, organizational areas, and user responsibility templates for use in your quality departments
- Configure the restriction drivers that are used in the jurisdictional control process

Supported Device Types

- Desktop

Related Information

Location [page 21]
Method of Release Type Determination [page 21]
Organizational Area [page 22]
Release Check [page 26]
Release Type [page 31]

2.2.13 Manage Business Rules

With this app, you can view the business rules provided by SAP and create your own rules.

Key Features

You can use this app to do the following:

- View the preconfigured rule projects provided by SAP
  Projects include the business rules entities, such as data objects, rules, rulesets, and rule services.
- Create your own rule projects

> **Note**
>
> This app is provided by the business rules capability within SAP Workflow Management. For more information about how to create rule projects, see Create a Project in the documentation for the capability.

Supported Device Types

- Desktop

Related Information

Business Rule [page 19]
Creating Custom Business Rules for Release Checks

2.2.14 Manage Quality Departments

With this app, you can organize the users, locations, and responsibilities relevant for the processing of release decisions for batches in your organization.

Key Features

You can use this app to do the following:

- Add users to a quality department and assign a business role to each user
- Assign locations to a quality department and structure them to reflect your supply chain

- Create responsibilities for the users and locations assigned to a quality department
  The user responsibilities determine which release decision items appear in each user's worklist in the *My Release Decisions* app.

Supported Device Types

- Desktop

Related Information

Quality Department [page 25]

2.2.15 Manage Repositories

With this app, you can set up and manage document repositories.

Key Features

You can use this app to add and remove internal and external repositories that are available for connection to SAP Batch Release Hub for Life Sciences.

Connection to a repository is required so that users can upload and download attachments and view certificates in the *My Release Decisions* app.

> **Note**
>
> This app is provided by SAP Document Management Service. For more information about how to work with the app, see *Onboarding Repository* in the documentation for SAP Document Management Service.

Supported Device Types

- Desktop

Related Information

Onboarding Repository

2.2.16 View User Responsibilities

With this app, you can view the responsibilities that have been assigned to the users in your quality departments.

The user's responsibilities determine which release decision items are shown in the user's worklist in the *My Release Decisions* and *My PCN Release Decisions* apps. For *My Release Decisions*, user responsibilities are defined in terms of release types, material types, and material groups. For *My PCN Release Decisions*, user responsibilities are defined only in terms of release types.

The user's assigned business role specifies the release activity that determines what a user is allowed to do in the *My Release Decision* and *My PCN Release Decision* apps.

> **Note**
>
> By default, only active users (users who have not reached their configured expiry date) are displayed.

Key Features

You can use this app to do the following:

- View the responsibilities that have been assigned to the users in your quality departments
- Apply filters to search for responsibilities based on attributes such as follows:
  - Users
  - Quality departments
  - Release types
  - Locations
  - Material types
  - Material groups
- Export the data to a spreadsheet or a PDF file

Supported Device Types

- Desktop

Related Information

Quality Department [page 25]

2.2.17 Transport Configuration Settings

With this app, you can transport your configuration settings from one tenant to another.

Key Features

You can use this app to streamline the process of testing and applying configuration changes and to avoid having to make configuration changes manually in each of your tenants. As there are dependencies between some of the configuration settings (for example, between release check statuses and release checks), a transport includes all of the following configuration settings:

- Release check statuses
- Release check messages
- Deviation statuses
- Release checks
- Quality batch statuses
- Usage decisions
- Release decisions
- Stock posting types
- Release types
- Combined release types
- Inspection types
- Material types
- Location types
- Organizational areas
- Processing steps
- Restriction drivers
- Assignments of restriction drivers

Supported Device Types

- Desktop

Related Information

Tenant [page 33]

2.2.18 Monitor Data Processing

With this app, you can monitor the flow and processing of event records for data used in release decisions for batches.

Key Features

You can use this app to do the following:

- Check the status of event records
- Get an overview of the events in the lifecycle of a record for a data object, such as a batch or a release check
- View details about the payload included in an event record
- View detailed information about any alerts

Supported Device Types

- Desktop

2.2.19 Monitor Alerts

With this app, you can get an overview of alerts that were triggered during processing of event records.

Key Features

You can use this app to do the following:

- View alerts that occurred for event records created at different points in the lifecycle of a data record
- Filter for different types of alerts and events

Supported Device Types

- Desktop

2.2.20 Manage Staging and Active Data

With this app, you can get an overview of the current status of the data in SAP Batch Release Hub for Life Sciences.

Key Features

You can use this app to do the following:

- Check the status of records in staging and those that are active for each entity
- View details about the data included in each record
- Activate records in the staging area
- Remove erroneous records from the staging area

Supported Device Types

- Desktop

2.2.21 View Change History

With this app, you can view changes made in objects used for batch release processing.

Key Features

You can use this app to do the following:

- View changes made to attributes in any object
- Check who made a change, what was changed, and when
- Apply filters to find changes according to relevant criteria, such as who made the change or the object type

Supported Device Types

- Desktop

2.2.22 View Signature Log

With this app, you can check who signed or attempted to sign a release decision in the *My Release Decisions* app.

Key Features

You can use this app to do the following:

- Check logged events related to the electronic signature provided when setting a release decision for a batch in the *My Release Decisions* app
  An event is logged whenever a user opens the *Set Release Decision* dialog in the *My Release Decisions* app.

  > ⓘ Note
  >
  > Batches that are released without an e-signature are not recorded in the signature log.

- Filter for specific attributes, such as a single batch or user, or for events logged in a period of time

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]

2.2.23 View PCN Signature Log

With this app, you can check who signed or attempted to sign a release decision in the *My PCN Release Decisions* app.

Key Features

You can use this app to do the following:

- Check logged events related to the electronic signature provided when setting a release decision for a packaging control number (PCN) in the *My PCN Release Decisions* app

> **Note**
>
> An event is logged whenever a user opens the *Set PCN Release Decision* dialog in the *My PCN Release Decisions* app.

- Filter for specific attributes, such as a single PCN or user, or for events logged in a period of time

Supported Device Types

- Desktop

Related Information

Release Decision [page 27]

2.2.24 View Authorized Supply Chain Map Signature Log

With this app, you can check who approved or published an authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Key Features

You can use this app to do the following:

- Check logged events related to the approval of authorized supply chain maps in the *Manage Authorized Supply Chain Maps* app
  An event is logged whenever a user chooses the *Approve* button when reviewing a map in the *Manage Authorized Supply Chain Maps* app.
- Check logged events related to the publishing of authorized supply chain maps in the *Manage Authorized Supply Chain Maps* app
  An event is logged whenever a user chooses the *Publish* button in the *Manage Authorized Supply Chain Maps* app.

Supported Device Types

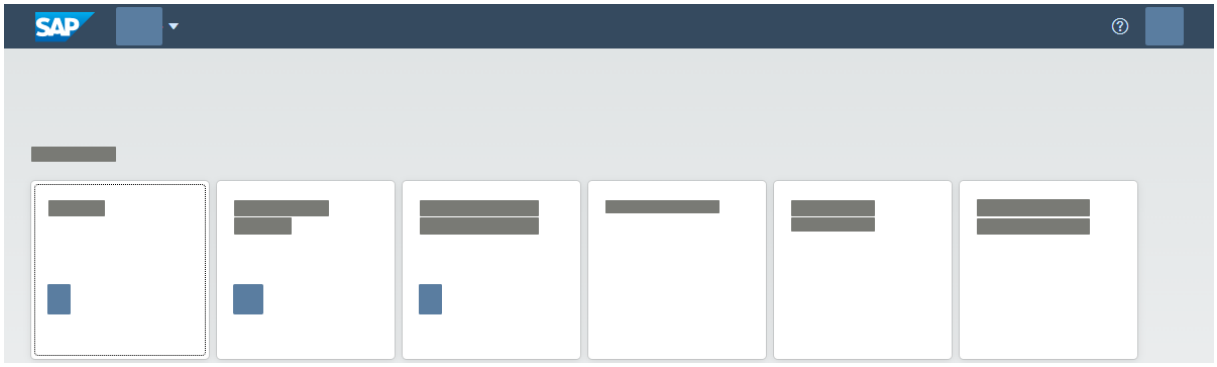
- Desktop

2.3 Working with In-App Help

Get the information you need, when you need it.

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 the shellbar in the app.

The following simplified screenshot shows you where to find the question mark.



Once you've opened the help, here's what you can do:

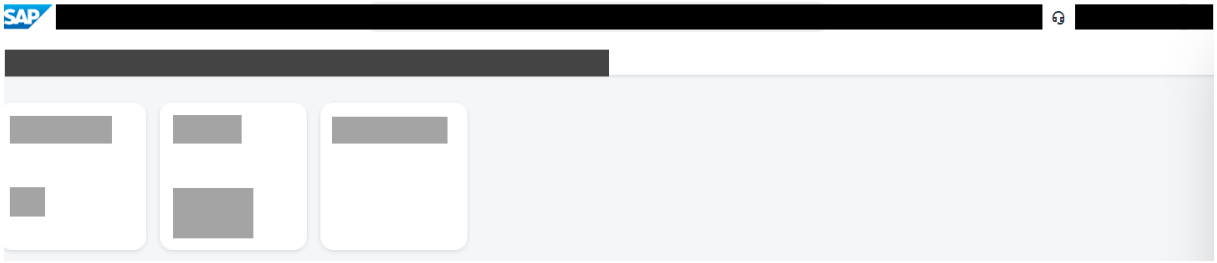
- To show more information for a field or screen area, choose the question mark shown near the element. Alternatively, you can choose the text in the help panel.
- Need more space on the screen? To minimize the help panel, choose » *(Show/Hide Panel)* in the bottom right corner of the panel.
- Use the search in the help panel to search all help texts available for the current screen.

2.4 Working with Built-In Support

Get the support you need, when you need it.

Support is embedded directly in apps. To open the built-in support, choose the headset *(Built-In Support)* in the upper right corner of the shellbar in the app.

The following simplified screenshot shows you where to find the headset.



You can use the built-in support to do the following:

- Search for information in SAP knowledge base.

- Report issues to SAP.

For more information about using the built-in support, see Built-In Support.

2.5 Finding the Software Release Version

Learn how to find the software release version for the tenant you are using.

SAP Batch Release Hub for Life Sciences is a cloud solution with regular software releases. You can find the software release version for the tenant you are currently using as follows:

1. In your SAP Fiori launchpad, go to your user profile menu in the upper right corner of the shellbar.
2. Choose *Technical Information*.
   The software release version consists of three numbers separated by periods. Each number represents a different release type as follows:
   - The first number represents the feature release version.
     As of the November 2025 release, this number is in the format YYMM (the year and the month of the release).
   - The second number represents the regular change version.
   - The third number represents the hotfix (emergency release) version.

For information about the different release types and the planned timelines for releases, see the Release Strategy for SAP Batch Release Hub for Life Sciences.

3 Getting Started with Release Decisions

Begin here if you are new to SAP Batch Release Hub for Life Sciences and need an overview of how to get started.

Before You Begin

Before you begin processing your release decision items, familiarize yourself with the basic concepts and terms used in SAP Batch Release Hub for Life Sciences:

- Important Concepts [page 18]
- Glossary [page 199]

In SAP Batch Release Hub for Life Sciences, you can process release decisions for individual batches and for packaging control numbers (PCNs). PCNs are used to group batches that belong together in a clinical trial.

Batch Release Decisions

To prepare, review, and set release decisions for individual batches, you use the following apps:

- *Release Decision Overview*
  This app is a dashboard that provides an overview of the status of your batch release decision items. It includes various cards that help you to manage your workload by identifying and prioritizing the release decision items that need your attention the most urgently. From each card, you can easily navigate to the *My Release Decisions* app to view and process your items.
- *My Release Decisions*
  This app aims to simplify the release decision process by gathering all the information that you need to make a batch release decision in one place. The app presents you with a worklist of release decision items. Each release decision item represents a release decision that you need to make for a specific batch, material, location, release type, and release decision trigger. At a glance, you can see the processing status of each release decision item, as well as the release check statuses and any deviations. You can process your release decision items and set release decisions as appropriate.

PCN Release Decisions

To prepare, review, and set release decisions for PCNs used in clinical trials, you use the following app:

- *My PCN Release Decisions*
  This app aims to simplify the release decision process for batches that are part of clinical trials. In a clinical trial, packaging control numbers (PCNs) are used to group together the batches that belong together in terms of blinding. Batches that are assigned to the same PCN must be processed and released together.

The app presents you with a worklist of PCN release decision items. Each PCN release decision item represents a release decision that you need to make for a specific PCN, PCN version, location, release type, and PCN release decision trigger. At a glance, you can see the processing status of each PCN release decision item, as well as the status of the assigned batches and the overall release check statuses. You can process your PCN release decision items and set PCN release decisions as appropriate.

> **Note**
>
> These apps display only the release decision items that fall within your responsibility in the quality departments to which you are assigned. If you are not seeing the release decision items that you expect, ask your administrator to check your quality department assignments.

Related Information

Batch Release Decisions [page 59]
PCN Release Decisions [page 108]

4 Batch Release Decisions

This section describes how you prepare, review, and set release decisions for batches using the *My Release Decisions* app.

4.1 Life Cycle of Batch Release Decision Items

Release decision items in the *My Release Decisions* app go through a sequence of processing steps, which are reflected by the *Processing Status*.

The following diagram illustrates the typical processing flow for a release decision item in the *My Release Decisions* app:

- Life Cycle of Batch Release Decision Items [page 59]
- Life Cycle of Batch Release Decision Items [page 59]
- Life Cycle of Batch Release Decision Items [page 59]
- Life Cycle of Batch Release Decision Items [page 59]
- Life Cycle of Batch Release Decision Items [page 59]

Here's a detailed list of all the possible processing statuses:

Processing Status	What It Means
New	Processing of the item has not yet started.
In Progress	Processing of the item has started. For example, the item has been assigned to a responsible person.

Processing Status	What It Means
Release in Progress	A release decision has been set for the item and the system is performing the following steps in the background: • Creating a snapshot of all the data for the release decision item • Rerunning the business rules for the release checks • Freezing all the data for the release decision item • Sending the release decision details to the source system
Completed	A release decision has been set for the item. The item can no longer be changed. The decision has not yet been confirmed in the source system.
Confirmed	Follow-on processing is completed and the release decision is confirmed in the source system.
Obsolete	The item was manually regenerated, invalidated due to changes in the configuration, or canceled through a release decision trigger. When an item is made obsolete due to manual regeneration or configuration changes, a new item is created with the latest configuration settings. Obsolete items can no longer be changed.
Canceled	The item was manually set to canceled by a responsible person. Only new and in progress items can be set to canceled. Canceled items can no longer be changed.
Regeneration in Progress	The item was manually regenerated by a responsible person. The system is in the process of creating a new item with the latest configuration settings. When the regeneration has completed, this item will be set to the processing status *Obsolete*.
Released Externally	The batch was released in the source system, outside of SAP Batch Release Hub for Life Sciences, and has been closed automatically. Only new and in progress items are closed automatically. Items that have been released externally can no longer be changed, but they can be regenerated if necessary.

Related Information

Final System Checks Before Setting the Release Decision [page 90]

4.2 What You See in Your Worklist

Here's a summary of the information available in the *My Release Decisions* app.

My Release Decision Worklist

The following table summarizes the main columns that are available in your worklist. Note that not all of these columns are displayed by default. To see the complete list of available columns and customize your worklist, choose ⚙ *View Settings*.

What You Can See	More Information
Number of release decision items	• The number of open release decision items is displayed on the *My Release Decisions* tile on your SAP Fiori launchpad. These release decision items have the processing status *New* or *In Progress*. • The total number of release decision items is displayed at the top of your worklist when you open the app.
Release decision item key information: • *Batch ID* • *Material ID* • *Material Description* • *Location* • *Release Decision Trigger ID* • *Release Decision Trigger Type* • *Release Type*	Each release decision item relates to a specific batch, material, location, release type, and release decision trigger. The *Release Decision Trigger Type* is the type of event that led to the creation of the release decision item. The possible release decision trigger types are as follows: • Goods receipt (GR) • Goods issue (GI) • Creation of an inspection lot (IL) The *Release Type* is the scenario within the overall release process flow (for example, technical release or market release). Release types are configured to reflect your business processes. The release type determines the release checks that must be completed and the release decisions that you can set.

What You Can See	More Information
Quality Department	Your quality department determines the release decision items that are displayed in your worklist. You must be assigned to at least one quality department. If you are assigned to more than one quality department, you can use the *Quality Department* filter in the header area to display release decision items for a specific quality department.
Deviations	The deviations column displays a chart that shows the number of deviations, if any, broken down as follows: • *Closed* • *Open* • *Closed with Restrictions* Hover your mouse over the chart to display more details.
Release Checks	The *Release Checks* column displays a stacked bar chart that shows the number of release checks for the release decision item. The status of the release checks is color-coded as gray, green, or red. Click on the stacked bar chart to display a list of the release checks and their current status.
Due Date	The *Due Date* column displays the due date that has been defined in the source system. You can choose the *Set Prioritized Due Date* button to set your own prioritized due date.
Assigned To	The *Assigned To* column displays the name of the person assigned to process the release decision item. You can choose the *Assign* button to assign or reassign a release decision item.
Processing Status	The possible processing statuses are as follows: • *New* • *In Progress* • *Release in Progress* • *Completed* • *Confirmed* • *Obsolete* • *Canceled*

What You Can See	More Information
Clinical trial details: • Packaging control number (*PCN*) • *PCN Expiry Date* • *Study* • *Protocol ID* • *Blinding Group* • *Blinded Description* • *Open Label* • *Kit Type* • *Regulatory Approved PCN Export Date* • *Technical PCN Expiry Date*	These columns provide additional information for release decision items that relate to batches for clinical trials.
Release process flow details: • *Predecessor Item* • *Status of Predecessor Item* • *Relevant Step*	These columns give you an insight into the overall release process flow. You must process your release decision items in the correct order. Therefore, you can set a release decision for an item only when the status of its predecessor item is *Processed*.

> **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 the shellbar in the app.

Release Decision Item Details

Click on a row in your worklist to see the complete details for the release decision item. Here you can see the following information:

What You Can See	More Information
Batch Details	The batch details come from the source system. Once you set a release decision, the data in this section is no longer updated from the source system.
Study Details	This section is visible only if the release decision item is for a clinical trial batch that has an associated study. The additional study attributes are displayed such as the study ID and description, the PCN, the protocol ID, and the expiry dates.

What You Can See	More Information
Release Check Summary	This section lists the release checks that must be completed for the release decision item. You can view the following information for each release check: • Status information The status is displayed along with how it was set (system or manual) and the date it was set. Note that your configuration settings control whether the status of a release check is set by the system or manually. Manual status changes take precedence over automatic ones. This means that if you manually change the status of a release check, it will no longer be updated automatically, even if new data is received from the source system. • Number of messages and number of comments Click on a number to view the details of the messages or comments. Click on a row to view more information about a release check.
Deviations	This section lists any deviations for the release decision item. Deviations indicate a difference between the required and the actual physical properties of a batch. This data comes from the source system and once you set a release decision, the data in this section is no longer updated.
Countries/Regions	This section lists the countries/regions that you can mark as suitable or not suitable for release. Initially, this data comes from the source system, but you can add more countries/regions, and you can change the suitability for each country/region.
Stock Postings	If applicable, this section displays the stock postings for the release decision item. Initially, this data comes from the source system, but you can adjust it if necessary.
Release Decision	Once a release decision has been set, this section shows the release decision, the date it was set, and who it was set by. In addition, you can see the confirmation details. When you set a release decision, the decision is sent back to the source system and follow-on processing is triggered. Once the follow-on processing is completed and the release decision is confirmed in the source system, you'll see the confirmation data in this section.

What You Can See	More Information
Attachments	This section shows the files that have been uploaded during the release decision process. You can upload and download files from here. Once a file has been uploaded, it cannot be removed.

4.3 Managing Your Batch Release Decisions

Learn how to use the *Release Decision Overview* app to manage your workload.

> ⓘ 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 the shellbar in the app.

Finding the Information You Need

The following table lists some typical tasks and the corresponding card you can use to help you:

Task	Card to Use
Find release decision items that are ready for release and set a release decision for them.	*Ready for Release*
Find and follow-up on release decision items that have open deviations.	*Open Deviations*
Find and process release decision items that require a release check status to be set manually.	*Items Requiring My Intervention*
Find and follow-up on release decision items that have pending or non-compliant release checks.	*Items with Pending or Non-Compliant Checks*
Find and process release decision items that are overdue and urgent.	*Critical Release Decision Items*
See a summary of my release decision items by urgency.	*My Release Decision Items*
See a summary of the release decision items that have been completed in recent days.	*Number of Release Decisions in the Past Days*

Tips for Working Effectively

- Use filters to narrow down the displayed items, for example, to a specific quality department.
- Customize your layout by dragging and dropping cards.
- Click on a card header or a section of a chart to go to the *My Release Decisions* app.
  Your worklist in the *My Release Decisions* app is automatically filtered to show only the items that are relevant for the card.
- Click on an item in a list card to open the details of the release decision item.

How Is Urgency Calculated?

The urgency of your release decision items is calculated based on due date (or prioritized due date) and lead time as follows:

Urgency	What It Means
On Time	The number of days to the due date (or prioritized due date) is greater than the lead time.
Urgent	The number of days to the due date (or prioritized due date) is less than or equal to the lead time.
Overdue	The due date (or prioritized due date) is in the past.

The lead time is configured in the *Manage Release Configurations* app.

4.4 Release Automation

Learn how your system can be configured to release batches without an e-signature and to automatically release batches once all release checks are in an appropriate status.

The release automation features are intended to save you time and simplify the batch release process so that you can focus on the batch release decisions that need your attention.

> **Note**
>
> These release automation features apply only for batch release decisions in the *My Release Decisions* app. Release automation is not available for PCN release decisions in the *My PCN Release Decisions* app.

The following release automation features can be configured for a release type:

- *Batch Release Without E-Signature*
  When this option is enabled, you are not prompted to enter a password when you set a release decision. Note that when a batch is released without an e-signature, there is no record in the signature log.

- *Automated Batch Release*
  When this option is enabled, batches are released automatically once all release checks are in a status with the impact *Release Without Restrictions* for at least 30 minutes and the configured minimum existence time has elapsed. To use this feature, batch release without e-signature must be enabled as well.

  > ⚠ Caution
  >
  > When configuring automated batch release, please keep in mind that configuration changes apply only to release decision items created after the configuration changes. Any existing new and in progress release decision items are not affected. This means that qualified persons need to regenerate their release decision items to apply the new configuration changes.

4.5 Working on Batch Release Decision Items

Here's a summary of what you can do in the *My Release Decisions* app with links to step-by-step instructions.

You Want To	More Information
Organize the release decision items in your worklist according to priority and responsibility.	• Assigning Release Decision Items for Processing [page 68] • Prioritizing Release Decision Items [page 69]
See more information about the release process flow and see the status of the predecessor item.	• Viewing the Release Process Flow for a Batch [page 70]
Verify the release checks for a release decision item and set a release decision.	• Reviewing Batch Release Checks [page 70] • Changing the Status of Batch Release Checks [page 72] • Editing the Suitability of Countries/Regions in Release Decision Items [page 77] • Adjusting the Stock Postings for Release Decision Items [page 81] • Working with Attachments [page 83] • Setting Batch Release Decisions [page 87]
Update a release decision item to include new information, configuration changes, or other business changes.	• Reprocessing Release Decision Items [page 92] • Regenerating Release Decision Items [page 97] • Changing the Release Type of Release Decision Items [page 98]
Cancel a release decision item that is no longer required.	• Canceling Release Decision Items [page 100]
View all the changes made to a release decision item.	• Viewing the Change History for Release Decision Items [page 101]

You Want To	More Information
Work on batches for clinical trials.	• Batch Release Decision Items for Clinical Trials [page 102]

4.5.1 Assigning Release Decision Items for Processing

Assign one or more release decision items to yourself or someone else.

Prerequisites

- You're authorized to assign release decision items.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

Context

If you're responsible for distributing work within your team, you can assign release decision items to people who are in the same quality department and have the same responsibilities as you.

> **Note**
>
> Once a release decision item has been assigned for processing, you can change the assignment but you can't unassign the item completely.

Procedure

1. Open the *My Release Decisions* app.
2. Select the release decision item that you'd like to assign.

   You can select multiple release decision items if you want to assign them to the same person.
3. Choose *Assign*.
4. Enter the name of the person you want to assign and choose *Assign*.

   If you want to assign the item to yourself, choose *Assign to Me* instead of entering a name.

4.5.2 Prioritizing Release Decision Items

Set a prioritized due date for a release decision item.

Prerequisites

- You're authorized to set prioritized due dates for release decision items.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

Context

Each release decision item in your worklist has a *Due Date*, which is set in the source system. To help you manage your workload, you can optionally set a separate *Prioritized Due Date*. The *Prioritized Due Date* is a separate field and does not change the original *Due Date* from the source system.

> → Tip
>
> If you do not see the *Prioritized Due Date* column in your worklist, you can add it by going to your settings and selecting *Prioritized Due Date*.

Procedure

1. Open the *My Release Decisions* app.
2. Select the release decision item that you want to prioritize.

   You can select multiple release decision items if required.
3. Choose *Set Prioritized Due Date*.
4. Enter the required prioritized due date.

   You can only enter a date in the future.
5. Save your changes.

4.5.3 Viewing the Release Process Flow for a Batch

Add the *Predecessor Item*, *Status of Predecessor Item*, and *Relevant Step* columns to your worklist for visibility of the release process flow.

Context

If your configuration is based on release process flows (rather than inspection types), then each release decision item in your worklist is part of a sequence of steps that must be processed in a defined order. This means that you cannot set a release decision for an item unless the predecessor item has been processed. To help you understand the overall release process flow and see whether the predecessor item has been processed, you can add the *Predecessor Item*, *Status of Predecessor Item*, and *Relevant Step* columns to your worklist.

Predecessor Item and *Status of Predecessor Item* are also shown on the details page of a release decision item. The *Predecessor Item* displays the release type of the predecessor item and provides a link so that you can navigate to the details of the item.

Procedure

1. Open the *My Release Decisions* app.
2. Choose ⚙ *View Settings*.
3. On the *Columns* tab, select *Predecessor Item*, *Status of Predecessor Item*, and *Relevant Step*.
4. Choose *OK*.
5. **Optional:** In your filters, enter the *Release Decision Trigger ID* of the relevant item and choose *Go*.
6. **Optional:** Click on the heading of the *Relevant Step* column to sort in ascending order.

4.5.4 Reviewing Batch Release Checks

Review the details of a release check for a release decision item in the *My Release Decisions* app.

Prerequisites

- You're authorized to view release check details or change the status of a release check.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To view details, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

- Changes are possible only if the release decision item has the processing status *New* or *In Progress*.

Context

The release type assigned to a release decision item in your worklist determines which release checks must be completed before a release decision can be set for the item. For each item in the *My Release Decisions* app, you can see an overview of all the release checks and their current statuses in the color-coded bar chart in the *Release Checks* column and in the details for the release decision item. As part of the release decision process, you review the details of all the release checks for the release decision item. If necessary, you can change the release status for a release check.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to review the release check details.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section and open the details for the release check you want to review.

   The information shown depends upon the type of release check.
5. Check for any release check messages.

   Release check messages are generated for release checks that are carried out by the system based on a defined business rule. These messages provide additional clarification if a release check ends in errors or warnings. Informational messages are also shown here, for example, to show that a check was completed.

   Until a release decision is set, a business rule run is triggered whenever new data is received from the source system.
6. Check for any attachments.

   If you're authorized, you can upload an attachment for a release check.
7. Check any comments for the release check.

   If you're authorized, you can add a comment for a release check.

Next Steps

If the release check is configured to allow manual setting by a user and you're authorized to do so, you can continue to change the release check status, if necessary.

4.5.5 Changing the Status of Batch Release Checks

Change the status of a release check in the *My Release Decisions* app to indicate the result of the check.

Prerequisites

- You're authorized to change the status of release checks.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The release decision item has the processing status *New* or *In Progress*.
- The release check is configured to allow manual setting by a user in the *My Release Decisions* app.

Context

The configuration of a release check in your system controls how the release check status is determined: by the system, by the user, or both.

The following table gives you an overview of what this means for you when working with release checks:

Release Check Status Set By	How It Works
System	• The release check status is determined automatically based on the business rule that's assigned to the release check. • The status can't be changed manually in the *My Release Decisions* app or the *My PCN Release Decisions* app. • Until a release decision is set for the item, the release check status is updated automatically whenever relevant new data is received from the source system.
User	• You set the release check status manually in the release check details in the *My Release Decisions* app or the *My PCN Release Decisions* app. • The release check status doesn't depend on data automatically received from a source system.

Release Check Status Set By	How It Works
System or User	• The initial release check status is determined automatically based on the assigned business rule. • You can change the status manually in the *My Release Decisions* app or the *My PCN Release Decisions* app. • If the automatic reset of a release check status is enabled in your configuration settings, the release check status is reset when new release check data is received from the source system or when you manually change the release check data. If the automatic reset is not enabled, then once a status is changed manually, it is no longer updated automatically, and the manual status change takes precedence over any automatic status changes.

> **Note**
>
> If a release check has the status *Pending* (gray), either information hasn't yet been received from the relevant source system or the release check hasn't yet been set manually.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to change the release check status.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section and open the details for the relevant release check.
5. If the status can be changed manually, you can choose the *Change Status* button.
6. In the dialog that opens, select the new status and add a comment.
7. Save your entries.

4.5.6 Reviewing Quality Deviations

Review the quality deviations for a release decision item in the *My Release Decisions* app. Deviations indicate a difference between the required and the actual physical properties of a batch.

Prerequisites

- You're authorized to view release check details or change the status of a release check.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To view details, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- Changes are possible only if the release decision item has the processing status *New* or *In Progress*.

Context

In the *My Release Decisions* app, you can review the quality deviations for a release decision item in the *Deviations* section on the details page. If the release decision item includes a deviation check, the same information appears in the release check details.

Separated Deviation Checks

Depending on how your system is configured, you may see more than one deviation check in the *Release Check Details* section. It's possible to configure separate deviation checks to evaluate different types of deviations.

Changes to Deviation Data

When deviations are changed in your source system, any outdated deviation data in SAP Batch Release Hub for Life Sciences can be flagged as inactive through the standard integration. This ensures that the deviation data in SAP Batch Release Hub for Life Sciences is accurate and corresponds exactly to the latest deviation data in your source system. Only active deviations are displayed in release decision items and considered in the standard business rules.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to review the quality deviations.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.

4. Go to the *Deviations* section.

   If there are any quality deviations, they are listed here. You can see the status, criticality, and release proposal for each deviation. Depending on how your system is configured, the *Release Proposal* column shows the usage decision or the quality batch status that was received from the source system. The release proposal helps you decide how a deviation impacts the release decision.
5. Go to the *Release Check Summary* section and open the deviation check.

   Depending on how your system is configured, there may be more than one deviation check.
6. Check for any attachments.

   If you're authorized, you can upload an attachment for a deviation check.
7. Check any comments for the deviation check.

   If you're authorized, you can add a comment for a release check.

Next Steps

If the deviation check is configured to allow manual setting by a user and you're authorized to do so, you can change the release check status, if necessary.

4.5.6.1 Example: Automatic Deactivation of Outdated Deviations

When you change the plant, batch, or material for a deviation in SAP S/4HANA, a new deviation record is replicated to SAP Batch Release Hub for Life Sciences with the latest details, and the original, outdated deviation record is automatically deactivated. This feature synchronizes the data between both systems and ensures you can make accurate release decisions based on current deviation information.

Example Deviation in SAP S/4HANA

In SAP S/4HANA, you can create and edit deviations, including changes to plant and batch assignments. Each deviation is identified by a unique combination of deviation ID and deviation type. However, attributes such as plant, batch, and material can be changed after the initial creation.

Consider the following example:

1. You create a deviation in SAP S/4HANA for a specific batch:
   - Deviation ID: 1234
   - Deviation Type: Type1
   - Material: MAT1
   - Plant: LOC1
   - Batch: B1

2. Later, you find the deviation affects all batches of material MAT1 in plant LOC1 due to a component issue.
3. Instead of creating multiple deviation records, you change the existing deviation in SAP S/4HANA by removing the specific batch assignment (B1), indicating that the deviation applies to all batches.

Replication to SAP Batch Release Hub for Life Sciences

1. When deviation 1234 is initially created, it is replicated to SAP Batch Release Hub for Life Sciences, as follows:

Deviation ID	Deviation Type	Material	Plant	Batch	Activation Status
1234	Type1	MAT1	LOC1	B1	Active (A)

2. When deviation 1234 is changed, the data is replicated again. A second deviation record is created, and the original deviation record is flagged as inactive, as follows:

Deviation ID	Deviation Type	Material	Plant	Batch	Activation Status
1234	Type1	MAT1	LOC1	B1	Inactive (I)
1234	Type1	MAT1	LOC1	*	Active (A)

In summary, when you change the plant, batch, or material for a deviation in SAP S/4HANA, the system:

- Creates a new deviation record in SAP Batch Release Hub for Life Sciences with the new plant or batch data
- Deactivates the outdated deviation record
- Ensures that only active deviation data is displayed in SAP Batch Release Hub for Life Sciences
- Recalculates the status of the deviation check to ensure it reflects only the active deviations
- Considers only active post-release component deviations when calculating the release check status for the component check

> → Tip
>
> You can check inbound deviation data in the *Manage Staging and Active Data* app.

Benefits

This feature provides the following benefits:

- **Data Accuracy**: Ensures deviation information in SAP Batch Release Hub for Life Sciences matches the source data in SAP S/4HANA
- **Compliance**: Maintains accurate deviation records for audit and regulatory purposes
- **Decision Support**: Enables you to make release decisions based on current deviation information
- **Efficiency**: Eliminates manual reconciliation of deviation data between systems

Implementation

The `Deviations` API includes the attribute `status_ID`, which accepts either *A* (Active) or *I* (Inactive) as values. For more information about this API, see Deviations on the Business Accelerator Hub.

4.5.7 Editing the Suitability of Countries/Regions in Release Decision Items

Review and, if necessary, edit the suitability of the countries and regions assigned to a batch release decision item in the *My Release Decisions* app. You can add countries and regions if necessary.

Prerequisites

- You're authorized to manage the countries and regions for a batch release decision item.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The batch release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The batch release decision item has the processing status *New* or *In Progress*.

Context

As part of the batch release decision process, you review the assigned countries and regions and decide whether the batch is suitable for each one. If necessary, you can add a country or region or edit the suitability of a country or region. Your changes are sent to the source system when the release decision is set.

As part of your review, you can consider the following information for each country or region:

- *Regulatory Suitability*
  The regulatory suitability represents the consolidated valuation of the attributes in the regulatory data check (if applicable). It has the following possible values:

Regulatory Suitability	What It Means
Yes	The valuations of all the attributes are available, and they are all in a green status.
No	The valuations of all the attributes are available, and the valuation of at least one attribute is in a status other than green.

Regulatory Suitability	What It Means
Yes (Excluding Pending Attributes)	The valuations of some attributes are still pending, and the valuations of all the attributes received so far are in a green status.
No (Excluding Pending Attributes)	The valuations of some attributes are still pending, and the valuation of at least one of the received attributes is in a status other than green.
Not Set (All Attributes Pending)	The valuations of all the attributes are still pending.
Blank	No regulatory suitability information is available for the country or region.

- *Analytical Suitability*
  The analytical suitability represents the valuation of a multiple specification quality characteristic for a country or region. *Yes* indicates that the batch is suitable for the country or region. *No* indicates that the batch is not suitable for the country or region. If this field is blank, it means that no analytical suitability information is available for the country or region.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to review the countries and regions.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.
4. Go to the *Countries/Regions* section and review the assigned countries and regions and their suitability.
5. **Optional:** If necessary, adjust the countries and regions as follows:

You Want To	What To Do
Add a country or region	1. Choose *Add*. 2. Select the countries or regions you want to add. 3. Save your changes. When you add a country or region, the business rule for the regulatory data check is rerun to ensure that the status of the regulatory data check is up to date and considers all the countries and regions.
Change the suitability of a country or region	1. Select one or more countries or regions. 2. Choose *Edit Suitability*. 3. Select the required suitability. 4. Save your changes.

You Want To	What To Do
Delete a country or region	It is not possible to delete a country or region from the list. Instead, you can set the country or region as not suitable.

Related Information

Evaluations of Multiple Specifications [page 80]

4.5.8 Editing the Suitability of Customers in Release Decision Items

Review and, if necessary, edit the suitability of the customers assigned to a batch release decision item in the *My Release Decisions* app.

Prerequisites

- You're authorized to edit the suitability of the customers assigned to a batch release decision item. The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The batch release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The batch release decision item has the processing status *New* or *In Progress*.

Context

As part of the batch release decision process, you review the assigned customers and decide whether the batch is suitable for each one. The customer information comes from your source system and is defined in the batch characteristics. The *Customers* section in the *My Release Decisions* app is displayed only when customer information has been defined in your source system. If necessary, you can edit the suitability of a customer. Your changes are sent to the source system when the release decision is set.

As part of your review, you can consider the *Analytical Suitability*. The analytical suitability represents the valuation of a multiple specification quality characteristic for a customer. *Yes* indicates that the batch is suitable for the customer. *No* indicates that the batch is not suitable for the customer. If this field is blank, it means that no analytical suitability information is available for the customer.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to review the customers.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.
4. Go to the *Customers* section and review the assigned customers and their suitability.

   If there is no *Customers* section, then no customers have been defined for this release decision item.
5. **Optional:** If necessary, adjust the suitability of the customers as follows:
   a. Select the customer that you want to adjust.
   b. Choose *Edit Suitability*.
   c. In the *Edit Suitability* dialog, select the appropriate suitability.
   d. Save your changes.

Related Information

Evaluations of Multiple Specifications [page 80]

4.5.9 Evaluations of Multiple Specifications

Multiple specifications are used when your batches need to conform to different specifications in different scenarios.

In your quality management system, different inspection specifications can be defined for an inspection characteristic. For example, multiple specifications may consist of different tolerances or attributes for an inspection characteristic. SAP Batch Release Hub for Life Sciences supports the evaluation of multiple specifications that are defined for customer-specific requirements or country/region-specific requirements.

When multiple specifications are enabled for an inspection type of a material in your source system, the source system checks these specifications when inspection results for the material are valuated. The results are sent to SAP Batch Release Hub for Life Sciences as a value called the *Analytical Suitability*, which can help you to determine whether or not the batch can be delivered to a specific customer or country/region.

Where Can I Review the Analytical Suitability of a Batch?

You can review the *Analytical Suitability* of a batch in the *My Release Decisions* app. The *Analytical Suitability* is displayed in the *Countries/Regions* section and the *Customers* section on the release decision item details page.

The *Analytical Suitability* is read-only and has the possible values *Yes*, *No*, or blank (when there is no value for a particular country/region or customer). You cannot change the *Analytical Suitability* in SAP Batch Release Hub for Life Sciences, but you can change the overall *Suitability for Release* for a country/region or customer.

Related Information

Editing the Suitability of Countries/Regions in Release Decision Items [page 77]
Editing the Suitability of Customers in Release Decision Items [page 79]

4.5.10 Adjusting the Stock Postings for Release Decision Items

Review, and if necessary, adjust the stock postings for a release decision item.

Prerequisites

- You're authorized to adjust the stock postings for a release decision item.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The release decision item has the processing status *New* or *In Progress*.
- The stock posting types have been configured.

Context

As part of the release decision process, you review the actual lot quantity for a release decision item. The actual lot quantity information comes from the stock postings in your source system. If necessary, you can adjust these stock postings. For example, you may need to adjust the stock postings if a particular handling unit has been damaged during loading or if you need to reserve some stock for sample testing. The updated stock postings are returned to the source system when the release decision is set.

> → Tip
>
> The stock postings aren't updated in the source system immediately. This is intentional and by design. There's a single outbound flow of data from SAP Batch Release Hub for Life Sciences to the source system, which is triggered when you set a release decision in SAP Batch Release Hub for Life Sciences. This design fulfills key GxP requirements by ensuring that a complete snapshot of the release decision is captured together with the required electronic signature before any updates are sent to the source system.

The stock postings for the actual lot quantity can be managed in the following ways:

- Based on handling units that come from a warehouse management solution
  In this scenario, you can see a list of handling units and each handling unit has a stock posting type.
- Based on quantities that come from an inventory management solution
  In this scenario, you can see the list of stock posting types and their corresponding quantities.

The stock posting types are configurable and correspond to your own business processes. For example, you can have a stock posting type for blocked, in quality, unrestricted, and so on.

> **Note**
>
> If a particular stock posting is fixed in your source system, then you cannot adjust it.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to manage the stock postings.

   Each entry or release decision item in the worklist represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger.
3. Open the details of the release decision item.
4. Go to the *Stock Postings* section and review the batch quantity information.

   This section displays the stock postings from your source system.
5. **Optional:** Adjust the stock postings if necessary.

Type of Stock Posting	What To Do
Stock managed at handling unit level	1. Select one or more handling units. 2. Choose *Set New Stock Posting Type*. > **Restriction** > If the stock posting type for a particular handing unit has already been fixed in your source system, then it cannot be changed. When you select a handling unit that has a fixed stock posting type, the *Set New Stock Posting Type* button is not enabled. 3. Select the new stock posting type. 4. Save your changes.
Stock managed at quantity level	1. Choose *Set New Stock Posting Quantities*. 2. Enter the new quantities for each stock posting type. Note that the overall quantity for the batch must remain the same.

Type of Stock Posting	What To Do
	Restriction If the quantity of a particular stock posting type has already been fixed in your source system, then it cannot be changed. In this case, the corresponding *New Quantity* field is read-only. 3. Save your changes.

Related Information

Integration with SAP Extended Warehouse Management
Configuring a Release Decision for Immediate Update of Stock Postings

4.5.11 Working with Attachments

Use attachments to gather additional information for release decision items in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Prerequisites

- You're authorized to manage attachments.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To view attachments, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
  In addition, if you are working on a PCN release decision item that is created by a country/region split, you must be assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The processing status of the release decision item is *New* or *In Progress*.

Context

You can upload attachments at the following levels:

- For a release decision item
- For a specific release check in a release decision item

In the *My PCN Release Decisions* app, you can upload attachments for PCN-level release checks, but not for batch-level release checks.

You can upload files of the following formats with a maximum file size of 40 MB.

> ⚠ Caution
>
> In general, we recommend you upload small files. Only upload large files when absolutely necessary.

File Type	Allowed File Formats
Document	• .pdf • .ppt and .pptx • .txt • .rtf • .doc and .docx • .xls and .xlsx • .csv
Image	• .png • .jpg • .jpeg • .gif • .svg

Once an attachment has been uploaded, it can't be removed. If an attachment becomes outdated or is no longer relevant, you can set it as inactive. Please note that this action can't be undone. Inactive attachments can't be reactivated. In addition, you can't inactivate attachments that have been used to generate AI-based proposals in the AI-assisted custom release check.

When a release decision is set, the release decision item is "frozen". At that point, you can no longer upload or inactivate attachments, but you can still download active attachments.

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app.
2. In the worklist, find the release decision item that you want to work on.
3. Open the details of the release decision item.

   You can go to the *Attachments* section and upload an attachment here at the item level, or you can upload an attachment for a specific release check.
4. To upload an attachment for a specific release check, open the details of the relevant release check.

   In the *My Release Decisions* app, you can open any of the release checks listed in the *Release Check Summary* section. In the *My PCN Release Decisions* app, you can open any of the PCN-level release checks listed in the *PCN Release Check Summary* section.

5. Go to the *Attachments* section, and follow the steps below for your specific task:

Task	What To Do
Upload an attachment	1. Choose *Upload*. 2. Select one or more files to upload. 3. Confirm your selection.
Download an attachment	1. Select one or more attachments. 2. Choose *Download*. You can also download a single attachment by clicking the hyperlinked file name. **Note** Only active attachments can be downloaded.
Set an attachment as inactive	1. Select one or more attachments. 2. Choose ... > *Set as Inactive*. 3. Enter a comment. 4. Choose *Set*.
Set an attachment as AI-relevant	1. Select one or more attachments. 2. Choose ... > *Set as AI-Relevant*. **Note** This option is available only in an AI-assisted custom release check.

Tip

In the *Attachments* table, you can choose *(Additional Information)* to display technical details that you can use to locate the relevant document in its storage location.

4.5.12 Completing Custom Release Checks

Complete a custom release check by entering results and valuations for all the mandatory checklist items and then setting the release check status.

Prerequisites

- You are authorized to change release checks.

To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.

- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
  In addition, if you are working on a PCN release decision item that is created by a country/region split, you must be assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The release decision item has the processing status *New* or *In Progress*.
- The custom release check has been configured and assigned to the appropriate release types in the *Manage Release Configurations* app.

Context

Custom release checks are used to implement manual checking activities for release decision items. A custom release check consists of a list of checklist items that must be completed manually and without the support of a connected source system. To complete a custom release check, you must enter a result and a valuation for each mandatory checklist item. When all mandatory checklist items are completed, you can set the status of the custom release check.

Custom release checks are supported in both the *My Release Decisions* app and the *My PCN Release Decisions* app. For PCN release decision items, custom release checks are completed at the PCN level, and not for the individual assigned batches.

> **Note**
>
> This section describes how to complete a custom release check manually without the support of SAP Business AI. If AI features are enabled in your system and the custom release check is configured to allow AI-based proposals, you can use SAP Business AI to help you complete the release check. For more information, see SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 189].

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app as appropriate.
2. In the worklist, find the release decision item that has the custom release check that you want to review.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section in the *My Release Decisions* app or the *PCN Release Check Summary* section in the *My PCN Release Decisions* app.
5. Open the details of the custom release check.
6. In the *Checklist Items* section, select one or more checklist items.
7. Choose *Complete Checklist Item*.
8. In the *Complete Checklist Item* dialog, enter a result, a valuation, and an optional comment for each checklist item.

Depending on how each checklist item is configured:

- You can either choose a predefined result or enter a result yourself.
- You can choose a valuation or the valuation is filled automatically based on the entered result.
  The valuation specifies the status of a checklist item, for example, whether it's compliant or not compliant. Valuations that have been configured as "Red" or "Yellow" are displayed in their configured color, so you can easily identify items that do not have a positive valuation.

9. Save your entries.

   Your entries are saved and displayed in the *Items* table. When all mandatory checklist items are completed, you can change the status of the release check.
10. Choose the *Change Status* button in the header area.
11. In the dialog that opens, select the release check status and add a comment.
12. Save your entries.

4.5.13 Setting Batch Release Decisions

Learn how to set a release decision for one or more batch release decision items when work on the items is finished and all the relevant release checks have been completed.

You can set a release decision in one of the following ways:

- Choose *Set Release Decision* in the details page for a release decision item.
  Using this method, you can review the information for one specific release decision item and then set a release decision for it.
- Choose *Set Release Decision* in your *My Release Decisions* worklist.
  Using this method, you can set a release decision for multiple items at once. Note that the items must have the same release type.

What Happens When You Set a Release Decision?

Initially, the processing status of the item changes to *Release in Progress* while the system performs the following steps:

- Creates a snapshot of all the data for the release decision item
- Reruns the business rules for the release checks (this step is also called the "safety net")

  > **Note**
  >
  > If the rerun of the business rules results in a change in a release check status, the release is stopped, and the status of the release decision item returns to *In Progress*. This is to ensure you have the very latest information when you make the decision to release the batch.

- Freezes all the data for the release decision item
- Sends the release decision details to the source system

When these steps are completed, the processing status of the item changes to *Completed*. The item can no longer be changed.

Follow-On Processing and Confirmation

When the follow-on processing is completed in the source system and the release decision has been confirmed, the processing status changes to *Confirmed*. In the *My Release Decisions* app, the confirmation data is displayed in the *Release Decision* section of the item.

Release Decision Certificates

If any release decision certificates are generated and sent to SAP Batch Release Hub for Life Sciences following the release decision, they are displayed in the *Certificates* table in the *Release Decision* section. The *Certificates* table is displayed only if release decision certificates have been generated, and a link is provided so you can open each certificate and review it. The generation of release decision certificates is a customer-specific task, which is done outside of SAP Batch Release Hub for Life Sciences.

4.5.13.1 Setting Release Decisions from the Details Page of an Item

Follow these steps when you want to review the information for one specific item and then set a release decision for it.

Prerequisites

- You're authorized to set batch release decisions.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The predecessor item has been processed.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to set a release decision.
3. Open the details of the release decision item.
4. Choose the *Set Release Decision* button in the header area.
5. Select the release decision that you want to set.
6. If required, enter a comment.

7. Enter your password.

   This is the same password that you use to sign in to the system.
8. Confirm your entries.

   The system checks whether there have been any changes to the release decision items since you chose the *Set Release Decision* button. If there have been any changes, a warning is displayed. From the warning dialog, you can continue to set the release decision or you can navigate to the change history to view the recent changes.

   > **Note**
   >
   > Every attempt at setting a release decision is logged, even if you cancel the process. As soon as you choose the *Set Release Decision* button, a log record is created.

4.5.13.2 Setting Release Decisions from Your Worklist

Follow these steps when you want to set a release decision for multiple items at once.

Prerequisites

- You're authorized to set batch release decisions.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The predecessor item has been processed.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, select the entries for which you want to set a release decision.

   The selected items must have the same release type.
3. Choose the *Set Release Decision* button in the header area.
4. Select the release decision that you want to set.
5. If required, enter a comment.
6. Enter your password.

   This is the same password that you use to sign in to the system.
7. Confirm your entries.

   The system checks whether there have been any changes to the release decision item since you chose the *Set Release Decision* button. If there have been any changes, a warning is displayed. From the warning

dialog, you can continue to set the release decision or you can navigate to the change history to view the recent changes.

> **Note**
>
> Every attempt at setting a release decision is logged, even if you cancel the process. As soon as you choose the *Set Release Decision* button, a log record is created.

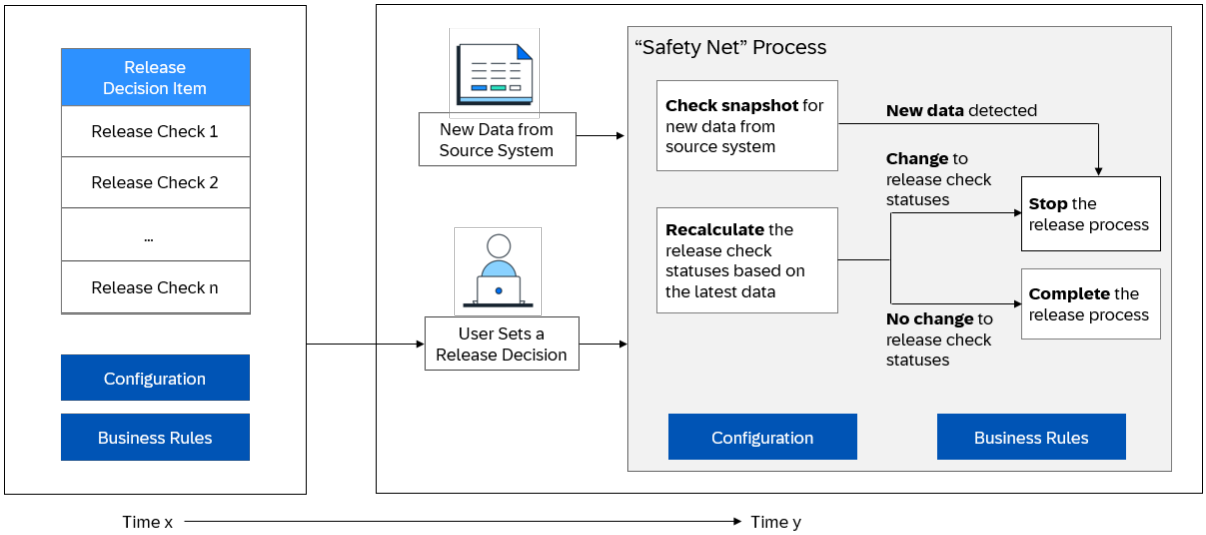
4.5.13.3 Final System Checks Before Setting the Release Decision

When you set a release decision, the system checks whether any data in the release decision item has changed and reruns the business rules. This feature acts as a "safety net" that ensures your decision is based on the very latest data.

The system changes the processing status of the release decision item to *Release in Progress* while it performs the following steps:

- Checks whether any data in the release decision item has changed
  As part of the release decision processing, the system creates a copy of all the data in the release decision item, which is known as a snapshot. This check ensures the snapshot reflects exactly what you saw in the system when you chose the *Set Release Decision* button. Note that some data changes might not necessarily impact the release check statuses. For example, an attachment could be uploaded by another user while you are reviewing the release decision item.
  The release decision processing happens in the background and could be delayed depending on the overall system load. Once the snapshot is complete, the system checks the captured data. If it detects that the snapshot contains data that is newer than the point when the release decision was set (data that the user didn't see when setting the release decision), the processing is stopped.
- Reruns the business rules and recalculates the release check statuses
  All of the release checks that have an assigned business rule are reevaluated based on the latest data. The business rules run automatically whenever new data is received from the source systems. However, if new data is received shortly before or after you set a release decision, the automatic run of the business rules might not have completed yet. The "safety net" ensures that the business rules are completed and the release check statuses are up to date.
  When the business rules have completed, the following outcomes are possible:
  - The release decision is set and the processing status of the item changes to *Completed*.
    If the release check statuses are unchanged, the release decision processing continues and the release decision is set.
  - The release decision is not set and the processing status of the item returns to *In Progress*.
    If a release check status is changed or if the business rules fail for any reason (for example, due to a deleted business rule project), the release decision process is stopped. You will receive a notification to inform you that the release decision was not set.

The following diagram illustrates the overall process:



Release decision items created at **time x** use the configuration settings and business rules of **time x.** Updates of the release checks use the configuration and business rules from **time x**.

The "Safety Net" runs the business rules on the latest data available in the system. The configuration settings and business rules from **time x** are used to calculate the new release check statuses.

What To Do When a Release Decision Is Not Set Successfully

If your release decision is not set successfully, please review the release decision item and the release check statuses again.

Here are some tips to help you figure out why your release decision was not set successfully:

- You can check the change history of the release decision item. If a release check status was changed by the rerun of the business rules, you will see it listed in the change history.
- You can also check the *Monitor Data Processing* app. The rerun of the business rules is recorded there and you can check the event status. New data received during the release process is also recorded there.

When you have reviewed the release decision item and all the release checks are completed to your satisfaction, you can set the release decision again.

Related Information

Business Rule [page 19]

4.5.14 Reprocessing Release Decision Items

Create a copy of a *Completed* or *Confirmed* release decision item for reprocessing.

Prerequisites

- Reprocessing is enabled in the configuration of the release type assigned to the release decision item.
- Subsequent release decisions are configured for the release decision in the configuration of the release type assigned to the release decision item.
- The release decision item has the processing status *Completed* or *Confirmed*.
- You're authorized to reprocess release decision items.
  The business role assigned to your user must have the release activity *Release Decision*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

Context

You might need to reprocess a completed release decision item, for example, if the initial release decision was preliminary or if new business information requires you to revise the original decision. When necessary, you can create a copy of the completed or confirmed release decision item and reprocess it.

> **Note**
>
> The steps below describe how to manually reprocess a release decision item. Reprocessing can also be performed automatically, depending on the release type configuration. If automatic reprocessing is configured for a release type, the system automatically creates a copy of the release decision item as soon as it's completed.

Procedure

1. Open the *My Release Decisions* app.
2. Select a release decision item that has the processing status *Completed* or *Confirmed*.
3. Choose *Reprocess*.
4. In the *Reprocess* dialog, enter a comment to explain the reason for the reprocessing and choose one of the following options:
   - *Keep*: Choose this option to copy any manually set release check statuses to the new item.
     The system keeps any manually set release check statuses unless the corresponding system-calculated status changes. When the new release decision item is created, the system reruns the business rules and recalculates the release check statuses with the latest business data. If the system-calculated status differs from the one that applied when the release decision was set, any

corresponding user-set release check status is reset. This is done to ensure compliance. As the release check data has changed, the manually set release check status might no longer be valid.

- *Reset* Choose this option to reset all manually set release check statuses.
  For release checks with the status determination method *System or User*, the system sets the release check status to the latest one calculated by the business rules. For release checks with the status determination method *User*, the system sets the release check status to *Pending*.

> **Note**
>
> Custom release checks are an exception: the statuses of custom release checks are always kept because there's no inbound data for custom release checks.

5. Choose *Reprocess* to confirm.

   A new release decision item is created for the same combination of material, batch, location, release type, and release decision trigger represented by the selected item. The new item is updated with the latest information from the source system and the business rules are run.

   The following information is copied from the original item and remains unchanged:

   - Key data, such as material, batch, location, release type, and release decision trigger
   - Prioritized due date
   - Statuses of release checks that do not allow an automated reset
   - Statuses of custom release checks
   - Comments
   - Attachments

   Your comment is not displayed in the release decision item details, but is recorded in the change history of the original item.

6. Check the new item for updated information and start processing it.

   The following information is not copied from the original item and requires checking:

Information	What Happens to the Information
Release check statuses that were set by the system	Release check statuses are updated based on the latest available business data.

Information	What Happens to the Information
Release check statuses that were set manually	The statuses of manually set release checks are updated depending on the option you select when reprocessing: • *Keep*: Manually set release check statuses are copied to the new item, unless the system-calculated status is different to the one that applied when the original release decision was set. • *Reset*: All manually set release check statuses are reset. **Note** Custom release checks are an exception: the statuses of custom release checks are always kept because there's no inbound data for custom release checks.
Regulatory attribute valuations	Manual changes are reset.
Person responsible assigned to the item	The assignment is reset.
Countries/regions suitable for release	Manual changes are reset.
Stock postings	Manual changes are reset.
Confirmation from the source system	Confirmation data is cleared.

Related Information

Processing Status [page 23]
Checking if Items Were Regenerated or Reprocessed [page 99]

4.5.14.1 Example: Reprocessing Items with Manually Set Release Check Statuses

When you reprocess a release decision item, you can choose whether to keep or reset the manually set release check statuses. This example illustrates how these two options differ.

Note

This feature applies only to release checks that have the following configuration settings:

- The release check status determination method is *System or User* or *User*.
- Automatic reset of the release check status is enabled.

In this example, there is a completed release decision item with four release checks. All four release checks have the release check status determination method *System or User*. This means the system calculates the release check status based on a business rule, but an authorized user can change the release status if required. The manually set release check status overrides the system-calculated status and is the status that you see in the system.

In the original, completed release decision item, the release check statuses are as follows:

Release Check	System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status	Comment
Certificate Check	To Be Reviewed (TR)	Completed (CD)	Completed (CD)	The system-calculated status is *To Be Reviewed (TR)*, which means the batch is relevant for the certificate check, but the certificate check status is not available in the source system. The responsible quality analyst investigates the missing certificate information, manually uploads the relevant certificate, and then changes the release check status to *Completed (CD)*.
Deviation Check	Open (OP)		Open (OP)	The system-calculated status is *Open (OP)*, which means at least one deviation is open, in process, or not closed. There is no manual change to the release check status.
Quality Control Data Check	Error (ER)	Open (OP)	Open (OP)	The system-calculated status is *Error (ER)*. The responsible quality analyst investigates the issue and changes the release check status to *Open (OP)* because the quality control testing is still in progress.

Release Check	System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status	Comment
Transport Check	Error (ER)	Not Completed (ND)	Not Completed (ND)	The system-calculated status is *Error (ER)*. The responsible quality analyst investigates the issue and changes the release check status to *Not Completed (ND)* because the transport check is still in progress.

When you reprocess this item, the system reruns the business rules and recalculates the release check statuses based on the latest available data. The system handles the manually set release check statuses differently, depending on whether you choose to *Keep* or *Reset* them.

Keep Manually Set Release Check Statuses

Here's what happens when the item is reprocessed with *Keep* manually set release check statuses selected:

Reprocessing with **Keep** manually set release check statuses

Original release decision item:

Release Check	System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status
Certificate Check	To Be Reviewed (TR)	Completed (CD)	Completed (CD)
Deviation Check	Open (OP)		Open (OP)
Quality Control Data Check	Error (ER)	Open (OP)	Open (OP)
Transport Check	Error (ER)	Not Completed (ND)	Not Completed (ND)

Reprocessing

New release decision item:

System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status
To Be Reviewed (TR)	Completed (CD)	Completed (CD)
Closed (CL)		Closed (CL)
Compliant (CT)		Compliant (CT)
Completed (CD)		Completed (CD)

Summary:

- Certificate Check: As there is no change to the system-calculated status, the original manually set release check status is retained and the release check status stays as *Completed (CD)*.
- Deviation Check: There is no manually set release check status to keep. The system recalculates the release check status based on the latest data from the source system and the status is updated from *Open (OP)* to *Closed (CL)*.
- Quality Control Data Check: The system recalculates the release check status based on the latest data from the source system and the status changes from *Error (ER)* to *Compliant (CT)*. As the system-calculated status has changed, the manually set release check status is reset, and the release check status is updated to *Compliant (CT)*.
- Transport Check: The system recalculates the release check status based on the latest data from the source system and the status changes from *Error (ER)* to *Completed (CD)*. As the system-calculated status has changed, the manually set release check status is reset, and the release check status is updated to *Completed (CD)*.

Reset Manually Set Release Check Statuses

Here's what happens when the item is reprocessed with *Reset* manually set release check statuses selected:

Reprocessing with **Reset** of manually set release check statuses

Original release decision item:

Release Check	System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status
Certificate Check	To Be Reviewed (TR)	Completed (CD)	Completed (CD)
Deviation Check	Open (OP)		Open (OP)
Quality Control Data Check	Error (ER)	Open (OP)	Open (OP)
Transport Check	Error (ER)	Not Completed (ND)	Not Completed (ND)

New release decision item:

System-Calculated Release Check Status	Manually Set Release Check Status	Release Check Status
To Be Reviewed (TR)		To Be Reviewed (TR)
Closed (CL)		Closed (CL)
Compliant (CT)		Compliant (CT)
Completed (CD)		Completed (CD)

In summary, all the manually set release check statuses are reset, and the latest system-calculated statuses apply.

4.5.15 Regenerating Release Decision Items

Regenerate a release decision item to recreate it with the latest configuration settings.

Prerequisites

- The release decision item has one of the following processing statuses:
  - *New*
  - *In Progress*
  - *Canceled*
  - *Released Externally*
- You're authorized to regenerate release decision items.
  The business role assigned to your user must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

Context

Occasionally, an administrator may need to adjust the configuration of SAP Batch Release Hub for Life Sciences, for example, to introduce a new release check. If requested to do so, you need to regenerate any new and in progress items in your worklist to recreate them with the latest configuration settings. If necessary, you can regenerate a canceled release decision item. You can also regenerate an item if you need to change the release type.

Procedure

1. Open the *My Release Decisions* app.
2. Select a release decision item that has the processing status *New*, *In Progress*, *Canceled*, or *Released Externally*.
3. Choose *Regenerate*.

   A dialog appears asking you to confirm that you want to regenerate the selected release decision item. You can also change the release type of the release decision item if required. You must enter a mandatory comment to explain the reason for the regeneration. The comment is not displayed in the release decision item details, but is recorded in the change history of the original item.
4. In the *Regenerate* dialog, select the release type, enter a comment, and choose *Regenerate*.

   A new release decision item is created for the same combination of material, batch, and location represented by the selected item. The new item is updated with the latest configuration information from the system and the relevant release checks are triggered again. The status of the new item is set to *In Progress* and the status of the original item is set to *Obsolete*. The new release decision item is automatically assigned to you.
5. Check the new item for updated information and start processing it.

Related Information

Processing Status [page 23]
Checking if Items Were Regenerated or Reprocessed [page 99]

4.5.16 Changing the Release Type of Release Decision Items

Change the release type of a release decision item by regenerating it.

Prerequisites

- The release decision item has the processing status *New*, *In Progress*, or *Canceled*.
- You're authorized to regenerate release decision items.
  The business role assigned to your user must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.

Procedure

1. Open the *My Release Decisions* app.
2. Select a release decision item that has the processing status *New*, *In Progress*, or *Canceled*.
3. Choose *Regenerate*.

   A message appears asking you to confirm that you want to regenerate the selected release decision item. You also have an option to change the release type of the release decision item.
4. Select the new release type and choose *Regenerate*.

   A new release decision item is created for the same combination of material, batch, and location represented by the selected item. The new item is updated with the latest information from the source system and the relevant release checks for the new release type are triggered. The status of the new item is set to *In Progress* and the status of the original item is set to *Obsolete*. The new release decision item is automatically assigned to you.
5. Check the new item and start processing it.

Related Information

Processing Status [page 23]

4.5.17 Checking if Items Were Regenerated or Reprocessed

Add the *Successor Item* column to your worklist to see whether a release decision item was created as a result of reprocessing or regeneration.

Procedure

1. Open the *My Release Decisions* app.
2. Choose *View Settings*.
3. On the *Columns* tab, select *Successor Item*.
4. Choose *OK*.

Successor Item has the following possible values:

Value Shown	What It Means
Reprocessed by User or *Reprocessed by System*	The successor item is a copy of a completed or confirmed release decision item. Reprocessing has been triggered either manually by a user or automatically by the system. Whether reprocessing is possible for an item depends on how release types are configured in your system.
Regenerated by User or *Regenerated by System*	The successor item is a new release decision item for the same combination of material, batch, plant, release type, and release decision trigger represented by the item that was selected for regeneration. Regeneration has been triggered either manually by a user or automatically by the system. The item that was selected for regeneration was marked as obsolete.
No value	The release decision item hasn't been reprocessed or re-generated.

4.5.18 Canceling Release Decision Items

Set the processing status of a release decision item to *Canceled*.

Prerequisites

- You're authorized to set the status of release decision items to *Canceled*.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The release decision item has the status *New* or *In Progress*.

Context

If a release decision item is no longer required, you can set its processing status to *Canceled*. When a release decision item is set to canceled, it is no longer updated from the source system and you cannot make any further changes to it.

You can regenerate a canceled release decision item if necessary.

Procedure

1. Open the *My Release Decisions* app.
2. Select the release decision items that you want to set to *Canceled*.

   You can select one or more release decision items. Note that only items that have the processing status *New* or *In Progress* can be canceled.
3. Choose *Set to Canceled*.
4. In the dialog that appears, enter a comment to explain the reason for the cancellation.
5. Confirm your entries.

Related Information

Processing Status [page 23]

4.5.19 Viewing the Change History for Release Decision Items

View a list of all the changes made to a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Context

SAP Batch Release Hub for Life Sciences automatically records all the changes made to a release decision item. You can view the change history of a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Procedure

1. Open the relevant app for the release decision: *My Release Decisions* for batch release decisions or *My PCN Release Decisions* for PCN release decisions for clinical trials.
2. In the worklist, find the entry for which you want to view the change history.
3. Open the details of the release decision item.
4. Choose the *View Change History* button in the header area.

   A list of all the changes to the release decision item is displayed. For each change, you can see the attribute that was changed, the person who made the change, the date of the change, and the before and after attribute values.

4.5.20 Batch Release Decision Items for Clinical Trials

Learn how to optimize the layout of your worklist for working with clinical trial batches in the *My Release Decisions* app.

> **Note**
>
> If you are using the *My PCN Release Decisions* app to process clinial trial batches, PCN-related release decision items are not displayed in the *My Release Decisions* app. This section is relevant only if you are not using the *My PCN Release Decisions* app to process clinical trial batches.

For batch release decisions that relate to clinical trials, additional information is provided from your source system (for example, packaging control number (*PCN*), *Study*, and *Protocol ID*). These additional attributes are not shown in your worklist in the *My Release Decisions* app by default. To work with clinical trial batches, you need to adjust your settings to display the additional columns that you would like to see. You can also adjust your settings to group your release decision items by *PCN*. Once you have arranged your worklist in your preferred layout, you can save your view so that you can easily return to it as necessary.

Optimizing the Layout of Your Worklist

You Want To	What To Do
Show information related to clinical trials in my worklist.	1. Choose ⚙ *View Settings*. 2. On the *Columns* tab, select the columns that you would like to see. 3. Choose *OK*.
View release decision items with the same PCN together.	1. Choose ⚙ *View Settings*. 2. Go to the *Group* tab. 3. Select *PCN* as the column to group by. 4. Choose *OK*.

You Want To	What To Do
Save the view I have created so that I can easily return to it.	1. Choose *My Views*. 2. Choose *Save As* and enter a name for the view. 3. (Optional) Specify if you want to save the new view as your default view and if you want to apply the view automatically. If you apply a view automatically, you don't have to choose *Go* to apply the filters that you've set as part of the view. 4. Choose *Save*.

4.6 Reports

This section summarizes the types of reports that you can create in SAP Batch Release Hub for Life Sciences.

4.6.1 Creating Release Decision Reports

Use the *My Release Decisions* app to create a report that includes all the information relating to a single release decision.

Prerequisites

- The processing status of the release decision item must be *Completed* or *Confirmed*.
- The SAP Forms service by Adobe has been set up.
  For more information, see (Optional) Configure Output Management for SAP Forms Service by Adobe.

Context

Once a release decision has been set, you can create a report for the release decision item. The report includes all of the information relating to the particular release decision, including the details of each release check. The information for a release decision item can be extensive. Therefore, depending on the size of the release decision item, the report consists of multiple documents.

Options for Extending the Release Decision Report Output

> **Note**
>
> The release decision report is in maintenance mode, and no further functional enhancements will be delivered.

If you require additional capabilities beyond the standard report, such as custom layouts, extended content, or advanced formatting, the following options are available:

- Use an Approved Partner Solution
  You can use an approved partner solution, such as Tenthpin Intelligent Certificate Generation (T/ICG), which is designed to integrate with SAP Batch Release Hub for Life Sciences.
- Enhance the PDF Template
  The release decision report is generated using the SAP Forms service by Adobe. A standard PDF template is provided. However, you can create your own customized template using the Adobe LiveCycle Designer. Note that customization options are limited by the constraints of the existing template architecture. For more information, see Using the Adobe LiveCycle Designer.
- Create a Custom Report Solution Using the `Release Decisions` API
  SAP Batch Release Hub for Life Sciences provides the `Release Decisions` API that can be used as the basis for building a fully custom report solution. This option provides the greatest degree of flexibility and control over the output format and content, but requires dedicated development resources and ongoing maintenance. For more information, see Release Decisions on the SAP Business Accelerator Hub.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to create a report.

   The processing status of the release decision item must be *Completed* or *Confirmed*.
3. Open the details of the release decision item.
4. Choose *Create Report*.

   > **Note**
   >
   > If the report has already been created, the title of the button is *View Report*. You can already choose *View Report* to open the *Report* screen and view the report.
5. In the *Create Report* dialog that opens, choose *Create* to confirm that you want to create the report.

   The creation of the report can take a few minutes, but you can continue working. You will receive a notification when the report is ready.
6. When the report is ready, open the details of the release decision item again.

   Once the report has been created, the title of the button changes from *Create Report* to *View Report*.
7. Choose *View Report*.

   In the *Report* screen that opens, you can download and view the report documents.

Related Information

Release Decision Item [page 29]
Setting Batch Release Decisions [page 87]
Life Cycle of Batch Release Decision Items [page 59]

4.6.1.1 Output Management: Splitting of Large Reports (PDF Chunking)

When a release decision report contains a large number of records, SAP Batch Release Hub for Life Sciences automatically splits the PDF output into multiple smaller files for more efficient and reliable report generation.

Why Reports Are Split

The SAP Forms service by Adobe (ADS) has performance limits when generating very large PDF documents. To ensure reliable and fast report generation, SAP Batch Release Hub for Life Sciences automatically splits oversized sections into separate PDF files rather than producing a single large PDF file that could fail or time out.

When Splitting Occurs

Splitting is triggered based on the number of records in specific sections of the report as follows:

- If the section contains more than 100 records, it is split into multiple files.
- Checklist items are evaluated for all custom release checks together. If the number of checklist item records in the entire report exceeds 800, every checklist item section is split.

The following sections of a report can be split:

- Component details for enhanced release checks such as:
  - Batch Record Review
  - Certificate Check
  - Change Control Data Check
  - Deviation Check
  - Quality Control Data Check
- Component trees and component flat lists
- Change control records
- Checklist items in custom release checks
- Additional batch characteristics

What You See in the Application

When a release decision report is split, the *Report Documents* area shows multiple PDF files instead of one. Each file covers a portion of the affected section. For example, if the change control records section of a report generated on July 15, 2026 is split, you might see the following files listed:

- Report_20260715_060798_CHANGE_1.pdf
- Report_20260715_060798_CHANGE_2.pdf

- Report_20260715_060798_CHANGE_3.pdf

Each split file is named after the section it contains and numbered consecutively. Sections without a specific section code use "Chunk" as the default identifier, for example, Report_20260715_060798_Chunk_1.pdf.

The unsplit sections of the report remain in the main PDF file. You need to download all files to have the complete report.

4.6.2 Creating Release Register Reports

Use the *My Release Register* app to export a summary of the release decisions made in one or more locations.

Prerequisites

- You're authorized to create a release register.
- You're assigned to at least one location in the *Manage Quality Departments* app.

  > **Note**
  >
  > You can create a release register only for the locations that you are assigned to.

- The SAP Forms service by Adobe has been set up.
  For more information, see (Optional) Configure Output Management for SAP Forms Service by Adobe.

Context

You can use the *My Release Register* app to create a formal report of the completed and confirmed release decisions made in one or more locations. You can use various filter criteria to identify the release decisions that you are interested in.

Once you have identified the list of relevant release decisions, you can export the list to a PDF report that is suitable for audit purposes. In addition to the list of release decisions, the release register report includes the name of the person who created the report, the date and time that the report was created, and the filter criteria used to generate the report.

Procedure

1. Open the *My Release Register* app.
2. Enter your filter criteria and choose *Go*.

   At minimum, you must select at least one *Batch Location*. Note that you can choose only from the locations and the quality departments that you are assigned to.

3. Choose *Export Register*.

   The release register report is generated in PDF format and then automatically downloaded.

Related Information

Release Decision [page 27]
Setting Batch Release Decisions [page 87]
Life Cycle of Batch Release Decision Items [page 59]

5 PCN Release Decisions

This section describes how you prepare, review, and set release decisions that are related to clinical trials using the *My PCN Release Decisions* app.

In a clinical trial, a packaging control number (PCN) is used to group together finished material batches that belong together in terms of blinding. This means that the batches assigned to the PCN must be managed and released together for the purposes of the clinical trial. The *My PCN Release Decisions* app helps to streamline this process by allowing you to manage, review, and set release decisions at PCN level, rather than for each individual batch.

Working With PCN Release Decisions

The *My PCN Release Decisions* app presents you with a worklist of PCN release decision items. You see only the items that fall within your responsibility in the quality departments to which you are assigned. In addition, for a release for a particular country/region, the PCN release decision item will be read-only unless you are assigned a PCN user authorization for the country/region in the *Manage Release Configurations* app.

Assigned Batches

Each PCN release decision item has a number of related batch-level release decision items (one for each assigned batch). The batch-level release decision items are created after the PCN release decision item and can be created at different times. You can see the total number of batches assigned to the PCN and the number of those batches that have a release decision item in the *Number of Batches with Release Decision Item* column in your worklist.

You can view all the details for an assigned batch, but you cannot make any changes to an individual batch release decision item. In addition, the PCN-related batch release decision items that are relevant for the *My PCN Release Decisions* app are not shown in the *My Release Decisions* app.

> → Tip
>
> A PCN release decision item cannot have two batch-level release decision items for the same batch. The system rejects any subsequent release decision triggers for an existing assigned batch. If a release decision trigger with the incorrect type is sent initially, the only way to resolve the scenario is to cancel all the items created by the PCN release process flow for your trigger. Then, send the PCN release decision trigger again to create a new PCN release decision item, and send the correct release decision triggers for the assigned batches. This procedure must be performed immediately after the creation of the PCN release decision items. It does not work if one of the items created by the PCN release process flow is not canceled. For example, this procedure does not work if an item related to the PCN release decision trigger is already completed/confirmed or was previously regenerated.

Release Checks

The release checks in the *My PCN Release Decisions* app can be performed at either batch level or PCN level depending on the release check type as follows:

Level at Which the Release is Performed	Release Check Type
PCN Level These release checks are listed in the *PCN Release Check Summary* section when they are relevant for the release type.	• PCN Certificate Check • PCN Ethics Committee Approval Check • Custom Release Checks
Batch Level These release checks are listed in the *Batch Release Check Summary* section when they are relevant for the release type.	• Annual Product Quality Review (APQR) Check • Artwork and Safety Label Check • Batch Genealogy Check • Batch Record Review • Certificate Check • Change Control Data Check • Clinical Trial Check • Component Check • Deviation Check • Quality Control Data Check • Regulatory Data Check • Serialization Data Check • Temperature Check • Transport Check

⚠ Restriction

The Jurisdictional Control Check is not supported in the *My PCN Release Decisions* app.

When release checks are performed at batch level, an aggregated release check status is calculated for the PCN. You can see a summary of the all the release checks and their aggregated statuses in the *Release Checks* column in your worklist. To view the release checks and the assigned batches in detail, choose an item in your worklist. If your configuration settings permit, you can change the status of a release check for a PCN release decision item. The new release check status is applied to each of the batches assigned to the PCN release decision item. You can view the details of an individual batch release decision item, but you cannot make any changes to it.

How Are Release Check Statuses Aggregated?

The batches assigned to each PCN release decision item have the same set of release checks. The release checks are evaluated separately for each batch, so at a point in time, the batches could have different statuses for the same release check. SAP Batch Release Hub for Life Sciences calculates the aggregated status of a particular release check by taking the most severe status for the assigned batches. For example, if there are 5 assigned batches, and the status of a particular release check is green for 4 batches and red for 1 batch, then the aggregated release check status is red.

The severity is applied in the following order:

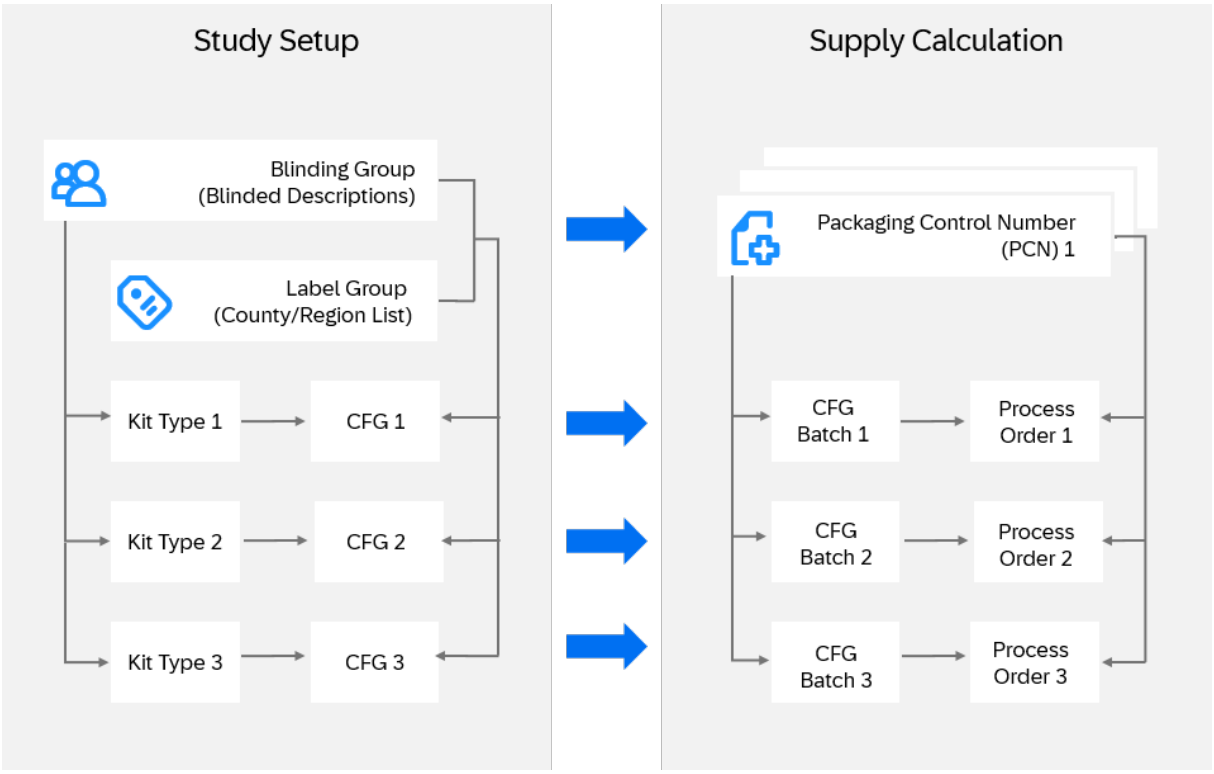
1. Red
2. Yellow
3. Gray
4. Green

> **Note**
>
> As gray is regarded as more severe than green, the release check status cannot be green if there are any pending assigned batches.

5.1 Example: Study Setup and Supply Calculation

See this example of a clinical study and the related supply calculation to understand how packaging control numbers (PCNs) are used.

The diagram below shows an example of a clinical study with a blinding group, a label group, and three different kit types that correspond to three different clinical finished goods (CFGs). In the supply calculation for the clinical study, there are three process orders (one for each CFG batch), and the three CFG batches are assigned to a PCN to maintain the grouping and ensure the CFG batches are blinded together. Over time, as more batches are manufactured for the study, there are further process orders and new PCNs to group the CFG batches that belong together.



5.2 Life Cycle of PCN Release Decision Items

PCN release decision items in the *My PCN Release Decisions* app go through a sequence of processing steps, which are reflected by the *PCN Processing Status*.

The following diagram illustrates the typical processing flow for a PCN release decision item in the *My PCN Release Decisions* app:

- Life Cycle of PCN Release Decision Items [page 111]
- Life Cycle of PCN Release Decision Items [page 111]
- Life Cycle of PCN Release Decision Items [page 111]
- Life Cycle of PCN Release Decision Items [page 111]
- Life Cycle of PCN Release Decision Items [page 111]

Here's a detailed list of all the possible processing statuses:

PCN Processing Status	What It Means
New	Processing of the item has not yet started.
In Progress	Processing of the item has started. A user has made a manual change. For example, an attachment has been uploaded or a release check status has been changed.
Release in Progress	A PCN release decision has been set for the item and the system is performing the following steps in the background: • Creating a snapshot of all the data for the PCN release decision item • Rerunning the business rules for the release checks • Freezing all the data for the PCN release decision item • Sending the PCN release decision details to the source system
Completed	The PCN release decision has been set and the background processing has completed. The item can no longer be changed. The decision has not yet been confirmed in the source system for the PCN.

PCN Processing Status	What It Means
Confirmed	Follow-on processing in the source system has been completed and all the assigned batch release decision items have been confirmed. Once all the assigned batch release decision items have been confirmed, the status of the PCN release decision item is set to *Confirmed*.
Obsolete	The item was manually regenerated by a responsible person. When an item is regenerated, a new item is created with the latest configuration settings. Obsolete items can no longer be changed.
Canceled	The item was manually set to canceled by a responsible person. Only new and in progress items can be set to canceled. Canceled items can no longer be changed.
Regeneration in Progress	The item was manually regenerated by a responsible person. The system is in the process of creating a new item with the latest configuration settings. When the regeneration has completed, this item will be set to the processing status *Obsolete*.

Related Information

Final System Checks Before Setting the Release Decision [page 90]

5.3 Working on PCN Release Decision Items

Here's a summary of what you can do in the *My PCN Release Decisions* app with links to step-by-step instructions.

You Want To	More Information
Organize the PCN release decision items in your worklist according to priority and responsibility.	• Assigning PCN Release Decision Items for Processing [page 113] • Prioritizing PCN Release Decision Items [page 114]
See more information about the PCN release process flow and see the status of the predecessor item.	• Viewing the Predecessor Item Details [page 124]

You Want To	More Information
Verify the release checks for a PCN release decision item and set a PCN release decision.	• Reviewing the Release Checks for PCN Release Decision Items [page 117] • Changing the Status of PCN Release Checks [page 119] • Editing the Suitability of Countries/Regions for PCNs [page 121] • Working with Attachments [page 83] • Setting PCN Release Decisions [page 126]
Update a PCN release decision item to include new information, configuration changes, or other business changes.	• Reprocessing PCN Release Decision Items [page 130] • Regenerating PCN Release Decision Items [page 131] • Changing the Release Type of PCN Release Decision Items [page 133]
Cancel a PCN release decision item that is no longer required.	• Canceling PCN Release Decision Items [page 135]
View all the changes made to a PCN release decision item.	• Viewing the Change History for Release Decision Items [page 101]

5.3.1 Assigning PCN Release Decision Items for Processing

Assign a PCN release decision item to yourself or someone else.

Prerequisites

- You're authorized to assign PCN release decision items.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Context

If you're responsible for distributing work within your team, you can assign PCN release decision items to people who are in the same quality department and have the same responsibilities as you.

> **Note**
>
> Once a PCN release decision item has been assigned for processing, you can change the assignment but you can't unassign the item completely.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select the PCN release decision item that you'd like to assign.
3. Choose *Assign*.
4. Enter the name of the person you want to assign and choose *Assign*.

   If you want to assign the item to yourself, choose *Assign to Me* instead of entering a name.

5.3.2 Prioritizing PCN Release Decision Items

Set a prioritized due date for a PCN release decision item.

Prerequisites

- You're authorized to set prioritized due dates for PCN release decision items.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Context

Each PCN release decision item in your worklist has a *Due Date*, which is set in the source system. To help you manage your workload, you can optionally set a separate *Prioritized Due Date*. The *Prioritized Due Date* is a separate field and does not change the original *Due Date* from the source system.

> **→ Tip**
>
> If you do not see the *Prioritized Due Date* column in your worklist, you can add it by going to your settings and selecting *Prioritized Due Date*.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select the PCN release decision item that you want to prioritize.
3. Choose *Set Prioritized Due Date*.
4. Enter the required prioritized due date.

   You must enter a date in the future.
5. Save your changes.

5.3.3 Reviewing the Assigned Batches for PCN Release Decision Items

Check the details of the batches assigned to a PCN release decision item in the *My PCN Release Decisions* app.

Prerequisites

- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Context

In the *My PCN Release Decisions* app, each PCN release decision item has a number of related batch-level release decision items, which must be processed together. The batch-level release decision items are created after the PCN release decision item and could be created at different times.

Here are the possible statuses for an assigned batch:

Status of Assigned Batch	What It Means
Available	The release decision item for the assigned batch is ready for review and release.
Pending	The release decision item for the assigned batch has not been created yet. This can happen, for example, if the batch has not been manufactured yet or if the goods receipt has not happened yet.

Status of Assigned Batch	What It Means
Not Relevant	The assigned batch is not included in the PCN stock transport order for a stock transport to depot scenario. A release decision item will not be created for this batch as it is not relevant for the PCN release decision.

> **Note**
>
> You cannot set a PCN release decision if any of the assigned batches are in the status *Pending*.

Procedure

1. Open the *My PCN Release Decisions* app.
2. In the worklist, find the entry for which you want to review the assigned batches.
3. Check the *Number of Batches with Release Decision Item* column.

   This column shows the total number of batches assigned to the PCN release decision item and the number of those batches that have a release decision item.
4. Open the details of the PCN release decision item.
5. Go to the *Assigned Batches* section.

   This section lists all the batches assigned to the PCN release decision item. Each row in the table represents a release decision item for an assigned batch. All of the assigned batches are subject to the same release checks.

   The PCN release decision item is created before the batch release decision items. If the creation of a batch release decision item is still pending, some details will be missing in this table.

   Note that the *Release Quantity* shows either the order quantity or the goods receipt quantity, depending on whether the goods receipt has been performed. Before the goods receipt is performed, the order quantity is displayed. After the goods receipt is performed, the goods receipt quantity is displayed.
6. Open the details of an assigned batch.
   You can review the complete details for the batch, including the release check details. Note that you cannot make any changes to an assigned batch.

5.3.4 Reviewing the Release Checks for PCN Release Decision Items

Check the details of the release checks for a PCN release decision item in the *My PCN Release Decisions* app.

Prerequisites

- You're authorized to view release check details or change the status of a release check.
  To change the status of a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To view details, the release activity *Release Review* is sufficient.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- Changes are possible only if the PCN release decision item has the processing status *New* or *In Progress*.

Context

The release type assigned to each PCN release decision item determines which release checks must be completed before a PCN release decision can be set for the item. The release checks cover the specifications, characteristics, or attributes relevant for the particular release type. As part of the release decision process, you review the details of all the release checks for the PCN release decision item. If necessary, and if your configuration permits, you can change the status of a release check. Ensure that all the release checks are completed and have an acceptable status before you set a PCN release decision.

You can review the release checks at the following levels:

- PCN Level
  On the PCN release decision item details page, you can review the aggregated statuses of the release checks and also see a summary of the release check statuses for the assigned batches. If your configuration permits, you can change the status of a release check. The change applies to all the batches assigned to the PCN.
- Batch Level
  From the PCN release decision item details page, you can open the details of an assigned batch, and then open the details of the individual release checks for the assigned batch. The information is read-only. You cannot change the status of a release check for an individual assigned batch.

Procedure

1. Open the *My PCN Release Decisions* app.

2. In the worklist, find the entry for which you want to review the release check details.
3. Check the color-coded bar chart in the *Release Checks* column.

   You can choose the bar chart to see an overview of the release checks and their aggregated statuses.

   All of the batches that are assigned to the PCN are subject to the same set of release checks. The release checks are evaluated separately for each batch, and the batches could have different statuses for the same release check. SAP Batch Release Hub for Life Sciences calculates the aggregated status of a particular release check by taking the most severe status for the assigned batches. For example, if there are 5 assigned batches, and the status of a particular release check is green for 4 batches and red for 1 batch, then the aggregated release check status is red.
4. Open the details of the PCN release decision item.
5. Go to the *PCN Release Check Summary* section.

   This section shows a list of all the release checks and their aggregated statuses.
6. Check if there are any comments for each release check.

   You can choose the number in the *Comments* column to see the comments.
7. Go to the *Assigned Batches* section.
8. Check the color-coded bar chart in the *Release Checks* column.

   This column shows an overview of the release checks and their statuses for each assigned batch.
9. Open the details of an assigned batch.
10. Go to the *Release Check Summary* section.

    This section shows the list of release checks for the assigned batch with the status for the specific batch.
11. Open the details of a release check.
12. Check any comments for the release check.
13. Check any release check messages.

    Release check messages are generated for release checks that are carried out by the system based on a defined business rule. These messages provide additional clarification if a release check ends in errors or warnings. Informational messages are also shown here, for example, to show that a check was completed.

Next Steps

If the release check is configured to allow manual setting by a user and you're authorized to do so, you can go to the PCN release decision item details page and change the release check status if necessary. Note that you cannot change the release check status for an individual batch. You can only change the release check status for the PCN, and the change applies to all the assigned batches.

Related Information

Changing the Status of PCN Release Checks [page 119]

5.3.5 Changing the Status of PCN Release Checks

Change the status of a release check in the *My PCN Release Decisions* app to indicate the result of the check.

Prerequisites

- You're authorized to change the status of release checks.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The PCN release decision item has the processing status *New* or *In Progress*.
- The release check is configured to allow manual setting by a user.

Context

The configuration of a release check in your system controls how the release check status is determined: by the system, by the user, or both. The following table gives you an overview of what this means for you when working with release checks:

Release Check Status Set By	How It Works
System	• The release check status is determined automatically based on the business rule that's assigned to the release check. • The status can't be changed manually in the *My Release Decisions* app or the *My PCN Release Decisions* app. • Until a release decision is set for the item, the release check status is updated automatically whenever relevant new data is received from the source system.
User	• You set the release check status manually in the release check details in the *My Release Decisions* app or the *My PCN Release Decisions* app. • The release check status doesn't depend on data automatically received from a source system.

Release Check Status Set By	How It Works
System or User	• The initial release check status is determined automatically based on the assigned business rule. • You can change the status manually in the *My Release Decisions* app or the *My PCN Release Decisions* app. • If the automatic reset of a release check status is enabled in your configuration settings, the release check status is reset when new release check data is received from the source system or when you manually change the release check data. If the automatic reset is not enabled, then once a status is changed manually, it is no longer updated automatically, and the manual status change takes precedence over any automatic status changes.

> **Note**
>
> If a release check has the status *Pending* (gray), either information hasn't yet been received from the relevant source system or the release check hasn't yet been set manually.

Procedure

1. Open the *My PCN Release Decisions* app.
2. In the worklist, find the entry for which you want to change the release check status.
3. Open the details of the PCN release decision item.
4. Go to the *PCN Release Check Summary* section.
5. Select the release check for which you want to change the status.

   If the release check is configured to allow manual setting by a user, the *Change Status* button is enabled.
6. Choose *Change Status*.
7. In the dialog that opens, select the new status and add a comment.
8. Save your entries.

5.3.6 Editing the Suitability of Countries/Regions for PCNs

Review and, if necessary, adjust the suitability of the countries/regions assigned to a PCN release decision item in the *My PCN Release Decisions* app.

Prerequisites

- You're authorized to change the suitability of the countries/regions for a PCN release decision item. The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The PCN release decision item has the processing status *New* or *In Progress*.

Context

As part of the PCN release decision process, you review the countries/regions assigned to the PCN release decision item. You cannot add or remove a country/region, but if necessary, you can change the suitability of a country/region. Your changes are sent to the source system when the PCN release decision is set.

Procedure

1. Open the *My PCN Release Decisions* app.
2. In the worklist, find the PCN release decision item for which you want to review the countries/regions.
3. Open the details of the PCN release decision item.
4. Go to the *Countries/Regions* section and review the assigned countries/regions and suitability settings.
5. **Optional:** If necessary, change the suitability of a country/region as follows:
    a. Select the relevant countries/regions.
    b. Choose *Edit Suitability*.
    c. Select the required suitability.
    d. Choose *OK*.

Results

Any changes that you make to the suitability of the countries/regions for the PCN are sent to your source system when the PCN release decision is set.

5.3.7 Working with Attachments

Use attachments to gather additional information for release decision items in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Prerequisites

- You're authorized to manage attachments.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To view attachments, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
  In addition, if you are working on a PCN release decision item that is created by a country/region split, you must be assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The processing status of the release decision item is *New* or *In Progress*.

Context

You can upload attachments at the following levels:

- For a release decision item
- For a specific release check in a release decision item
  In the *My PCN Release Decisions* app, you can upload attachments for PCN-level release checks, but not for batch-level release checks.

You can upload files of the following formats with a maximum file size of 40 MB.

> ⚠ Caution
>
> In general, we recommend you upload small files. Only upload large files when absolutely necessary.

File Type	Allowed File Formats
Document	• .pdf • .ppt and .pptx • .txt • .rtf • .doc and .docx • .xls and .xlsx • .csv

File Type	Allowed File Formats
Image	• .png • .jpg • .jpeg • .gif • .svg

Once an attachment has been uploaded, it can't be removed. If an attachment becomes outdated or is no longer relevant, you can set it as inactive. Please note that this action can't be undone. Inactive attachments can't be reactivated. In addition, you can't inactivate attachments that have been used to generate AI-based proposals in the AI-assisted custom release check.

When a release decision is set, the release decision item is "frozen". At that point, you can no longer upload or inactivate attachments, but you can still download active attachments.

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app.
2. In the worklist, find the release decision item that you want to work on.
3. Open the details of the release decision item.

   You can go to the *Attachments* section and upload an attachment here at the item level, or you can upload an attachment for a specific release check.
4. To upload an attachment for a specific release check, open the details of the relevant release check.

   In the *My Release Decisions* app, you can open any of the release checks listed in the *Release Check Summary* section. In the *My PCN Release Decisions* app, you can open any of the PCN-level release checks listed in the *PCN Release Check Summary* section.
5. Go to the *Attachments* section, and follow the steps below for your specific task:

Task	What To Do
Upload an attachment	1. Choose *Upload*. 2. Select one or more files to upload. 3. Confirm your selection.
Download an attachment	1. Select one or more attachments. 2. Choose *Download*. You can also download a single attachment by clicking the hyperlinked file name. **Note** Only active attachments can be downloaded.

Task	What To Do
Set an attachment as inactive	1. Select one or more attachments. 2. Choose ... > *Set as Inactive*. 3. Enter a comment. 4. Choose *Set*.
Set an attachment as AI-relevant	1. Select one or more attachments. 2. Choose ... > *Set as AI-Relevant*. **Note** This option is available only in an AI-assisted custom release check.

Tip

In the *Attachments* table, you can choose *(Additional Information)* to display technical details that you can use to locate the relevant document in its storage location.

5.3.8 Viewing the Predecessor Item Details

Add the *Predecessor Item* and *Status of Predecessor Item* columns to your worklist in the *My PCN Release Decisions* app, and optionally, open the details of the predecessor item.

Context

Each PCN release decision item in your worklist is part of a sequence of steps based on a PCN release process flow. To help you understand the overall PCN release process flow and see whether the predecessor item has been processed, you can add the *Predecessor Item* and *Status of Predecessor Item* columns to your worklist. The *Predecessor Item* column displays the release type of the predecessor item and provides a link so that you can open the details of the item.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Choose *View Settings*.
3. On the *Columns* tab, select *Predecessor Item* and *Status of Predecessor Item*.
4. Choose *OK*.

5. **Optional:** Choose the link in the *Predecessor Item* column to open the details of the predecessor item.

5.3.9 Completing Custom Release Checks

Complete a custom release check by entering results and valuations for all the mandatory checklist items and then setting the release check status.

Prerequisites

- You are authorized to change release checks.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
  In addition, if you are working on a PCN release decision item that is created by a country/region split, you must be assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The release decision item has the processing status *New* or *In Progress*.
- The custom release check has been configured and assigned to the appropriate release types in the *Manage Release Configurations* app.

Context

Custom release checks are used to implement manual checking activities for release decision items. A custom release check consists of a list of checklist items that must be completed manually and without the support of a connected source system. To complete a custom release check, you must enter a result and a valuation for each mandatory checklist item. When all mandatory checklist items are completed, you can set the status of the custom release check.

Custom release checks are supported in both the *My Release Decisions* app and the *My PCN Release Decisions* app. For PCN release decision items, custom release checks are completed at the PCN level, and not for the individual assigned batches.

> **Note**
>
> This section describes how to complete a custom release check manually without the support of SAP Business AI. If AI features are enabled in your system and the custom release check is configured to allow AI-based proposals, you can use SAP Business AI to help you complete the release check. For more information, see SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 189].

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app as appropriate.
2. In the worklist, find the release decision item that has the custom release check that you want to review.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section in the *My Release Decisions* app or the *PCN Release Check Summary* section in the *My PCN Release Decisions* app.
5. Open the details of the custom release check.
6. In the *Checklist Items* section, select one or more checklist items.
7. Choose *Complete Checklist Item*.
8. In the *Complete Checklist Item* dialog, enter a result, a valuation, and an optional comment for each checklist item.

   Depending on how each checklist item is configured:

   - You can either choose a predefined result or enter a result yourself.
   - You can choose a valuation or the valuation is filled automatically based on the entered result. The valuation specifies the status of a checklist item, for example, whether it's compliant or not compliant. Valuations that have been configured as "Red" or "Yellow" are displayed in their configured color, so you can easily identify items that do not have a positive valuation.
9. Save your entries.

   Your entries are saved and displayed in the *Items* table. When all mandatory checklist items are completed, you can change the status of the release check.
10. Choose the *Change Status* button in the header area.
11. In the dialog that opens, select the release check status and add a comment.
12. Save your entries.

5.3.10 Setting PCN Release Decisions

Set a PCN release decision for a PCN release decision item when work on the item is finished and all the relevant release checks have been completed.

Prerequisites

- You're authorized to set PCN release decisions.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

- There is a release decision item for all the assigned batches.
- The suitability has been set for all the countries/regions.
- If a predecessor item exists, it has been processed.
- The *Business Rule Status* is *Active*.
- You have reviewed all the release checks and they all have an appropriate status.

Context

What Happens When You Set a PCN Release Decision?

When you set a PCN release decision, the processing status of the item initially changes to *Release in Progress* while the system performs the following steps:

- Creates a snapshot of all the data for the PCN release decision item
- Reruns the business rules for the release checks (this step is also called the "safety net")

> **Note**
>
> If the rerun of the business rules results in a change in a release check status, the release is stopped, and the status of the PCN release decision item returns to *In Progress*. This is to ensure you have the very latest information when you make the decision to release the PCN.

- Freezes all the data for the PCN release decision item
- Sends the PCN release decision details to the source system

When these steps are completed, the processing status of the item changes to *Completed*. The item can no longer be changed.

Procedure

1. Open the *My PCN Release Decisions* app.
2. In the worklist, find the entry for which you want to set a PCN release decision.
3. Open the details of the PCN release decision item.
4. Choose the *Set PCN Release Decision* button in the header area.
5. Select the PCN release decision that you want to set.
6. If required, enter a comment.
7. Enter your password.

   This is the same password that you use to sign in to the system.
8. Save your entries.

> **Note**
>
> Every attempt at setting a PCN release decision is logged, even if you cancel the process. As soon as you choose the *Set PCN Release Decision* button, a log record is created.

Results

Follow-On Processing and Confirmation

After the release decision is set, there is follow-on processing for each of the assigned batches in the source system. When the follow-on processing is completed and the release decision is confirmed for each assigned batch, the confirmation data for the batch is shown in the *PCN Release Decision* section in the *My PCN Release Decisions* app. Once the release decision is confirmed for all of the assigned batches, the processing status of the PCN release decision item changes to *Confirmed*.

Release Decision Certificates

If any release decision certificates are generated and sent to SAP Batch Release Hub for Life Sciences following the PCN release decision, they are displayed in the *Certificates* table in the *PCN Release Decision* section. The *Certificates* table is displayed only if certificates have been generated, and a link is provided so you can open each certificate and review it. The generation of PCN release decision certificates is a customer-specific task, which is done outside of SAP Batch Release Hub for Life Sciences.

5.3.10.1 Final System Checks Before Setting the Release Decision

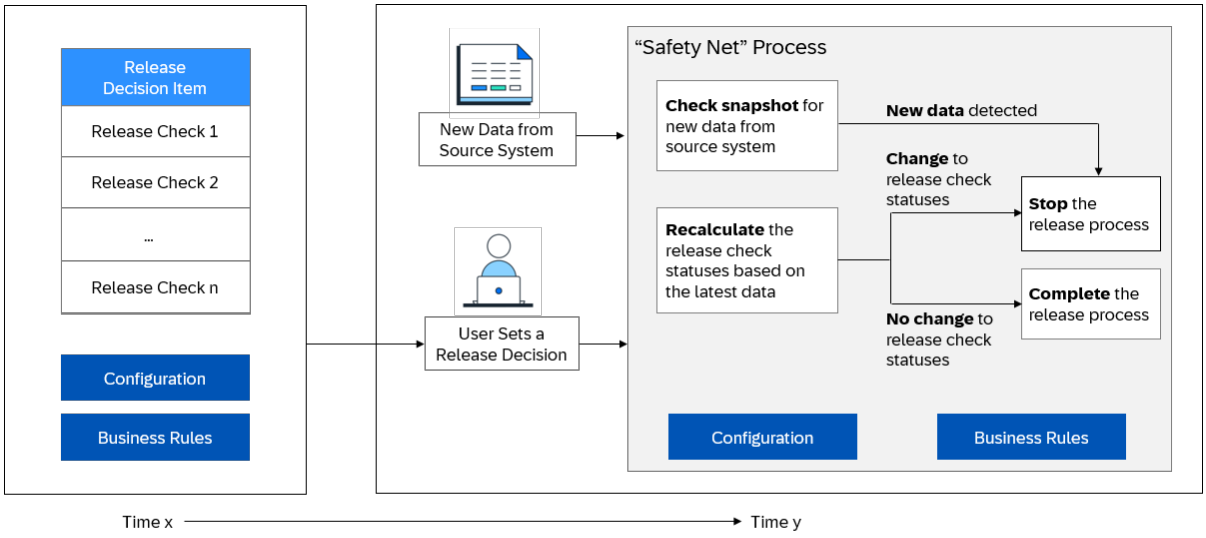
When you set a release decision, the system checks whether any data in the release decision item has changed and reruns the business rules. This feature acts as a "safety net" that ensures your decision is based on the very latest data.

The system changes the processing status of the release decision item to *Release in Progress* while it performs the following steps:

- Checks whether any data in the release decision item has changed
  As part of the release decision processing, the system creates a copy of all the data in the release decision item, which is known as a snapshot. This check ensures the snapshot reflects exactly what you saw in the system when you chose the *Set Release Decision* button. Note that some data changes might not necessarily impact the release check statuses. For example, an attachment could be uploaded by another user while you are reviewing the release decision item.
  The release decision processing happens in the background and could be delayed depending on the overall system load. Once the snapshot is complete, the system checks the captured data. If it detects that the snapshot contains data that is newer than the point when the release decision was set (data that the user didn't see when setting the release decision), the processing is stopped.
- Reruns the business rules and recalculates the release check statuses
  All of the release checks that have an assigned business rule are reevaluated based on the latest data. The business rules run automatically whenever new data is received from the source systems. However, if new data is received shortly before or after you set a release decision, the automatic run of the business rules might not have completed yet. The "safety net" ensures that the business rules are completed and the release check statuses are up to date.
  When the business rules have completed, the following outcomes are possible:
  - The release decision is set and the processing status of the item changes to *Completed*.
    If the release check statuses are unchanged, the release decision processing continues and the release decision is set.

- The release decision is not set and the processing status of the item returns to *In Progress*.
  If a release check status is changed or if the business rules fail for any reason (for example, due to a deleted business rule project), the release decision process is stopped. You will receive a notification to inform you that the release decision was not set.

The following diagram illustrates the overall process:



Release decision items created at **time x** use the configuration settings and business rules of **time x.** Updates of the release checks use the configuration and business rules from **time x**.

The "Safety Net" runs the business rules on the latest data available in the system. The configuration settings and business rules from **time x** are used to calculate the new release check statuses.

What To Do When a Release Decision Is Not Set Successfully

If your release decision is not set successfully, please review the release decision item and the release check statuses again.

Here are some tips to help you figure out why your release decision was not set successfully:

- You can check the change history of the release decision item. If a release check status was changed by the rerun of the business rules, you will see it listed in the change history.
- You can also check the *Monitor Data Processing* app. The rerun of the business rules is recorded there and you can check the event status. New data received during the release process is also recorded there.

When you have reviewed the release decision item and all the release checks are completed to your satisfaction, you can set the release decision again.

Related Information

Business Rule [page 19]

5.3.11 Reprocessing PCN Release Decision Items

Create a copy of a *Completed* or *Confirmed* PCN release decision item for reprocessing.

Prerequisites

- Reprocessing is enabled in the configuration of the release type assigned to the PCN release decision item.
- Subsequent PCN release decisions are configured for the PCN release decision in the configuration of the release type assigned to the PCN release decision item.
- The PCN release decision item has the processing status *Completed* or *Confirmed*.
- You're authorized to reprocess PCN release decision items.
  The business role assigned to your user must have the release activity *Release Decision*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Context

It may be necessary to reprocess a completed or confirmed PCN release decision item, for example, if the initial PCN release decision was a preliminary one or if new business information requires the original decision to be revised. In such cases, you can create a copy of the completed or confirmed PCN release decision item for reprocessing.

> **Note**
>
> The steps described here refer to manual reprocessing of a PCN release decision item. If the release type is configured accordingly, reprocessing can also occur automatically. In this case, a new item is created as a copy immediately when the PCN release decision item is completed.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select an item that has the processing status *Completed* or *Confirmed*.
3. Choose *Reprocess*.
4. In the *Reprocess* dialog, enter a comment to explain the reason for the reprocessing and then choose *Reprocess* to confirm.

   A new PCN release decision item is created for the same combination of PCN, PCN version, location, release type, and PCN release decision trigger represented by the selected item. The new item is updated with the latest information from the source system and the relevant release checks are triggered again.

The following information is copied from the original item and remains unchanged:

- Key data, such as PCN, PCN version, location, release type, and PCN release decision trigger
- Prioritized due date
- Release check statuses that were set manually
- Comments
- Attachments

Your comment is not displayed in the PCN release decision item details, but is recorded in the change history of the original item.

5. Check the new item for updated information and start processing it.

   The following information is not copied from the original item and requires checking:

Information	What Happens to the Information
Release check statuses that were set by the system	Release check statuses are updated according to the latest changes in the source system.
Person responsible assigned to the item	The assignment is reset.
Countries/regions suitable for release	Manual changes are reset.
Confirmation from the source system	Confirmation data is cleared.

Related Information

Checking if Items Were Regenerated or Reprocessed [page 134]

5.3.12 Regenerating PCN Release Decision Items

Regenerate a PCN release decision item to recreate it with the latest configuration settings

Prerequisites

- The PCN release decision item has the processing status *New*, *In Progress*, or *Canceled*.
- You're authorized to regenerate PCN release decision items.
  The business role assigned to your user must have the release activity *Release Decision* or *Release Preparation*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Context

Occasionally, an administrator may need to adjust the configuration of SAP Batch Release Hub for Life Sciences, for example, to introduce a new release check. If requested to do so, you need to regenerate any new and in progress items in your worklist to recreate them with the latest configuration settings. If necessary, you can regenerate a canceled PCN release decision item.

You can also regenerate an item if you need to change the PCN release type.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select an item that has the processing status *New*, *In Progress* or *Canceled*.
3. Choose *Regenerate*.

   A dialog appears asking you to confirm that you want to regenerate the selected item. You can also change the release type of the PCN release decision item if required. You must enter a mandatory comment to explain the reason for the regeneration. Your comment is not displayed in the release decision item details, but is recorded in the change history of the original item.
4. In the *Regenerate* dialog, select the release type, enter a comment, and choose *Regenerate*.

   A new PCN release decision item is created for the same combination of PCN, PCN version, location, release type, and PCN release decision trigger represented by the selected item. The new item is updated with the latest configuration information from the system and the relevant release checks are triggered again. The status of the new item is set to *In Progress* and the status of the original item is set to *Obsolete*. The new PCN release decision item is automatically assigned to you. Note that any manual changes such as uploaded attachments are not copied to the new item.

   Regenerating Canceled PCN Release Decision Items

   When you cancel a PCN release decision item, its predecessor information is removed, and it is removed from the sequence defined in the PCN release process flow. If you regenerate a canceled PCN release decision item, a new item is created as an independent PCN release decision item, and it is not included back into the original sequence.
5. Check the new item for updated information and start processing it.

Related Information

Checking if Items Were Regenerated or Reprocessed [page 134]

5.3.13 Changing the Release Type of PCN Release Decision Items

Change the release type of a PCN release decision item by regenerating it.

Prerequisites

- The PCN release decision item has the processing status *New* or *In Progress*.
- You're authorized to regenerate PCN release decision items. The business role assigned to your user must have the release activity *Release Decision* or *Release Preparation*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select an item that has the processing status *New* or *In Progress*.
3. Choose *Regenerate*.

   A message appears asking you to confirm that you want to regenerate the selected PCN release decision item. You also have an option to change the release type of the PCN release decision item.
4. Select the new release type and choose *Regenerate*.

   A new PCN release decision item is created for the same combination of PCN, PCN version, and location represented by the selected item. The new item is updated with the latest information from the source system and the relevant release checks for the new release type are triggered. The status of the new item is set to *In Progress* and the status of the original item is set to *Obsolete*. The new PCN release decision item is automatically assigned to you. Note that any manual changes such as uploaded attachments are not copied to the new item.
5. Check the new item and start processing it.

5.3.14 Checking if Items Were Regenerated or Reprocessed

Add the *Successor Item* column to your worklist to see whether a PCN release decision item was created as a result of reprocessing or regeneration.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Choose *View Settings*.
3. On the *Columns* tab, select *Successor Item*.
4. Choose *OK*.

   Successor Item has the following possible values:

Value Shown	What It Means
Reprocessed by User or *Reprocessed by System*	The item is a copy of a completed or confirmed PCN release decision item. Reprocessing has been triggered either manually by a user or automatically by the system. Whether reprocessing is possible for an item depends on how release types are configured in your system.
Regenerated by User	The item is a new PCN release decision item for the same combination of PCN, PCN version, location, release type, and PCN release decision trigger as the item that was selected for regeneration. Regeneration was triggered manually by a user. The item that was selected for regeneration is marked as obsolete.
No value	The item hasn't been reprocessed or regenerated.

5.3.15 Canceling PCN Release Decision Items

Set the processing status of a PCN release decision item to *Canceled*.

Prerequisites

- You're authorized to set the status of PCN release decision items to *Canceled*.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision*.
- The PCN release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- If the PCN release decision item is created by a country/region split, you're assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- The PCN release decision item has the status *New* or *In Progress*.

Context

If a PCN release decision item is no longer required, you can set its processing status to *Canceled*. When a release decision item is set to canceled, it is no longer updated from the source system and you cannot make any further changes to it.

You can regenerate a canceled release decision item if necessary.

Procedure

1. Open the *My PCN Release Decisions* app.
2. Select the PCN release decision items that you want to set to *Canceled*.

   You can select only one. Note that the item must have the processing status *New* or *In Progress*.
3. Choose *Set to Canceled*.
4. In the dialog that appears, enter a comment to explain the reason for the cancellation.
5. Save your entries.

5.3.16 Viewing the Change History for Release Decision Items

View a list of all the changes made to a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Context

SAP Batch Release Hub for Life Sciences automatically records all the changes made to a release decision item. You can view the change history of a release decision item in the *My Release Decisions* app or the *My PCN Release Decisions* app.

Procedure

1. Open the relevant app for the release decision: *My Release Decisions* for batch release decisions or *My PCN Release Decisions* for PCN release decisions for clinical trials.
2. In the worklist, find the entry for which you want to view the change history.
3. Open the details of the release decision item.
4. Choose the *View Change History* button in the header area.

   A list of all the changes to the release decision item is displayed. For each change, you can see the attribute that was changed, the person who made the change, the date of the change, and the before and after attribute values.

5.4 Creating PCN Release Register Reports

Use the *My PCN Release Register* app to export a summary of the PCN release decisions made in one or more locations.

Prerequisites

- You're authorized to create a PCN release register.
- You're assigned to at least one location in the *Manage Quality Departments* app.

> **Note**
>
> You can create a release register only for the locations that you are assigned to.

Context

You can use the *My PCN Release Register* app to create a register of completed and confirmed PCN release decisions made in one or more locations. You can use various filter criteria to identify the PCN release decisions that you are interested in.

Once you have identified the list of relevant PCN release decisions, you can export the list to a spreadsheet.

Procedure

1. Open the *My PCN Release Register* app.
2. Enter your filter criteria and choose *Go*.

   At minimum, you must select at least one *Release Responsible Location*. Note that you can choose only from the locations and the quality departments that you are assigned to.
3. Choose *Export*.

   The release register report is generated as a spreadsheet and then automatically downloaded.

6 Jurisdictional Control

This section describes how you can use SAP Batch Release Hub for Life Sciences to document the supply chain for your pharmaceutical products and evaluate compliance with health authority regulations in the destination markets.

Jurisdictional control is an examination of whether the procurement, manufacturing, and distribution processes within the supply chain of a Life Sciences company are compliant with the specifications authorized by the relevant health authority. SAP Batch Release Hub for Life Sciences provides the following features to help you implement and automate your jurisdictional control process:

- Documentation of the Supply Chain
  You can document your supply chain using authorized supply chain maps and supply chain tables. Authorized supply chain maps document the activities that are subject to regulation and they form the basis for evaluating the jurisdictional control check. Supply chain tables are similar to authorized supply chain maps, but are used for documentation purposes only.
- Jurisdictional Control Check
  The jurisdictional control check evaluates the compliance of a batch based on the specifications documented in the authorized supply chain maps. If the jurisdictional control check has been configured and assigned to one or more release types, you will see it listed along with other release checks in the *My Release Decisions* app.

  > **Note**
  >
  > The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

- Management of Externally Produced Batches
  SAP Batch Release Hub for Life Sciences can support Life Sciences companies that work with contract manufacturing organizations (CMOs). You can capture the details of externally produced batches so that they can be included in the jurisdictional control check.

6.1 Documentation of the Supply Chain

This section describes how SAP Batch Release Hub for Life Sciences can support you in documenting the supply chain activities for your pharmaceutical products.

The end-to-end supply chain activities for pharmaceutical products and their destination countries/regions are documented in supply chain maps. Supply chain maps provide traceability and support Qualified Persons (QPs) with their certification responsibilities. By ensuring that you have complete visibility and documentation of the entire pharmaceutical supply chain, supply chain maps help you to make informed certification decisions for batch release.

In SAP Batch Release Hub for Life Sciences, there are two different types of supply chain maps as follows:

- **Authorized supply chain maps** are used in the jurisdictional control check to evaluate the suitability of batches for use in target materials and destination countries/regions.

- **Supply chain tables** are for used for documentation purposes only.

Supply chain maps are available in both a tabular format and a graphical format.

How Are Supply Chain Maps Created?

SAP Batch Release Hub for Life Sciences provides inbound APIs that you can use to create and maintain supply chain map data. In addition, you can use the *Manage Authorized Supply Chain Maps* app to manually create authorized supply chain maps.

Here's a summary of how the different types of maps are created and viewed:

Type of Map	How It's Created	Where to View It
Authorized Supply Chain Map	By API or manually in the *Manage Authorized Supply Chain Maps* app	*View Authorized Supply Chain Maps* app **Note** The latest data takes precedence. A manually created map can be overwritten if data is received later by API, and a map received by API can be overwritten if the map is created manually later.
Supply Chain Table	By API only	*View Supply Chain Tables* app

6.1.1 Overview of Supply Chain Maps in SAP Batch Release Hub for Life Sciences

Learn how supply chain information is represented in a graphical and tabular format in SAP Batch Release Hub for Life Sciences.

You can view supply chain maps in both a graphical and a tabular format in the following apps:

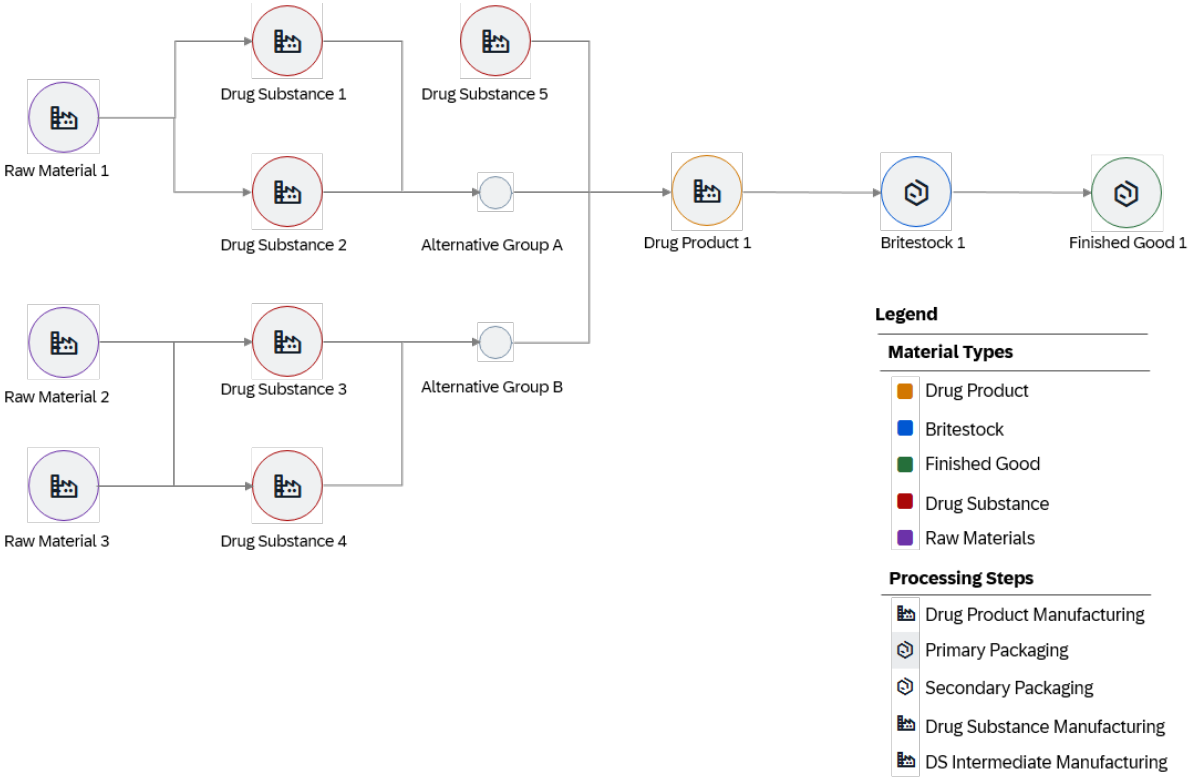
- *Manage Authorized Supply Chain Maps*
- *View Authorized Supply Chain Maps*
- *View Supply Chain Tables*

Graphical View

The diagram below shows the graphical view of a simple supply chain map. The map provides a high-level overview of the manufacturing process for a particular target material, in particular the included materials and processing steps that are subject to regulation. The manufacturing process flows from left to right, with the raw materials on the left and the final target material on the right. Each circle on the map is a "node", which represents a specific material at a processing step. Material types are indicated by colors, and processing steps are indicated by icons. The colors and icons can be configured in the *Manage Release Configurations* app. In

addition to nodes, a map can include alternative groups. Alternative groups are used when any one of a set of alternative materials can be used in the next processing step.

The restriction drivers that are relevant for the jurisdictional control process can be documented at each node (that is, for each material and processing step). As regulations can differ in each destination market, each supply chain map is specific to one country/region.



- This node represents a manufacturing step for Drug Substance 2. Drug Substance 1 and Drug Substance 2 are alternatives. Either one can be used to manufacture Drug Product 1. [page 139]
- This node represents a manufacturing step for Raw Material 2, which is used in the next step to manufacture Drug Substance 3 and Drug Substance 4. [page 139]
- This node represents a manufacturing step for Raw Material 3, which is used in the next step to manufacture Drug Substance 3 and Drug Substance 4. [page 139]
- This node represents a manufacturing step for Drug Substance 1. Drug Substance 1 and Drug Substance 2 are alternatives. Either one can be used to manufacture Drug Product 1. [page 139]
- This node represents a manufacturing step for Drug Substance 3. Drug Substance 3 and Drug Substance 4 are alternatives. Either one can be used to manufacture Drug Product 1. [page 139]
- This node represents a manufacturing step for Drug Substance 4. Drug Substance 3 and Drug Substance 4 are alternatives. Either one can be used to manufacture Drug Product 1. [page 139]
- This node represents a manufacturing step for Drug Substance 5, which is used in the next step to manufacture Drug Product 1. [page 139]
- This node represents Alternative Group A, which includes Drug Substance 1 and Drug Substance 2. Either one can be used in the manufacture of Drug Product 1. [page 139]
- This node represents Alternative Group B, which includes Drug Substance 3 and Drug Substance 4. Either one can be used in the manufacture of Drug Product 1. [page 139]

- This node represents a manufacturing step for Drug Substance 1, which is used in the next packaging step to make Britestock 1. [page 139]
- This node represents a packaging step for Britestock 1, which is used in the final packaging step to make Finished Good 1. [page 139]
- This node represents a manufacturing step for Raw Material 1, which is used in the next step to manufacture Drug Substance 1 and Drug Substance 2. [page 139]
- This node represents the packaging of Finished Good 1. Finished Good 1 is the target material of this authorized supply chain map. [page 139]
- At each node, the material type is represented by a color, and the processing step is represented by an icon. The colors and icons are configurable. [page 139]

Tabular View

In the tabular view of a supply chain map, each row corresponds to a node in the graphical view. A particular node (material and processing step) can have more than one entry in the table if it has more that one parent material and parent processing step. The parent material and parent processing step are the material and processing step at the next step in the manufacturing process. If a particular raw material can be used in two drug substances, it will have two entries in the table.

Here is the tabular representation of the supply chain map in the graphical view above:

Level	Material	Processing Step	Alternative Group	Parent Material	Parent Processing Step
0	Finished Good 1	Secondary Packaging			
1	Britestock 1	Primary Packaging		Finished Good 1	Secondary Packaging
2	Drug Product 1	Manufacturing		Britestock 1	Primary Packaging
3	Drug Substance 1	Manufacturing	Alternative Group A	Drug Product 1	Manufacturing
	Drug Substance 2	Manufacturing	Alternative Group A	Drug Product 1	Manufacturing
	Drug Substance 3	Manufacturing	Alternative Group B	Drug Product 1	Manufacturing
	Drug Substance 4	Manufacturing	Alternative Group B	Drug Product 1	Manufacturing
	Drug Substance 5	Manufacturing		Drug Product 1	Manufacturing
4	Raw Material 1	Manufacturing		Drug Substance 1	Manufacturing
				Drug Substance 2	Manufacturing
	Raw Material 2	Manufacturing		Drug Substance 3	Manufacturing
				Drug Substance 4	Manufacturing
	Raw Material 3	Manufacturing		Drug Substance 3	Manufacturing

Level	Material	Processing Step	Alternative Group	Parent Material	Parent Processing Step
				Drug Substance 4	Manufacturing

6.1.2 Creating Authorized Supply Chain Maps

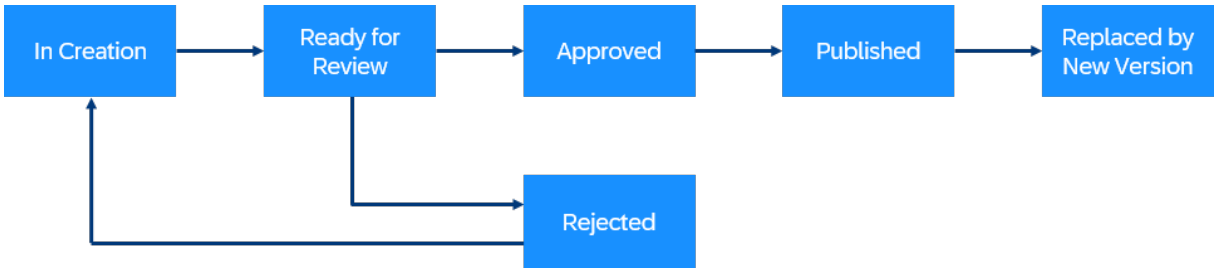
This section describes how you can use the *Manage Authorized Supply Chain Maps* app to create, review, and publish authorized supply chain maps.

Authorized supply chain maps document the activities in the supply chain of a pharmaceutical product that are subject to regulatory control. The published maps are used in the jurisdictional control check to evaluate whether a batch is suitable for use in a particular target material and destination country/region. Each authorized supply chain map is defined for a target material and a destination country/region. The target material is usually a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company. Each authorized supply chain map can include several materials at various processing steps throughout the manufacturing, testing, and distribution process.

6.1.2.1 Life Cycle of Authorized Supply Chain Maps

Learn about the different statuses of authorized supply chain maps, from creation through to publication. This information is helpful for understanding the process for creating and managing authorized supply chain maps.

Here's an overview of the typical status flow for an authorized supply chain map. In addition, an authorized supply chain map can be set to the status *Obsolete* at any point prior to publishing.



The table below explains the possible statuses in detail:

Status	What It Means
In Creation	The data entry for the authorized supply chain map is in progress. This is the initial status when an authorized supply chain map is created.

Status	What It Means
Ready for Review	The data entry has been completed, and the user responsible for the data entry has set the status as *Ready for Review*. The authorized supply chain map remains in this status until the reviewer approves or rejects it.
Approved	The authorized supply chain map has been reviewed and approved. Note that an approved authorized supply chain map is not considered in the jurisdictional control process until it is published.
Rejected	The authorized supply chain map has been reviewed and rejected. A rejected authorized supply chain map can be edited to resolve issues. When a rejected authorized supply chain map is opened in edit mode, the status changes back to *In Creation*.
Published	The authorized supply chain map has been published. This is the final step in the creation of the authorized supply chain map and it makes the map available for use in the jurisdictional control process. When an authorized supply chain map is published, it replaces any previously published version of the map. Only approved authorized supply chain maps can be published. A published authorized supply chain map can no longer be edited. To make a change to a published map, you need to create a new version of it.
Replaced by New Version	The authorized supply chain map has been republished, which means there is a newer version of the map available.
Obsolete	The authorized supply chain map has been set as obsolete. An authorized supply chain map can be set as obsolete at any point prior to publishing.

6.1.2.2 Creating Authorized Supply Chain Maps from Scratch

Create a new authorized supply chain map for a target material and destination country/region from scratch in the *Manage Authorized Supply Chain Maps* app. Add all the included materials, processing steps, and restriction drivers.

Prerequisites

- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
- You are authorized to create supply chain maps.

Context

You create the authorized supply chain map in a tabular view, and side-by-side, you can see the graphical representation of the map. A material at a particular processing step is represented by a "node" in the graphical view of the authorized supply chain map. For each material at a processing step, you can define the relevant restriction drivers and their authorized reference values.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. Choose *Create*.
3. In the *Create* dialog, enter the *Target Material ID*, *Country/Region*, and *Processing Step*.

   The target material is the final material in the authorized supply chain map. Usually, the target material is a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company (for example, sellable brite stock).

   Note that if there is already an existing map for the selected target material, country/region, and processing step, it is not possible to create a new map. If you need to make changes to a map that has already been published, you can create a new version of it.
4. Choose *Create*.

   The new authorized supply chain map opens in display mode with the tabular view and the graphical view side-by-side.
5. Choose *Edit*.

6. Add an included material as follows:
    - Choose *Add Material* in the header of the tabular view.
    - Choose the + *(Add)* icon in the row for the relevant parent material.
      With this option, the *Parent Material ID* and *Parent Processing Step* are automatically entered for you.
7. In the new row in the tabular view, enter the *Material ID* and the *Processing Step*. If you chose the *Add Material* button in the previous step, you also need to enter the *Parent Material ID* and the *Parent Processing Step*.

    When you have entered all the required details, the new material will appear in the graphical view.
8. Continue to add materials as necessary.

    If you have two or more materials that are alternatives, you can group them using the *Alternative Group* field.
9. Enter the restriction drivers for each material as follows:
    a. Choose a row in the *Materials* table to open the restriction driver details.
    b. Choose *Add Restriction Driver*.

       The restriction drivers listed in the *Add Restriction Driver* dialog depend on your configuration settings. You can only select from the restriction drivers that are assigned to the material type and the processing step.
    c. In the *Add Restriction Driver* dialog, select one or more restriction drivers and choose *Add*.

       The restriction drivers are added to the table. Note that a restriction driver can have more than one attribute.
    d. Enter the authorized values for the restriction driver attributes.

       If there is more than one authorized value for a restriction driver, you can choose *Add Option*.

       If you need to remove an option, choose the × *(Remove)* icon in the row for the relevant option.
    e. Choose *Apply*.

       You are returned to the authorized supply chain map page.
10. Save your changes.

    You can continue work on your new authorized supply chain map all the time it is in the status *In Creation*.

Next Steps

When you have completed the entry of an authorized supply chain map, you can submit it for review. The reviewer can either approve or reject the map. Once an authorized supply chain map is approved, it can be published. Note that only authorized supply chain maps in the status *Published* are used in the jurisdictional control check. If you need to change a published authorized supply chain map, you must create a new version of it.

Related Information

Restriction Driver [page 32]

Adding Materials [page 148]
Removing Materials [page 150]
Adding Restriction Drivers [page 151]
Removing Restriction Drivers [page 152]

6.1.2.3 Copying Authorized Supply Chain Maps

Select an authorized supply chain map and copy it to a different target material, destination country/region, and processing step.

Prerequisites

- You are authorized to create authorized supply chain maps.

Context

You can, for example, use this option when you want to create a new map for the same target material and processing step, but with a different destination country/region.

> → Tip
>
> If you need to update an existing published map for a target material and country/region, you should create a new version of it.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, select the authorized supply chain map that you want to copy.
3. Choose *Copy*.
4. In the *Copy* dialog, enter the required *Target Material ID*, *Country/Region*, and *Processing Step*.

   The values are defaulted from the selected map and you must change at least the *Target Material ID* or the *Country/Region*. Note that if there is already an existing map for the selected target material and country/region, it is not possible to create the copy.
5. Choose *Copy*.

   A copy of the authorization supply chain map is created with the specified target material, country/region, and processing step. This new map has the status *In Creation* and you can edit the map and make any required changes.

Next Steps

When you have completed making the changes to the new map, you can submit it for review by setting its status to *Ready for Review*.

Related Information

Adding Materials [page 148]
Removing Materials [page 150]
Adding Restriction Drivers [page 151]
Removing Restriction Drivers [page 152]

6.1.2.4 Creating New Versions of Authorized Supply Chain Maps

Create a new version of a published authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Prerequisites

- You are authorized to create authorized supply chain maps.

Context

Published authorized supply chain maps are used in the jurisdictional control check. When a map is in the status *Published*, it cannot be edited in the *Manage Authorized Supply Chain Maps* app. If you need to make changes to a published authorized supply chain map, you must create a new version of it. Your changes must be reviewed and approved, and then the map must be published for the changes to be applied in the jurisdictional control check. The published map remains in effect until your new version is published.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, select the authorized supply chain map that you want to create a new version of.

   Note that the authorized supply chain map must be in the status *Published*.

3. Choose *Create* > *Create New Version*.

   A new version of the authorization supply chain map is created. This new version is in the status *In Creation* and you can edit the map and make any required changes.

Next Steps

When you have completed making the changes to the new version of the map, you can submit it for review by setting its status to *Ready for Review*. To replace the existing published version of the authorized supply chain map, your new updated map must be reviewed, approved, and published.

Related Information

Life Cycle of Authorized Supply Chain Maps [page 142]
Adding Materials [page 148]
Removing Materials [page 150]
Adding Restriction Drivers [page 151]
Removing Restriction Drivers [page 152]

6.1.2.5 Adding Materials

Add materials and processing steps to an existing authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Prerequisites

- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
- You are authorized to create supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

While an authorized supply chain map is in the status *In Creation*, you can continue to add and remove materials and also enter the restriction drivers for each material.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.

   On the details page for the authorized supply chain map, the *Materials* table lists all the materials and processing steps that have been entered so far. Next to the *Materials* table, you can see the graphical view of the map.
3. Choose *Edit* to go into edit mode.
4. Add an included material as follows:
   - Choose *Add Material* in the header of the tabular view.
   - Choose the + *(Add)* icon in the row for the relevant parent material.
     With this option, the *Parent Material ID* and *Parent Processing Step* are automatically entered for you.
5. In the new row in the tabular view, enter the *Material ID* and the *Processing Step*. If you chose the *Add Material* button in the previous step, you also need to enter the *Parent Material ID* and the *Parent Processing Step*.

   When you have entered all the required details, the new material will appear in the graphical view.
6. Continue to add materials as necessary.

   If you have two or more materials that are alternatives, you can group them using the *Alternative Group* field.
7. Save your changes.

Next Steps

When you have added a material, you can proceed to add the restriction drivers for the material.

Related Information

Removing Materials [page 150]
Adding Restriction Drivers [page 151]
Removing Restriction Drivers [page 152]

6.1.2.6 Removing Materials

Remove one or more materials from an existing authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Prerequisites

- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
- You are authorized to create supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

While an authorized supply chain map is in the status *In Creation*, you can continue to add and remove materials and also enter the restriction drivers for each material.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.

   On the details page for the authorized supply chain map, the *Materials* table lists all the materials and processing steps that have been entered so far. Next to the *Materials* table, you can see the graphical view of the map.
3. Choose *Edit* to go into edit mode.
4. In the *Materials* table, choose the ✕ *(Remove)* icon in the row for the material that you want to remove.

   The material is removed from the table.
5. Save your changes.

Related Information

Adding Materials [page 148]
Adding Restriction Drivers [page 151]

Removing Restriction Drivers [page 152]

6.1.2.7 Adding Restriction Drivers

Add the restriction drivers and authorized values for a material and processing step in an authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Prerequisites

- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
- You are authorized to create supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

The restriction drivers are an important element of an authorized supply chain map because they document the regulatory requirements for a material at a processing step. A restriction driver consists of one or more attributes of the supply chain that are subject to regulatory control. For each restriction driver attribute, you enter the authorized value. A restriction driver attribute can have more than one authorized value, and in this case you can enter multiple "options" for the restriction driver.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.
3. Choose *Edit* to go into edit mode.
4. In the *Materials* table, open the material that you want to work on.

   The *Restriction Drivers* table lists any restriction drivers that have been entered so far.
5. Choose *Add Restriction Driver*.
6. In the *Add Restriction Driver* dialog, select one or more restriction drivers and choose *Add*.

   The restriction drivers are added to the table. Note that a restriction driver can have more than one attribute.

The listed restriction drivers depend on your configuration settings. You can only select from the restriction drivers that are assigned to the material type and the processing step.

7. Enter the authorized values for the restriction driver attributes.

   If there is more than one authorized value for a restriction driver, you can choose *Add Option*.

   If you need to remove an option, choose the ✕ *(Remove)* icon in the row for the relevant option.

8. Save your changes.

Related Information

Restriction Driver [page 32]
Removing Restriction Drivers [page 152]

6.1.2.8 Removing Restriction Drivers

Remove one or more restriction drivers from a material and a processing step in an authorized supply chain map in the *Manage Authorized Supply Chain Maps* app.

Prerequisites

- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
- You are authorized to create supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

The restriction drivers are an important element of an authorized supply chain map because they document the regulatory requirements for a material at a processing step. The restriction drivers are defined in your configuration settings, and they may change from time to time. If a restriction driver is no longer required, you can remove it from a material and processing step.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.
3. In the *Materials* table, open the material that you want to work on.

   On the details page for the material, the *Restriction Drivers* table lists all the restriction drivers that have been entered so far.
4. Choose *Edit* to go into edit mode.
5. In the *Restriction Drivers* table, choose the ✕ *(Remove)* icon in the row for the restriction driver that you want to remove.

   The restriction driver is removed from the table.
6. Save your changes.

Related Information

Restriction Driver [page 32]
Adding Restriction Drivers [page 151]

6.1.2.9 Assigning Authorized Supply Chain Maps

Assign an authorized supply chain map to yourself or a colleague for processing.

Context

You can assign a map, for example, to yourself for the data entry and then to a colleague for review. You can use the *Assigned To* filter to quickly find the maps that are assigned to someone.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, select the authorized supply chain map that you want to assign.
3. Choose *Assign*.
4. In the *Assign* dialog, if you are assigning the map to a colleague, select the user that you want to assign.

   If you want to assign the map to yourself, you don't need to select a user. You can simply choose *Assign to Me* in the next step.

5. Choose *Assign* or *Assign to Me*.

Related Information

Setting Authorized Supply Chain Maps to Ready for Review [page 154]

6.1.2.10 Setting Authorized Supply Chain Maps to Ready for Review

Set an authorized supply chain map to the status *Ready for Review* when you have completed the creation of the authorized supply chain map and would like a colleague to review it.

Prerequisites

- You are authorized to create supply chain maps.
- You have completed the creation of a new authorized supply chain map and it is in the status *In Creation*.

Context

When you change the status of an authorized supply chain map to *Ready for Review*, it indicates that the data entry step is complete and the map is ready to be reviewed and checked by another authorized user. You can assign the reviewer when you set the map to Ready for Review, or you can assign the reviewer later on as a separate step.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, select the authorized supply chain map that you want to set to ready for review.
3. Choose *Set to Ready for Review*.
4. In the *Set to Ready for Review* dialog, you can optionally select the reviewer and enter a note for the reviewer.

   Alternatively, you can assign the reviewer later on.
5. Choose *Set*.

6.1.2.11 Reviewing Authorized Supply Chain Maps

Review an authorized supply chain map in the *Manage Authorized Supply Chain Maps* app and either reject or approve it.

Prerequisites

- You are authorized to review authorized supply chain maps and set their status to *Approved* or *Rejected*.
- The authorized supply chain map has been set to the status *Ready for Review*.

Context

Before an authorized supply chain map can be published and made available for the jurisdictional control process, an authorized user must review it. The reviewer can either approve or reject the map. If the map is approved, it can be published. If the map is rejected, the assigned user can continue work on it to correct any issues and then submit it for review again.

Note that you cannot review a map that you have created or edited yourself.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to review.
   The map should be in the status *Ready for Review*.
3. In the *Materials* table, review each material to ensure that all the material details are correct.
   You can review the materials in the tabular view and the graphical view.
4. Open the details of each material to review the restriction drivers or the material and processing step.
5. When you have reviewed all the materials and restriction drivers, complete your review as follows:
   - If all the details in the map are correct, approve the map:
     1. On the authorized supply chain map details page, choose *Approve*.
     2. Enter a note and your password.
     3. Choose *Approve*.
        Every attempt at approving a map is logged. You can view the approval log in the *View Authorized Supply Chain Map Signature Log* app.
   - If the details in the map are incorrect, reject the map:
     1. On the authorized supply chain map details page, choose *Reject*.
     2. Enter a note to explain your findings.
     3. Choose *Reject*.

Next Steps

If the map is approved, it is ready to be published. If the map is rejected, the responsible person can open it and make the required corrections, and then submit it for review again.

6.1.2.12 Publishing Authorized Supply Chain Maps

Change the status of an authorized supply chain map from *Approved* to *Published* in the *Manage Authorized Supply Chain Maps* app to make it available for use in the jurisdictional control process.

Prerequisites

- The authorized supply chain map has been reviewed and approved.
- You are authorized to publish authorized supply chain maps.

Context

Publishing an authorized supply chain map makes it available for the jurisdictional control process. You can only publish authorized supply chain maps that are in the status *Approved*, and the publishing replaces any previously existing published version. Published authorized supply chain maps can also be viewed in the *View Authorized Supply Chain Maps* app.

> ⚠ Caution
>
> You cannot undo a publishing action. If you need to change a published map, you have to create a new version of it, and then submit it for review, approval, and publishing again.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, select the authorized supply chain map that you want to publish.
3. Choose *Publish*.
4. In the *Publish* dialog, enter your password.

   This is the same password that you use to log onto the system.
5. Choose *Publish*.

   The status of the map changes to *Published*. If there is an existing published version of the map, the status of the previously published version is changed to *Replaced by New Version*.

Every attempt at publishing a map is logged. You can view the publishing log in the *View Authorized Supply Chain Map Signature Log* app.

6.1.2.13 Working with Attachments for Authorized Supply Chain Maps

Use attachments to gather and record any additional information relevant for authorized supply chain maps.

Prerequisites

- You are authorized to create authorized supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

You can upload files of the following formats with a maximum file size of 40 MB.

> ⚠ Caution
>
> In general, we recommend you upload small files. Only upload large files when absolutely necessary.

File Type	Allowed File Formats
Document	• .pdf • .ppt and .pptx • .txt • .rtf • .doc and .docx • .xls and .xlsx • .csv
Image	• .png • .jpg • .jpeg • .gif • .svg

Once an attachment has been uploaded, it can't be removed, but you can set it as inactive if it's outdated or no longer required for any reason. Once an attachment is set as inactive, it can't be reactivated.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.
3. Go to the *Attachments* section and choose the required option.

Task	What To Do
Upload an attachment	1. Choose *Upload*. 2. Select one or more files to upload. 3. Confirm your selection.
Download an attachment **Note** Only active attachments can be downloaded.	1. Select one or more attachments. 2. Choose *Download*. You can also download a single attachment by clicking the hyperlinked file name.
Set an attachment as inactive	1. Select one or more attachments. 2. Choose ... > *Set as Inactive*.

6.1.2.14 Adding Comments to Authorized Supply Chain Maps

Add a comment to an authorized supply chain map to record additional relevant information and share it with other colleagues working on the map.

Prerequisites

- You are authorized to create authorized supply chain maps.
- The status of the authorized supply chain map is *In Creation*.

Context

The *Comments* section shows a summary of all the comments entered so far for the map. You are prompted to enter a comment when you perform the following actions:

- Approve map
- Reject a map
- Set a map as obsolete
- Publish a map

You can also add a comment manually in the *Comments* section. Note that you need to be in display mode to add a comment.

Procedure

1. Open the *Manage Authorized Supply Chain Maps* app.
2. In the worklist, open the details of the authorized supply chain map that you want to work on.
3. Go to the *Comments* section.

   You will see a tabular summary of all the comments entered so far for the map.
4. In the header area, choose *Add*.
5. Enter your comment.
6. Save your changes.

6.1.2.15 Applying Configuration Changes

Learn what to do if there are configuration changes that need to be applied to an authorized supply chain map before it can be published.

Authorized supply chain maps should reflect the latest configuration settings for materials, processing steps, and restriction drivers. These configuration settings are maintained in the *Manage Release Configurations* app by authorized users. While you are in the process of creating or updating an authorized supply chain map, configuration settings that impact the map could be updated, for example:

- A new restriction driver could be assigned to a material type and processing step in your map
- The attributes of a restriction driver in your map could be changed
- A restriction driver assignment for a material type and processing step in your map could be set as inactive

If there are configuration changes that impact a map you are working on in the *Manage Authorized Supply Chain Maps* app, you will be prompted to check the map and apply the latest configuration. Note that to make changes to a map, it must be in the status *In Creation*.

6.1.3 Viewing Authorized Supply Chain Maps

View the authorized supply chain maps for your target materials in each relevant country or region in the *View Authorized Supply Chain Maps* app.

Prerequisites

- You have permission to view authorized supply chain maps.

- You have made the following settings in the *Manage Release Configurations* app:
  - You have configured processing steps.
  - You have configured restriction drivers.
  - You have assigned material types and processing steps to restriction drivers.
  - You have selected colors for material types.

Context

Authorized supply chain maps document the supply chain activities that are relevant for jurisdictional control. An authorized supply chain map is defined for a target material and for a country or region. The target material is usually a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company (for example, sellable brite stock). Each target material can have a different map for each relevant country or region. Each map has multiple materials included in it.

You can view an authorized supply chain map in either a graphical or a tabular view. For each included material at each processing step, you can view the restriction drivers and their authorized reference values. The restriction drivers and their authorized reference values are used in the jurisdictional control check in the batch release process.

You can create authorized supply chain maps in the *Manage Authorized Supply Chain Maps* app. Alternatively, maps can be received from a source system through an API. The latest data takes precedence. A manually created map can be overwritten if data is received later by API, and a map received by API can be overwritten if the map is created manually later. You can check the *Last Data Source* column in the *View Authorized Supply Chain Maps* app to see whether the map was created manually or received by API.

> → Tip
>
> You can also navigate directly to an authorized supply chain map from the jurisdictional control check in the *My Release Decisions* app.

Procedure

1. Open the *View Authorized Supply Chain Maps* app.
2. Locate the relevant authorized supply chain map.

   Each supply chain map is for a specific target material and a specific country or region. You can use various filter criteria to locate the map that you're interested in.
3. Open the relevant map.

   By default, the map opens in a graphical view. Each node on the map represents a specific included material at particular processing step.

   Here's what you can do in the graphical view:

   - See an overview of the supply chain, including the materials and the processing steps.
   - See the alternative groups and the alternative component materials for a processing step.

- Choose a node to view its restriction drivers, the restriction driver attributes, and their authorized reference values.

4. Choose a node on the map.

   In the popup dialog that appears, you can see the restriction drivers, restriction driver attributes, and authorized reference values for the material at the processing step.

5. Choose *Show Tabular View* to see the information in a tabular format.

   Here's what you can do in the tabular view:

   - Choose *Show Restriction Drivers* in the *Restriction Driver* column to view the restriction driver attributes and their authorized reference values in a popup dialog.
   - Choose *Show All Restriction Drivers* to view all the restriction driver attributes and their authorized reference values in the table. Choose *Hide All Restriction Drivers* to revert this.
   - Choose *Export Table* to download the data to a spreadsheet.

Related Information

Authorized Supply Chain Map [page 18]
Restriction Driver [page 32]
View Authorized Supply Chain Maps [page 41]

6.1.4 Viewing Supply Chain Tables

View the supply chain tables for your target materials in each relevant country or region in the *View Supply Chain Tables* app.

Prerequisites

- You have permission to view supply chain tables.
- You have made the following settings in the *Manage Release Configurations* app:
  - You have configured processing steps.
  - You have configured restriction drivers.
  - You have assigned material types and processing steps to restriction drivers.
  - You have selected colors for material types.

Context

A supply chain table documents the end-to-end supply chain activities related to a specific pharmaceutical material and its destination country/region. It outlines manufacturing, testing, and distribution steps, along

with relevant control attributes. While it supports traceability and Qualified Person (QP) certification, it is maintained for documentation purposes only and is not directly used for jurisdictional control checks during batch release decisions.

The target material of a supply chain table is usually the final material in the specification of the supply chain, but it could also be a step before the finished good if the final production and logistics are done outside the company. For example, it could be a sellable brite stock material. A target material can have a different supply chain table for each relevant country or region. Each supply chain table has multiple materials included in it.

You can view a supply chain table in either a graphical or a tabular view. Each supply chain table includes "nodes" that represent a material at a particular processing step. For each node, you can view the relevant restriction driver attributes and their authorized reference values. Any authorized reference values that are relevant for jurisdictional control are identified with an icon in the graphical view and in a separate column in the table view.

> → Tip
>
> The *View Supply Chain Tables* app is similar to the *View Authorized Supply Chain Maps* app. The key difference is that supply chain tables are for documentation purposes only while authorized supply chain maps are used for jurisdictional control checks during batch release decisions. For a particular target material and country/region, you may see more processing steps and restriction drivers in the *View Supply Chain Tables* app than in the *View Authorized Supply Chain Maps* app.

Procedure

1. Open the *View Supply Chain Tables* app.
2. Locate the relevant supply chain table.

   Each supply chain table is for a specific target material and a specific country or region. You can use various filter criteria to locate the supply chain table that you're interested in.
3. Open the relevant supply chain table.

   By default, the supply chain table opens in a graphical view. Each node in the graphical view represents a specific included material at a particular processing step.

   Here's what you can do in the graphical view:

   - See an overview of the supply chain, including the materials and the processing steps.
   - See the alternative groups and the alternative component materials for a processing step.
   - Choose a node to view its restriction drivers, the restriction driver attributes, and their authorized reference values.
4. Choose a node in the graphical view.

   In the dialog that appears, you can see the restriction drivers, restriction driver attributes, and authorized reference values for the material at the processing step. Authorized reference values that are relevant for jurisdictional control are indicated by an icon.
5. Choose *Show Tabular View* to see the information in a tabular format.

   Here's what you can do in the tabular view:

   - Choose *Show Restriction Drivers* in the *Restriction Driver* column to view the restriction driver attributes and their authorized reference values in a popup dialog.

- Choose *Show All Restriction Drivers* to view all the restriction driver attributes and their authorized reference values in the table. Choose *Hide All Restriction Drivers* to revert this.
- Choose *Export Table* to download the data to a spreadsheet.

Related Information

Restriction Driver [page 32]
View Supply Chain Tables [page 42]

6.2 Jurisdictional Control Check

This section describes how to work with the jurisdictional control check in the *My Release Decisions* app.

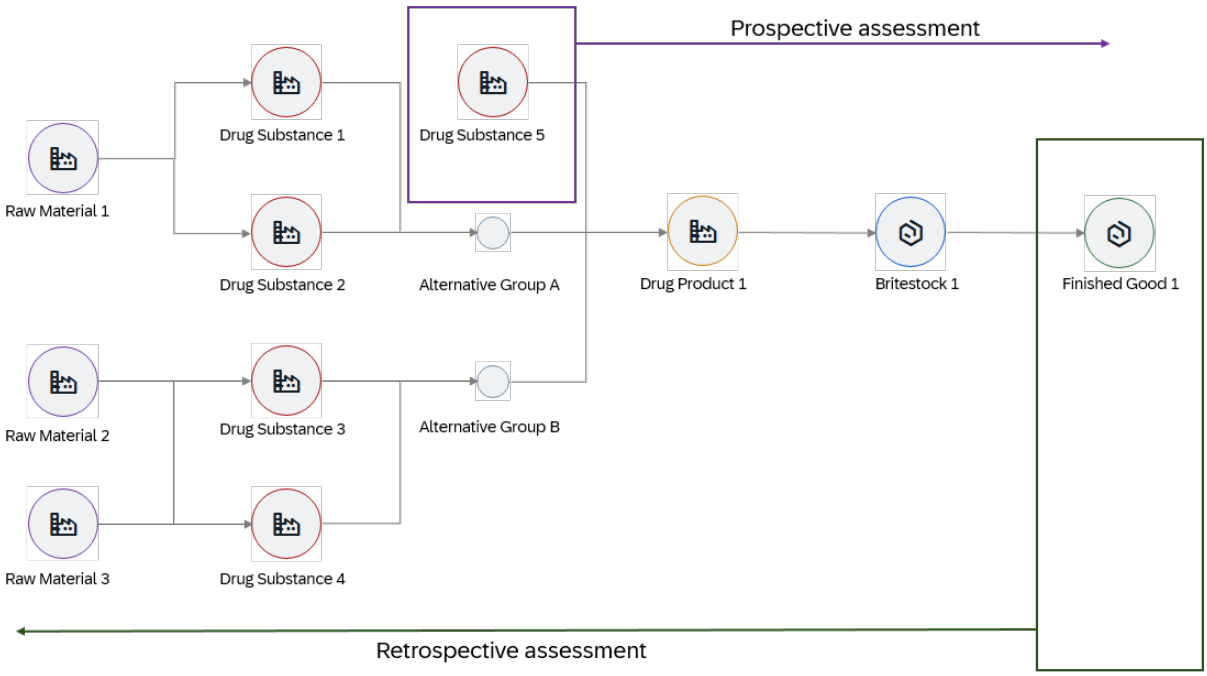
The jurisdictional control check evaluates the compliance of the procurement, manufacturing, and distribution processes for a batch with the specifications authorized by the relevant health authority. If the jurisdictional control check has been configured and assigned to one or more release types, you will see it listed along with other release checks in the *My Release Decisions* app.

> **Note**
>
> The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

The jurisdictional control check aims to answer the following questions:

- If the batch is a finished product, is it compliant with the regulations in each destination country/region? This is a retrospective assessment that checks whether the batch and all the batches in its genealogy are compliant.
- If the batch is not the finished product yet, can we predict if the finished product will be compliant with the regulations in each country/region?
  This is a prospective assessment that checks if there are any potential restrictions for the usage of the batch based on the subsequent production steps for the target material.

The following diagram illustrates a prospective and a retrospective assessment on an example supply chain map:



6.2.1 Overview of the Jurisdictional Control Check Process

This section summarizes the steps that the system performs to generate the jurisdictional control check results that you see in the *My Release Decisions* app.

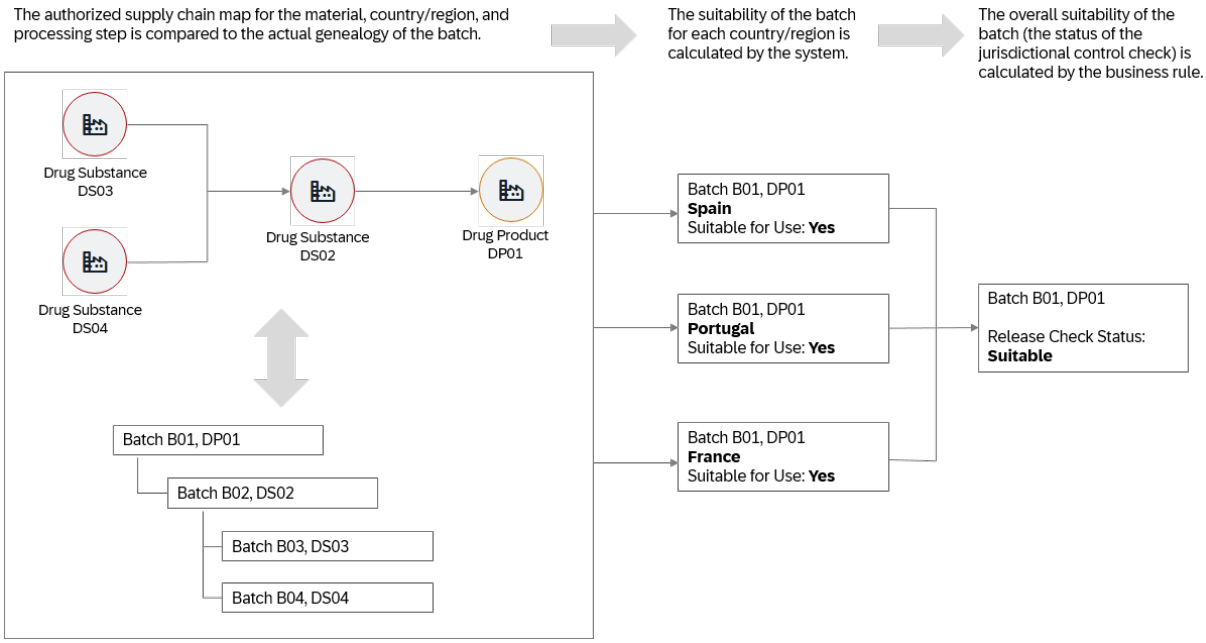
The jurisdictional control check process runs each time the following events occur:

- A new release decision item with a release type that includes the jurisdictional control check is created.
- New or changed actual data for the release decision item is received.
- New or changed authorized reference values for the restriction drivers of the release decision item are received.
- New or changed authorized supply chain map data is received.
- The release decision item is regenerated.
- The release decision item is reprocessed.

> **Note**
>
> When a release decision item is reprocessed, any release check status that was manually set by a user is not overwritten.

High Level Overview

The following diagram gives a high level overview of the jurisdictional control check process for the example batch, B01:



Processing Steps

Each time the jurisdictional control check runs, the system performs the following steps:

1. Determines the authorized supply chain maps that include the material and the processing step of the relevant batch.
2. Determines the relevant target materials for the release decision item based on the authorized supply chain maps.
3. Compares the authorized reference values of the restriction driver attributes in each authorized supply chain map to the actual values of the batch and records the results.
   Depending on how the restriction driver is configured, the comparison is done in one of the following ways:
   - *Match All*: This is the default configuration setting for restriction drivers. In this scenario, all actual values for the restriction driver must match an authorized reference value.
   - *Match One*: In this scenario, at least one actual value for the restriction driver must match an authorized reference value. For example, this could apply to the evaluation of specifications if there are many specifications received as actual values for a drug substance, but there is one specific authorized reference value per target material.

   You can see the detailed results of this comparison in the *Restriction Driver Overview* section in the *My Release Decisions* app.

> **Note**
>
> Some restriction drivers consist of unstructured data that cannot be evaluated automatically by the system. Any restriction drivers that are configured as requiring manual evaluation are not included in these processing steps, and they need to be reviewed manually in the *My Release Decisions* app. Initially, manual restriction drivers have the status *Manual Check Needed*. After reviewing them, you can set their status to *Compliant* or *Not Compliant* as appropriate.

4. Determines whether the target materials are suitable for use in each country/region based on the results of the comparison of the restriction drivers.
   You can see the results in the *Suitability by Country/Region* section in the *My Release Decisions* app.
   The system does a retrospective assessment of whether the batches in the genealogy are compliant with respect to the authorized reference values of the restriction drivers. In addition, the system does a proactive assessment for the target materials of each authorized supply chain map to identify any potential restrictions for the usage of the batch in the subsequent milestones in the supply chain. While performing this assessment, the system considers any alternative groups in the authorized supply chain map.
   If the authorized supply chain map contains a material that is not contained in the batch genealogy, the system returns a warning or error, which is later evaluated by the business rule.
5. Runs the business rule for the jurisdictional control check.
   The business rule uses the results of the previous steps as input and returns the release check status for the release decision item.

Related Information

Authorized Supply Chain Map [page 18]
Restriction Driver [page 32]
Viewing Jurisdictional Control Check Results [page 166]

6.2.2 Viewing Jurisdictional Control Check Results

Check whether the target materials in the supply chain of a batch are suitable for use in each country/region and whether the actual batch values match the authorized reference values of the restriction drivers.

Prerequisites

- You are authorized to view release check details or change the status of a release check.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To edit the suitability of batches for use in target materials and countries/regions, the business role assigned to your user in the relevant quality department must have the release activity *Jurisdictional Suitability*. To view details, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types

- Jurisdictional control check
  The jurisdictional control check has been configured and assigned to the appropriate release types.

Context

The results of the jurisdictional control check are displayed in the *My Release Decisions* app for each relevant release decision item.

> **Note**
>
> The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

You can view the results of the jurisdictional control check at the following levels of detail:

- The overall release check status of the jurisdictional control check for the release decision item
- The suitability of the batch for use in the target materials in each country/region based on the authorized supply chain maps
- The status of the restriction drivers for each target material in each country/region

Retrospective and Prospective Assessment

The jurisdictional control check evaluates a particular batch from two different perspectives as follows:

- A retrospective assessment of whether the batches in the genealogy are compliant with respect to the authorized reference values.
- A prospective assessment of potential restrictions for the usage of the batch in the subsequent milestones for the target material in the supply chain, as these restrictions can be derived from the authorized reference values.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to review the jurisdictional control check details.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section and find the entry for the jurisdictional control check.

   Here you can see the overall status of the jurisdictional control check for the release decision item.
5. Check the *Release Check Messages* column and the *Comments* column.

   Release check messages are generated by the system based on the result of the business rule for the jurisdictional control check. These messages provide additional clarification if the release check ends in errors or warnings. Informational messages are also shown here, for example, to show that a check was completed.

   Comments can be added manually by authorized users.
6. Open the jurisdictional control check.

In the *Suitability by Country/Region* section, you can see whether each target material is suitable for use in each relevant country/region. You can also see the number of compliant restriction drivers and the number of non-compliant restriction drivers.

Here are some tips for working with the *Suitability by Country/Region* information:

- Choose the linked number in the *Number of Non-Compliant Restriction Drivers* column to view the non-compliant restriction drivers in a popup dialog.
- Choose the link in the *Target Material ID* column to view the authorized supply chain map for a particular target material and country/region.
- Choose *View Settings* to add the parent material to the table.
  The parent material is the material at the next processing step in the authorized supply chain map for the target material. A target material can be used in more than one parent material, and in this case, all parent materials are displayed.

> **Note**
>
> If the release decision item is for the target material of an authorized supply chain map (a finished good), there is only one entry in the release check details table and the target material for that entry is equal to the material of the batch to be released.

7. Check for any attachments.

   If you're authorized, you can upload an attachment.
8. Check any comments.

   If you're authorized, you can add a comment.
9. Open a row for a target material and country/region.

   In the *Restriction Driver Overview* section, you can see the details of the restriction drivers, the restriction driver attributes, and the actual values for the material and processing step. You can also see the status of each restriction driver and the restriction drivers that require manual evaluation.
10. Choose *Show Reference Values* in the *Restriction Driver* column to see the authorized reference values of the restriction driver attributes.
11. Choose the *View Authorized Supply Chain Map* button in the header area to view the authorized supply chain map for the target material and country/region.

Next Steps

If you have the required authorization, you can do the following:

- Edit the actual values of restriction drivers that are configured as requiring manual data entry
- Set the status of restriction drivers that are configured as requiring manual evaluation
- Edit the suitability of a batch for use in a target material and country/region

Related Information

Restriction Driver [page 32]

Authorized Supply Chain Map [page 18]
Overview of the Jurisdictional Control Check Process [page 164]
Entering Missing Actual Values of Restriction Drivers [page 169]
Editing the Status of Manual Restriction Drivers [page 171]
Editing the Suitability of Batches [page 173]

6.2.3 Entering Missing Actual Values of Restriction Drivers

Enter the actual values of restriction drivers that are configured as requiring manual data entry.

Prerequisites

- You are authorized to enter missing actual values.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
  - Jurisdictional control check
    The jurisdictional control check has been configured and assigned to the appropriate release types.
- At least one restriction driver is configured as requiring manual entry of actual values in the *Manage Release Configurations* app under *Configure Restriction Drivers* > *Restriction Drivers*.

Context

The actual values of restriction drivers are required to complete the calculation of the jurisdictional control check and determine whether the restriction drivers are compliant. Usually, the actual values of restriction drivers are received from a source system automatically. However, restriction drivers can be configured as requiring manual data entry, for example, when there is no system integration for the actual values. For any restriction drivers that are configured as requiring manual data entry, you enter the actual values in the *My Release Decisions* app.

When batches are produced externally by contract manufacturing organizations (CMOs), the actual batch values need to be entered manually in the *Manage Externally Produced Batches with Missing Actual Values* app. You cannot change the manually entered values of CMO batches in the *My Release Decisions* app.

Procedure

1. Open the *My Release Decisions* app.

   > **Note**
   >
   > The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

2. In the worklist, find the entry that you want to work on.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section, and open the jurisdictional control check.
5. Go to the *Suitability by Country/Region* section, and open the country/region that you want to work on.
6. In the *Restriction Driver Overview* section, review the *Actual Value* column.

   For any restriction drivers that have missing actual values, the app displays *Missing Value* in the *Actual Value* column. If the restriction driver is configured as requiring manual data entry, there is an *Edit Actual Values* link in the *Restriction Driver* column.
7. In the *Restriction Driver* column for the restriction driver with missing actual values, choose *Edit Actual Values*.
8. In the *Edit Actual Values* dialog, enter the actual value ID and description for each restriction driver attribute.

   If a restriction driver attribute is configured to be equal to an actual value, you can select one of the available reference values or enter your own value.
9. **Optional:** Choose *Add* to enter another actual value for a restriction driver.

   If necessary, you can enter more than one set of actual values. If a restriction driver has more than one attribute, a new entry is added that includes all of the attributes.

   > **Example**
   >
   > Here's an example of a restriction driver with two attributes and two entries of actual values:

Entry Number	Restriction Driver Attribute	Actual Value ID	Actual Value Description
1	Testing Type TST_Type	TST123	Sterility Testing
	Business Partner BP_ID	BP9876	Acme Testing Services
2	Testing Type TST_Type	TST456	Biological Testing
	Business Partner BP_ID	BP5432	Pharma Quality Testing Services

10. Save your entries.

6.2.4 Editing the Status of Manual Restriction Drivers

Review the restriction drivers that are configured as requiring manual evaluation and set the appropriate status for each one.

Prerequisites

- You are authorized to change the status of a release check.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
  - Jurisdictional control check
    The jurisdictional control check has been configured and assigned to the appropriate release types.
- At least one restriction driver is configured as requiring manual evaluation in the *Manage Release Configurations* app under *Configure Restriction Drivers* > *Restriction Drivers*.

Context

A restriction driver can be configured as requiring manual evaluation, for example, when the restriction driver consists of unstructured data that cannot be evaluated automatically by the system. In this case, you need to review the restriction driver manually by comparing the actual values of the batch to the authorized reference values of the restriction driver attributes. Initially, manual restriction drivers have the status *Manual Check Only*. When you have reviewed a manual restriction driver, you can set its status to *Compliant* or *Not Compliant* as appropriate.

You can change the restriction driver status for the current batch (that is, the batch to be released) or for the batches a level below provided that a release decision item for the lower level batch doesn't exist in your worklist.

If a batch has a manual restriction driver, it's not the batch to be released, and its restriction driver status has not been set, then you should navigate to the release decision item of that particular batch and set the restriction driver status there.

Procedure

1. Open the *My Release Decisions* app.

   > ⓘ Note
   >
   > The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

2. In the worklist, find the entry for which you want to edit manual restriction drivers.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section, and open the jurisdictional control check.

   In the *Suitability by Country/Region* section, you can see the number of manual restriction driver attributes that require a review in the *Number of Manual Restriction Driver Attributes* column. Choose the link in this column to see the details of the restriction driver attributes.
5. Edit the manual restriction drivers, using one of the following options:

   - In the *Suitability by Country/Region* section, choose *Edit All Manual Restriction Drivers*.
   - In the *Suitability by Country/Region* section, choose a row to open the restriction driver details. In the *Restriction Driver Overview* table, choose *Edit All Manual Restriction Drivers*.

     > → Tip
     >
     > In the *Restriction Driver Overview* table, you can choose the *Manual Check Only* quick filter to find all the restriction drivers that have the status *Manual Check Only*.

6. In the *Edit All Manual Restriction Drivers* dialog, review the restriction drivers by comparing the actual value of each restriction driver attribute to the authorized reference value.
7. Select one or more restriction drivers.
8. Choose *Edit Restriction Driver Status*.
9. Select the appropriate restriction driver status and enter a comment.
10. Save your entries.

    > ⓘ Note
    >
    > When you set a release decision for the release decision item, any manual changes to restriction driver statuses are reflected in subsequent release decision items in the release process flow.

Related Information

Restriction Driver [page 32]

6.2.5 Editing the Suitability of Batches

Change the suitability of a batch for use in a target material and country or region.

Prerequisites

- You are authorized to change the suitability of batches for use in target materials and countries or regions. The business role assigned to your user in the relevant quality department must have the release activity *Jurisdictional Suitability*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The following settings have been configured in the *Manage Release Configurations* app:
  - Processing steps
  - Restriction drivers
  - Assignments of material types and processing steps to restriction drivers
  - Colors for material types
  - Jurisdictional control check
    The jurisdictional control check has been configured and assigned to the appropriate release types.

Context

Initially, the system determines whether the batch is suitable for use in the target material and country or region by evaluating its restriction drivers. You can review and set the status of any manual restriction drivers by choosing *Edit All Manual Restriction Drivers*. If you have the required authorization, you can choose *Edit Suitability* to change the suitability of the batch for one or more selected target materials and countries or regions.

Procedure

1. Open the *My Release Decisions* app.

   > **Note**
   >
   > The jurisdictional control check is not supported in the *My PCN Release Decisions* app.

2. In the worklist, find the entry for which you want to review the jurisdictional control check details.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section, and open the jurisdictional control check.

   In the *Suitability by Country/Region* section, you can see the suitability of the batch for each target material and country or region.

5. Edit the suitability of the batch, using one of the following options:
    - In the *Suitability by Country/Region* section, select one or more rows and then choose *Edit Suitability*.
    - In the *Suitability by Country/Region* section, choose a row to open the restriction driver details, and then choose *Edit Suitability*.
6. In the *Edit Suitability* dialog, select the appropriate suitability and enter a comment.
7. Save your entries.

Results

> → Tip
>
> For more information about the suitability, you can choose ⚙ *(Settings)* and add the following columns to the table:
>
> - *System Suitability Status*: This shows the suitability determined by the system.
> - *Manual Suitability Status*: This shows the suitability set by a user if a manual change was made.

Suitable for Use shows the "final" suitability, which is determined by the system based on the *System Suitability Status* and the *Manual Suitability Status* as follows:

System Suitability Status	Manual Suitability Status	Suitable for Use
Yes or *No*	Blank	*Yes* or *No* When there is no manual change, *Manual Suitability Status* is blank, and *Suitable for Use* is the same as *System Suitability Status*.
Yes	*No*	*No* If a user changes the suitability of the target material to *No*, it overrides the system-determined suitability of *Yes*. This applies when the suitability is changed for the current batch and also when the suitability was changed for a batch at a previous step in the production process.

System Suitability Status	Manual Suitability Status	Suitable for Use
No	*Yes* Changed for a batch at a previous step in the production process	*No* If a user changed the suitability of the target material to *Yes* for a batch at a previous step in the production process, but the system-determined suitability for the current batch is *No*, the final suitability for the current batch is *No*.
No	*Yes* Changed for the current batch	*Yes* If a user changes the suitability of the target material to *Yes* for the current batch, it overrides the system-determined suitability of *No*.

6.2.6 Reevaluation of the Jurisdictional Control Check

After a release decision has been set, a batch may need to be reevaluated with regards to the jurisdictional control check.

This is because the actual data and the authorized reference data can change during the subsequent life cycle of the batch, and the changes could impact the compliance of any remaining stock of the batch. For example, the possible changes could include the following:

- Shelf life update
- Retest interval update
- Rework or reprocessing

To implement a reevaluation process for the jurisdictional control check, you need to configure a release process flow that has the release decision trigger type *Reevaluation (RE)*.

6.2.6.1 Viewing Reevaluation Changes for Jurisdictional Control Checks

Review a reevaluated jurisdictional control check to check whether the target materials in the supply chain of a batch are still suitable for use in each country/region.

Prerequisites

- You are authorized to view release check details or change the status of a release check.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*. To edit the suitability of batches for use in target materials and countries/regions, the business role assigned to your user in the relevant quality department must have the release activity *Jurisdictional Suitability*. To view details, the release activity *Release Review* is sufficient.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- You have made the following settings in the *Manage Release Configurations* app:
  - You have configured processing steps.
  - You have configured restriction drivers.
  - You have assigned material types and processing steps to restriction drivers.
  - You have selected colors for material types.
  - You have configured the jurisdictional control check.
  - You have assigned the jurisdictional control check to the appropriate release types.
- In the *Manage Release Configurations* app, you have configured a release process flow that has the release decision trigger type *Reevaluation (RE)*.
- In your SAP S/4HANA source system, you have configured the restriction drivers that are relevant for reevaluation in Customizing for *Life Sciences* under *Integration Hub for Life Sciences* > *Mapping* > *Define Actual Data Mapping for Restriction Drivers*.

Context

When a jurisdictional control check is reevaluated, the system summarizes the changes since the previous release decision was set, so you can identify which actual values or authorized reference values have changed since the last evaluation. Note that the status of any manually evaluated restriction drivers is copied from the previous release decision item. Any manually entered actual values are also copied. The suitability of the batch is not copied and instead is recalculated based on the latest authorized supply chain maps and the latest actual values.

Procedure

1. Open the *My Release Decisions* app.
2. In the worklist, find the entry for which you want to reevaluate the jurisdictional control check details.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section and find the entry for the jurisdictional control check.

   Here you can see the overall status of the jurisdictional control check for the release decision item.
5. Open the jurisdictional control check.
6. Open a row for a target material and country/region.
7. In the *Reevaluation Changes* section, review the summary of changes to the actual values or authorized reference values of restriction drivers.

   If there are any changes to the actual or authorized reference values of manually evaluated restriction drivers, a warning message is displayed. You should review and adjust the restriction driver status if necessary.

6.3 Working with Externally Produced Batches

This section describes how you can use the *Manage Externally Produced Batches with Missing Actual Values* app to manage externally manufactured or packaged batches.

Pharmaceutical companies can use contract manufacturing organizations (CMOs) to outsource production, increase manufacturing capacity, access specialized expertise or equipment, and focus on core competencies such as research and development. When batches are externally manufactured or packaged, the actual batch values that are required for the jurisdictional control check are not received from a source system as they would be for internally manufactured batches. Instead, the actual batch values need to be entered manually in the *Manage Externally Produced Batches with Missing Actual Values* app.

> **Note**
>
> If you want to use the *Manage Externally Produced Batches with Missing Actual Values* app, you must turn on *Enable Processing of Externally Produced Batches* in the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*.

6.3.1 User Authorizations for Managing Externally Produced Batches

User authorization is required to work on batches in the *Manage Externally Produced Batches with Missing Actual Values* app.

You create the user authorizations by assigning suppliers and/or locations to users as follows:

1. In the *Manage Suppliers of Externally Produced Batches* app, you create the suppliers that are relevant for batches produced externally by contract manufacturing organizations (CMOs).

2. In the *Manage User Authorizations for Externally Produced Batches* app, you assign the suppliers and/or locations (CMO plants) to the relevant users.

In the *Manage Externally Produced Batches with Missing Actual Values* app, users will see only the batches that belong to the suppliers and plants to which they are assigned.

> **Note**
>
> Note that internal and external users are handled differently based on the role collection they are assigned in the SAP BTP cockpit, as follows:
>
> - Users with the CMO internal role see all batches in the *Manage Externally Produced Batches with Missing Actual Values* app by default, and it is not necessary to assign any authorizations the *Manage User Authorizations for Externally Produced Batches* app.
> - Users with the CMO external role see no batches in the *Manage Externally Produced Batches with Missing Actual Values* app by default, and specific authorizations must be added in the *Manage User Authorizations for Externally Produced Batches* app.

6.3.1.1 Creating Suppliers of Externally Produced Batches

Create a contract manufacturing organization (CMO) supplier in the *Manage Suppliers of Externally Produced Batches* app.

Context

CMO suppliers are used to assign user authorizations in the *Manage User Authorizations for Externally Produced Batches* app. These authorizations determine which batches a user sees in the *Manage Externally Produced Batches with Missing Actual Values* app.

Procedure

1. Open the *Manage Suppliers of Externally Produced Batches* app.
2. Choose *Create*.
3. Enter the supplier ID and supplier name.
4. **Optional:** Enter the city, address, and country/region of the supplier if required.
5. Save your changes.

   Note that once you save the supplier, the supplier ID cannot be changed.

   It is not possible to delete suppliers, but you can set a supplier as inactive. Inactive suppliers are not available for selection in the *Manage User Authorizations for Externally Produced Batches* app.

6.3.1.2 Creating User Authorizations for Externally Produced Batches

Create authorizations for users of the *Manage Externally Produced Batches with Missing Actual Values* app.

Prerequisites

You have created the required suppliers in the *Manage Suppliers of Externally Produced Batches* app.

Context

Authorizations are assigned for batch locations and/or suppliers. Note that these authorizations work in conjunction with the role collection assigned to the user in the SAP BTP cockpit. Internal users and external users are handled differently as follows:

- Users with the CMO internal role see all batches in the *Manage Externally Produced Batches with Missing Actual Values* app by default, and it is not necessary to assign any authorizations the *Manage User Authorizations for Externally Produced Batches* app.
- Users with the CMO external role see no batches in the *Manage Externally Produced Batches with Missing Actual Values* app by default, and specific authorizations must be added in the *Manage User Authorizations for Externally Produced Batches* app.

Procedure

1. Open the *Manage User Authorizations for Externally Produced Batches* app.
2. In the toolbar of the *CMO Users* table, choose *Create*.
3. Select a user and specify an activation status.
4. In the toolbar of the *CMO User Authorizations* table, choose *Create*.

   A new entry appears in the table.
5. Enter an authorized batch location and an authorized supplier.

   You can continue to add more entries as necessary.
6. In the bottom-right corner of the app, choose *Create*.

6.3.2 Processing Status of Externally Produced Batches

The current stage of processing of a batch in the *Manage Externally Produced Batches with Missing Actual Values* app is reflected by the *Processing Status*.

Here's a summary of the possible values of the processing status:

Processing Status	What It Means
New	Processing of the batch has not yet started.
In Progress	Processing of the batch has started. A user has made a manual change, for example, the batch has been assigned, or actual values have been entered.
Completed	The batch has been manually set to completed. Completed batches can no longer be changed.
Canceled	The batch has been manually set to canceled. New and in progress batches can be set to canceled. Canceled batches can no longer be changed.
Obsolete	The batch has been manually regenerated. New, in progress, canceled, and completed batches can be regenerated. When a batch is regenerated, the original batch is set to the processing status *Obsolete* and a new batch is created with the processing status *In Progress*. You can regenerate batches for the following reasons: • To apply the latest configuration changes such as changes to restriction drivers or authorized supply chain maps • To process a batch that was previously canceled or completed

6.3.3 Assigning Externally Produced Batches for Processing

Assign one or more externally produced batches to yourself or someone else for processing.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.

- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.

Context

If you're responsible for distributing work within your team, you can assign batches to people who have the same responsibilities as you.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. Select the batch that you'd like to assign.

   You can select multiple batches if you want to assign them to the same person.
3. Choose *Assign*.
4. Enter the name of the person you want to assign and choose *Assign*.

   If you want to assign the batch or batches to yourself, choose *Assign to Me* instead of entering a name.

   > **Note**
   >
   > Once a batch has been assigned for processing, you can change the assignment but you can't unassign the item completely.

6.3.4 Entering Actual Values of Restriction Drivers of Externally Produced Batches

Enter the actual values of the restriction drivers of an externally produced batch.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.
- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.

Context

Restriction drivers are used in the jurisdictional control process. In the jurisdictional control check, the actual values of a batch are compared to the authorized reference values of the restriction driver attributes to determine compliance. When batches are externally manufactured or packaged, the actual batch values that are required for the jurisdictional control check are not received through integration with a source system. Instead, they need to be entered manually in the *Manage Externally Produced Batches with Missing Actual Values* app.

You enter actual values of restriction drivers for the main batch and also for any component batches.

> **Note**
>
> The *Manage Externally Produced Batches with Missing Actual Values* app is specifically for externally produced batches. If you need to enter actual values for internally produced batches that have restriction drivers that are configured to be entered manually, you do so in the jurisdictional control check in the *My Release Decisions* app.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. In your worklist, find the batch that you want to work on.
3. Open the details of the batch and choose *Edit*.
4. Find the relevant restriction drivers as follows:
   - To enter actual values for the main batch, go to the *Restriction Drivers* table.
   - To enter values for a component batch, open the component batch and then go to the *Restriction Drivers* table.
5. In the *Restriction Driver* column, choose the *Edit Actual Values* link for the relevant restriction driver.
6. In the *Edit Actual Values* dialog, enter the actual values for each restriction driver attribute.
7. **Optional:** Choose *Add* to enter another actual value for a restriction driver.

   If necessary, you can enter more than one set of actual values. If a restriction driver has more than one attribute, a new entry is added that includes all of the attributes.

   > **Example**
   >
   > Here's an example of a restriction driver with two attributes and two entries of actual values:

Entry Number	Restriction Driver Attribute	Actual Value ID	Actual Value Description
1	Testing Type TST_Type	TST123	Sterility Testing

Entry Number	Restriction Driver Attribute	Actual Value ID	Actual Value Description
	Business Partner BP_ID	BP9876	Acme Testing Services
2	Testing Type TST_Type	TST456	Biological Testing
	Business Partner BP_ID	BP5432	Pharma Quality Testing Services

8. Save your changes.

6.3.5 Entering Component Batches of Externally Produced Batches

Enter the component batches of an externally produced batch.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.
- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.

Context

If the main externally produced batch has component batches, you need to enter them manually. Once you have entered the component batches, you need to enter the actual values of their restriction drivers.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. In your worklist, find the batch that you want to work on.
3. Open the details of the batch and choose *Edit*.

4. Go to the *Component Batches* table, and choose *Add*.
5. Enter the batch ID and material ID of the component batch.
6. **Optional:** Choose *Add* again and continue to add more component batches as necessary.
7. Save your changes.

Next Steps

You can open the details of each component batch and enter the actual values of the component batch's restriction drivers.

6.3.6 Setting Externally Produced Batches to Completed

Set the processing status of one or more externally produced batches to *Completed* when work on the batches is finished.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.
- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.
- The batch must be in the status *New* or *In Progress*.
- The parent batch has at least one actual value for a restriction driver, or a component batch has at least one actual value for a restriction driver.

Context

When a batch is set to *Completed*, you cannot make further changes to it. If you need to reprocess a completed batch, you can regenerate it.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. Select the batch or batches you'd like to set as completed.
3. Choose *Set to Completed*.

4. In the confirmation message, add an optional note if required and then choose *Set*.

   The processing status changes to *Completed*.

6.3.7 Setting Externally Produced Batches to Canceled

Set the processing status of one or more externally produced batches to *Canceled* if the batches are no longer required.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.
- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.
- The batch must be in the status *New* or *In Progress*.

Context

> ⚠ Caution
>
> When a batch is set to canceled, you cannot make any further changes to it.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. Select the batch or batches you'd like to set as canceled.
3. Choose *Set to Canceled*.
4. In the confirmation message, add a comment and choose *Set*.

   The processing status changes to *Canceled*.

6.3.8 Regenerating Externally Produced Batches

Regenerate an externally produced batch to recreate it with the latest configuration settings or to process a batch that was previously canceled or completed.

Prerequisites

- In the *Manage Release Configurations* app under *Make General Settings* > *Jurisdictional Control*, *Enable Processing of Externally Produced Batches* has been turned on.
- You have been assigned user authorizations in the *Manage User Authorizations for Externally Produced Batches* app.
- The batch must be in the processing status *New*, *In Progress*, *Canceled*, or *Completed*.
  Obsolete items cannot be regenerated.

Context

Occasionally, an administrator may need to adjust the configuration of SAP Batch Release Hub for Life Sciences, for example, to introduce a new restriction driver or to adjust the processing steps in an authorized supply chain map. If requested to do so, you need to regenerate any new and in progress batches in your worklist to recreate them with the latest configuration settings. In addition, you can regenerate a batch if you need to process a batch that was previously set to canceled or completed.

Procedure

1. Open the *Manage Externally Produced Batches with Missing Actual Values* app.
2. Select a batch that has the processing status *New*, *In Progress*, *Canceled*, or *Completed*.
3. Choose *Regenerate*.

   A dialog appears asking you to confirm that you want to regenerate the batch.
4. In the dialog, choose *Regenerate* to confirm.

   The selected batch is marked as obsolete and can no longer be changed. The app creates a new batch with the processing status *In Progress*. The new batch is assigned to you for processing.

   Any changes in the restriction driver configuration and authorized supply chain maps are automatically applied to the new batch. Actual values and component batches are copied to the new batch if available.

Next Steps

You can check the new batch for updated information and start processing it.

7 AI in SAP Batch Release Hub for Life Sciences

This section describes the AI features that are available in SAP Batch Release Hub for Life Sciences.

Use of AI in SAP Batch Release Hub for Life Sciences is optional, and customers can decide based on their own business needs whether they want to use AI. The AI features can be turned on or off for the entire solution in the *Manage Release Configurations* app under *Make General Settings* > *AI*. If AI features are turned off in your configuration settings, you will not see any AI-related options in your apps.

The AI-assisted features are intended to help you complete your work while ensuring that you have agency and transparency. You retain the control and final say in all decisions.

> **Note**
>
> AI in SAP Batch Release Hub for Life Sciences does not provide the technical capabilities to support the collection, processing, and storage of sensitive/personal data.

Disclaimer: While the embedded AI feature can help to get the proposed result, customers must validate the data received from the connecting systems and in turn validate the proposed results manually before accepting the proposed result. The accountability of the end result will be solely with the customer.

7.1 AI Usage Acknowledgment Statement

Learn about the AI usage acknowledgment statement, which you must accept as a one-time activity before using the AI-assisted features.

If AI-assisted features are enabled in SAP Batch Release Hub for Life Sciences, an acknowledgment message is displayed when you choose any AI-assisted capability. This message informs you about the possible inaccuracies of the results generated by AI systems and recommends you to review all AI-generated content before completing your work.

Once you accept the acknowledgment as a one-time activity, the message doesn't reappear in subsequent sessions when you engage with AI-assisted features across the SAP Batch Release Hub for Life Sciences solution. However, if the acknowledgment statement is revised at any point later, the acknowledgment message will be displayed again. You must review and accept the updated acknowledgment statement before you can continue using any AI-assisted feature.

7.2 SAP Batch Release Hub, AI-Assisted Custom Release Checks

SAP Business AI in SAP Batch Release Hub for Life Sciences uses generative AI to analyze the documents attached to custom release checks and propose results for the release check items.

Generative AI in SAP Batch Release Hub for Life Sciences supports in analyzing unstructured documents for custom release checks, streamlining what was previously a manual process. You upload relevant documents and initiate AI-proposed results, which you then review and validate. Your productivity is improved while human oversight is retained throughout the complete process.

SAP Batch Release Hub, AI-assisted custom release checks help you to save a significant amount of time by focusing on reviewing the recommendations provided, while keeping the role of the final decision-maker. This accelerates the batch release process, while empowering you to ensure compliance and quality.

You can learn more on the SAP Discovery Center: SAP Batch Release Hub for Life Sciences, custom release checks

Key Benefits

- Generative AI-powered analysis of documents and images
- Reduction of manual effort
- Faster review, check of references, and sign off
- Extensive searching is no longer needed
- Batch release decisions are accelerated
- User experience is improved

Custom Release Checks in Detail

Custom release checks are used to integrate checking activities that must be completed manually, without a connected source system. For example, you can use a custom release check to ensure that certain information is captured and validated. A custom release check includes a list of checklist items. Each checklist item is defined with the following information:

- *Step*: The number of the item in the checklist sequence
- *Item ID* and *Item Description*: A unique ID and meaningful description
- *Condition for Acceptance*: Free text that describes what the checklist item requires
  If you allow an AI-based proposal, the *Condition for Acceptance* is mandatory and should be worded carefully, because the AI generation uses the condition for acceptance as the basis for proposing a sensible result.
- *Mandatory*: A setting that indicates whether the checklist item is mandatory
- *Enable AI-Based Proposal*: A setting that indicates whether an AI-based proposal is allowed for the item
- *Enable Comparison*: A setting that indicates whether an AI-based comparison of attributes is performed during the generation of the AI-based proposal

- *Attributes for Comparison*: The attributes to be compared during the generation of the AI-based proposal
- *Allowed Results*: An optional set of allowed results
  If no allowed results have been defined in your configuration settings, you can enter free text for the result.

To complete a checklist item, you need to enter the following information:

- A *Result*, which can be one of the defined allowed results, or free text if no allowed results have been configured
  When an AI-based proposal is allowed for a checklist item, you can use AI to analyze selected attachments and propose a result for the checklist item. After you review the generated proposal, you can choose to accept or discard it. If you prefer not to use AI, you can enter the result manually in the usual way.
- A *Valuation*, which is one of the release check statuses configured for the release check
  If a valuation has been defined for each possible result in your configuration settings, then the valuation is entered automatically.

When all mandatory checklist items are completed, you can set the release check status.

1. Preparing Attachments for SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 190]
   Upload attachments and then set them as AI-relevant to prepare them for use with SAP Batch Release Hub, AI-assisted custom release checks.
2. Generating AI-Based Proposals for SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 192]
   Generate AI-based proposals for the result of checklist items in SAP Batch Release Hub, AI-assisted custom release checks.

7.2.1 Preparing Attachments for SAP Batch Release Hub, AI-Assisted Custom Release Checks

Upload attachments and then set them as AI-relevant to prepare them for use with SAP Batch Release Hub, AI-assisted custom release checks.

Prerequisites

- You're authorized to upload attachments.
  The business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
- The processing status of the release decision item is *New* or *In Progress*.
- You've purchased the AI units license. For more information about the AI units license, please contact your Account Executive.
- In the *Manage Release Configurations* app under *Make General Settings* > *AI*, the *Enable AI-Based Proposals* setting is turned on.
  This setting can be edited only if you've purchased the AI units license.

- In the *Manage Release Configurations* app under *Configure Release Checks* > *Release Checks*, the custom release check has been configured to allow an AI-based proposal for one or more checklist items.

Context

Before you can use the AI-based *Generate Result* button for a checklist item in the SAP Batch Release Hub, AI-assisted custom release checks, you need to upload the relevant documents and set them as AI-relevant. When you set an attachment as AI-relevant, the system converts the document into a format that AI can work with. Depending on the size of the attachment, this process can take some time.

> **Note**
>
> Once a file has been uploaded, it can't be removed again.

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app.
2. In the worklist, find the release decision item that you want to work on.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section and open the details of the custom release check.
5. Go to the *Attachments* section and choose *Upload*.
6. Select one or more files to upload.

   For use with AI, you can upload files of the following formats with a maximum file size of 40 MB.

   > **Caution**
   >
   > In general, we recommend you upload small files. Only upload large files when absolutely necessary.

File Type	Allowed File Formats
Document	• .pdf • .txt • .docx
Image	• .png • .jpg • .jpeg • .gif • .svg

7. When the upload has completed, select the documents that are relevant for AI and choose *...* > *Set as AI-Relevant*.

The *AI Processing Status* changes from *Not AI-Relevant* to *AI-Relevant (Getting Ready)*. The process can take some time depending on the size of the file. Refresh to see the latest *AI Processing Status*.

Results

When the *AI Processing Status* of an attachment is *AI-Relevant*, it is ready for use in the *Generate Result* feature in the custom release check.

Task overview: SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 189]

Next task: Generating AI-Based Proposals for SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 192]

7.2.2 Generating AI-Based Proposals for SAP Batch Release Hub, AI-Assisted Custom Release Checks

Generate AI-based proposals for the result of checklist items in SAP Batch Release Hub, AI-assisted custom release checks.

Prerequisites

- You are authorized to change release checks.
  To make any changes in a release check, the business role assigned to your user in the relevant quality department must have the release activity *Release Decision* or *Release Preparation*.
- The release decision item falls within your responsibilities defined in a quality department to which you're assigned.
  In addition, if you are working on a PCN release decision item that is created by a country/region split, you must be assigned the PCN user authorization for the country/region in the *Manage Release Configurations* app.
- You've purchased the AI units license. For more information about the AI units license, please contact your Account Executive.
- In the *Manage Release Configurations* app under *Make General Settings* > *AI*, the *Enable AI-Based Proposals* setting is turned on.
  This setting can be edited only if you've purchased the AI units license.
- In the *Manage Release Configurations* app under *Configure Release Checks* > *Release Checks*, the custom release check has been configured to allow an AI-based proposal for one or more checklist items.
- You have uploaded the relevant attachments and set them as relevant for AI.
  This is an important step that prepares the documents and saves them in a format that AI can understand and process.

Context

This is an optional feature that uses AI to review documents and propose a result for a checklist item based on its *Condition for Acceptance*. You can review the AI-generated result and decide whether to accept or discard it. You also have the option to complete the checklist items manually if you prefer.

Please note that the quality of the proposed result depends on the specific large-language model (LLM) used and the quality of the input document.

> ⚠ Caution
>
> AI can make mistakes. Please review the proposed result carefully before completing the checklist item.

Procedure

1. Open the *My Release Decisions* app or the *My PCN Release Decisions* app.
2. In the worklist, find the release decision item that you want to work on.
3. Open the details of the release decision item.
4. Go to the *Release Check Summary* section in the *My Release Decisions* app or the *PCN Release Check Summary* section in the *My PCN Release Decisions* app.
5. Open the details of the custom release check.
6. Go to the *Checklist Items* section and select one or more checklist items that have *AI-Based Proposal Enabled* set as *Yes*.

   You can select a maximum of 50 items.
7. Choose *Generate Result*.

   The *Generate Result* dialog appears. By default, the *Documents* column for each checklist item includes all the active AI-relevant attachments. Inactive attachments are not considered.
8. If necessary, adjust the list of documents for each checklist item.
9. Select one or more checklist items and choose *Generate*.
10. When the generation has finished, choose *Review* to see how the proposed result for an item was generated.

    In the dialog that appears, there are links to the source documents for the result. Review these to ensure the result is accurate. Note that you cannot use the proposed result until you review it.
11. Choose *OK* to return to the *Generate Result* dialog.

    You now have options to accept, discard, or revise the proposed result for the item.
12. If you agree with the proposed result for the checklist item, choose *Accept*.

> ⓘ Note
>
> If you do not agree with the proposed result, you can do one of the following:
> - Choose *Discard* and proceed to complete the checklist item manually.
> - Choose *Revise*, select different documents, and try again.

13. If necessary, enter a valuation and a comment for the checklist item.

    If a valuation has been configured for each possible result in your configuration settings, then the valuation is entered automatically.
14. Continue to review each checklist item and accept or discard the proposed result as appropriate.
15. Save your changes.

    Note that you can save your work at any time, but only accepted items with valuations will be saved. AI-generated results are indicated by the ✦ *AI* icon, so it is always transparent which results were generated by AI.

    Valuations that have been configured as "Red" or "Yellow" are displayed in their configured color, so you can easily identify items that do not have a positive valuation.

Task overview: SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 189]

Previous task: Preparing Attachments for SAP Batch Release Hub, AI-Assisted Custom Release Checks [page 190]

7.3 Using SAP's Generative AI Copilot, Joule

Learn how to use Joule, SAP's generative AI copilot, to help you manage your release decision workload and make informed decisions in SAP Batch Release Hub for Life Sciences.

> ⓘ Note
>
> At present, Joule is supported only in the preproduction landscape.

With Joule, you can interact with SAP Batch Release Hub for Life Sciences in a conversational way using natural language. Joule provides the specific capabilities described in this section to help you access information, automate repetitive tasks, and make data-driven decisions.

> → Remember
>
> Joule is powered by Generative AI and all output should be reviewed before use. Please do not enter any sensitive personal data, and avoid entering any other personal data you do not wish to be processed. For more information, see Data Protection and Privacy in the Joule documentation on SAP Help Portal.

Prerequisites and Onboarding Joule

For information about setting up and onboarding Joule, see Integrating Joule with SAP Solutions in the Joule documentation on SAP Help Portal.

Getting Started and Key Features

To open Joule, choose *(Joule)* in the upper right corner of the shellbar. To get started, you can choose the quick action *Show me my tasks for today* or enter the question "How can you help me?".

For more information about using Joule, see Using Joule in the Joule documentation on SAP Help Portal.

Using Joule in GxP Environments

Joule operates under a robust and transparent AI governance framework that supports its deployment in Good Practice (GxP) regulated environments. Joule is not a decision-making system for GxP-critical actions. It is a decision-support solution with outputs that must be validated within a controlled, auditable, and compliant framework.

For a detailed analysis showing how Joule can be deployed as a decision-support solution in a GxP environment, see the white paper, Reap the Benefits of AI in GxP Environments with Joule.

This SAP white paper provides a comprehensive comparative analysis demonstrating how Joule aligns with the following two critical industry frameworks:

- ISPE's GAMP 5 Appendix D11 for AI/ML validation
- ISO 42001 for AI management systems

This alignment enables both regulatory compliance and robust AI governance through a human-in-the-loop approach.

7.3.1 Conversational Access to Product Documentation

Joule offers you conversational access to the product documentation.

Using natural language, you can ask Joule a question about SAP Batch Release Hub for Life Sciences, and Joule will search the product documentation on SAP Help Portal to find the answer. Joule summarizes the search results in the background. This summarization is then displayed to you as Joule's answer to your question, along with links to the source documents. If you select the link for a source document, you are taken directly to the relevant topic on SAP Help Portal.

> **Example**
>
> Here are some examples of the types of questions you can ask:
>
> - How do I reprocess a release decision item?
> - How do I add a user to a quality department?
> - What is a restriction driver?
> - Where can I review PCN release decisions?
> - How do I configure an AI-assisted custom release check?

7.3.2 Showing Items That Are Blocked or Ready for Release

Joule can help you to quickly find your release decision items that are either blocked or ready for release.

Definitions

- *Ready for Release*: An item is considered to be ready for release when all its release checks are in a green status.
- *Blocked for Release*: An item is considered to be blocked for release when it has at least one release check in a red status.

> ⓘ Note
>
> When identifying the items that are blocked or ready for release, Joule excludes any items that are configured for automated release. Joule includes only items that need to be released manually in the result list.

Getting Started

To get started, you can do one of the following:

- Choose the quick action *Show me my tasks for today* or enter the question "How can you help me?". Joule presents you with some more quick actions. Choose one of the following actions to continue:
  - *Show Items Ready for Release*
  - *Show Items Blocked for Release*
- Enter a statement like "Show all my items that are ready for release" or "Show all my items that are blocked for release".
  You can narrow down your search by adding more criteria. For example, you can search for items with a specific red release check, batch, inspection lot, material, or open deviations.

  > ✤ Example
  >
  > Here are some examples:
  >
  > - Show me all items that are blocked by the regulatory data check
  > - Show me all items for batch XYZ that are ready for release
  > - Show me all items with open deviations
  > - Show me all items that are ready for release with closed deviations

There could be many matching items, so Joule tells you how many there are in total and lists the top 10 items maximum. The items are sorted by due date in ascending order. In the result list, you can choose *Open* next to an item to navigate to the item details in the *My Release Decisions* app.

> **Note**
>
> All release decision items have a due date, and some might also have a prioritized due date if one is set. Joule uses the prioritized due date when available. If there is no prioritized due date, Joule uses the regular due date to identify and sort release decision items. In addition, the relevant date must be in the future.

7.3.3 Showing Batch Release History

Joule can help you find the previous release decisions made for a particular batch, material, and location combination.

This information can provide insights into the release decision history of a batch and help you to assess any current release decisions for the batch. You can refine your search by specifying the release decision that was set and the processing status of the items.

Getting Started

To get started, you can do one of the following:

- Choose the quick action *Show me my tasks for today* or enter the question "How can you help me?". Joule presents you with some more quick actions. Choose *Show Batch Release History* to continue, and Joule will prompt you to enter the batch ID, material ID, and location ID.
- Enter your request in natural language specifying the batch ID, material ID, and location ID.

  > **Example**
  >
  > Here are some examples of the types of requests you can enter:
  >
  > - Show me all release decisions for batch XYZ, material MAT1, and location ABC
  >   Note that Joule assumes you are looking for items where a release decision has been set, which means the processing status is *Completed* or *Confirmed*.
  > - Show me all completed release decisions for batch XYZ, material MAT1, and location ABC
  > - Show me all rejected release decisions for batch XYZ, material MAT1, and location ABC
  > - Show me all rejected and confirmed release decisions for batch XYZ, material MAT1, and location ABC

There could be many matching items, so Joule tells you how many there are in total and lists the top 10 items maximum. The items are sorted by the last modified timestamp of the item's processing status in descending order. In the result list, you can choose *Open* next to an item to navigate to the item details in the *My Release Decisions* app.

7.3.4 Showing Items with Recent Changes

Joule can help you to find your release decision items with recent changes to release checks.

Joule considers only items that meet the following criteria:

- *Due Date* or *Prioritized Due Date* is in the future.
- *Processing Status* is *New* or *In Progress*.

Getting Started

To get started, you can do one of the following:

- Choose the quick action *Show me my tasks for today* or enter the question "How can you help me?". Joule presents you with some more quick actions. Choose *Show Items with Recent Changes* to continue.
- Enter your request in natural language.

> **Example**
>
> Here are some examples of the types of requests you can enter:
>
> - Show me all items with the latest data changes
> - Show me all items with data updates since yesterday
> - Show me all items with data updates in the last 2 hours

There could be many matching items, so Joule tells you how many there are in total and lists the top 10 items maximum. The items are sorted by the last modified timestamp. In the result list, you can choose *Open* next to an item to navigate to the item details in the *My Release Decisions* app.

8 Glossary

This glossary gives you an overview of the most important terms you'll need when working with batch releases.

For the complete list of relevant terms, you can search under component `IS-LS-BRH` in the following resources:

Link	Comment
https://help.sap.com/glossary	Terms and definitions are available in English and German only.
https://www.sapterm.com	Terms are available in English, German, French, Spanish, Portuguese, Chinese, Japanese, and Russian. Definitions are available in English and German only.

Term	Definition
annual product quality review check Abbreviation: APQR check	A release check to evaluate the status of the annual review of quality standards for a product associated with a batch.
analytical suitability	The valuation of a multiple specification quality characteristic.
artwork and safety label check	A release check to evaluate the compliance and correctness of information on the packaging and labeling for a batch.
authorized reference value	An item of regulatory data from health authorities' specifications that is documented as the permitted value of a restriction driver attribute. Each restriction driver attribute can have multiple authorized reference values.
authorized supply chain map	A documentation of the activities from a Life Sciences company's supply chain that are relevant for regulatory control. The map includes restriction driver attributes that are used for jurisdictional control in the batch release process. To satisfy health authority regulations, the actual values from the company's activities must match the authorized reference values for the map's restriction driver attributes.
batch	The total quantity of a material that has been created under uniform conditions.
batch genealogy	A complete "family" history of a given batch, traced through process order splits, movements, and rework.

Term	Definition
batch genealogy check	A release check for the evaluation of information related to the entire manufacturing process of a batch and its related batches.
batch record review Abbreviation: BRR	A release check for the evaluation of a batch (master) record. This check determines whether the batch is compliant with regulations.
batch release	The certification of a batch of a medicinal or drug product by an authorized person. The batch release is a prerequisite for the clinical or commercial use of the product included in the batch.
blinded description	The description used in a blinded clinical study. It is used on the material and later appears on the blinded printouts of documents such as invoices and delivery notes.
blinding group	The group assigned to a kit type in a blinded clinical study to identify the materials that must be blinded together.
certificate check	A release check to evaluate the availability of relevant certificates for a batch.
change control data check	A release check to evaluate the status of change records for a batch.
clinical trial regulatory check	A release check that evaluates the health authority approval and approved shelf life for batches used in clinical studies.
clinical trial technical check	A release check that evaluates the status of the clinical trial technical check as imported from your source system.
combined release type	An entity that combines release types so that a release decision for the included release types can be made in a single step.
component batch	A specific quantity of a material that is managed and tracked as a unit within the production process and used as a raw material or an intermediate product in the manufacture of other materials. A finished product batch can be composed of multiple component batches, and a component batch can itself be composed of other component batches. The relationships between a finished product and its component batches form a batch hierarchy. Component batches enable companies to trace materials throughout the production process, from receipt to finished product, and are important for tracking the exact origin and processing history of materials.
component check	A release check to evaluate the availability of the batch status for component batches.

Term	Definition
contract manufacturing organization Abbreviation: 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.
custom release check	A freely configurable release check that includes a list of checklist items to be evaluated. Custom release checks can be configured to meet individual business needs
deviation check	A release check to evaluate the status of deviation records for a batch.
flavor	A version of a material, typically defined by product type, material-related characteristics, and batch-related characteristics. The use of flavors is optional but helps reduce the proliferation of SAP materials by allowing multiple materials with the same shelf-life version to share the same flavor ID, specific to each study.
import release	A release type that applies when the manufacturing plant and distribution warehouse or targeted country/region for release are located in different regions, for example, EU and non-EU. This release confirms that the batch meets local requirements and also confirms compliance with marketing authorization and current Good Manufacturing Practice.
inspection lot	A request to a location to carry out a quality inspection for a specific quantity of material.
inspection type	Determines how an inspection is to be carried out. Each inspection type is assigned to an inspection lot origin. There can be several inspection types for an inspection lot origin. For example, the inspection lot origin "goods receipt for a purchase order" can have inspection types: • Model inspection • Normal inspection
jurisdictional control	An examination of whether procurement, manufacturing, and distribution processes within the supply chain of a Life Sciences company are compliant with the specifications as they are authorized by the health authorities in the various countries or regions of the sales market of the Life Sciences company.

Term	Definition
jurisdictional control check	A release check that evaluates whether the procurement, manufacturing, and distribution processes in the supply chain are compliant with the specifications authorized by the health authorities in the various countries or regions of the sales market of the Life Sciences company.
kit type	The clinical finished good (CFG) as stored in the warehouse that is distributed to sites over the course of a study. Materials, and successor materials if necessary, are assigned to each kit type.
location	A combination of attributes (plant or customer, organizational area, location type) used to reflect the organizational structure and responsibilities within a quality department.
market release / regulatory release	A release type that confirms that a batch has been manufactured and tested in compliance with the relevant marketing authorization and current Good Manufacturing Practice. This enables release of a finished product for sale or distribution.
multiple specifications	Several different inspection specifications for an inspection characteristic. These different specifications may result from customer requirements or country/region-specific requirements.
open label	An indicator that identifies whether a study is blinded.
organizational area	An attribute that provides an additional differentiating factor for defining the locations in a quality department.
packaging control number Abbreviation: PCN	A virtual batch used to group together process orders that are packaged together to maintain blinding in the case of blinded orders, or that share the same expiry date. The expiry date is printed on the labels of all the clinical finished goods (CFGs) included in the PCN.
prioritized due date	A date indicating the urgency of a release decision. The prioritized due date takes precedence over the due date originating from the source system of the relevant batch.
processing status	A status that shows the current stage of processing for a release decision item.
processing step	A step in a batch's supply chain, for example, procurement or manufacturing, that is used in jurisdictional control. A processing step is uniquely assigned to each release decision item to identify the correct node in the authorized supply chain map as well as the reference and actual values for restriction drivers.

Term	Definition
procurement type	A classification indicating whether a material is produced internally, procured externally, or both.
protocol	The guidelines that form the basis of a clinical study. They define the objective, design, methodology, and statistical consideration for the study, while ensuring the safety of the participants.
qualified person Abbreviation: QP	A business user who makes the final decision and takes responsibility for the release of a batch. This role is only used in the European Union (Directive 2001/83/EC for medicinal products for human use).
quality analyst Abbreviation: QA	A business user responsible for preparing the final release decision to be made by the qualified person or the release-responsible person.
quality control data check Abbreviation: QC data check	A release check for evaluating characteristics that are relevant for compliance with quality specifications during the manufacturing process.
quality department	An organizational entity that reflects the production supply chain for pharmaceutical products. Quality (assurance) departments are used to structure and streamline the release decision worklist for batches and packaging control numbers (PCNs).
regenerate	To create a new release decision item based on an existing one that is not yet completed. This may be necessary, for example, to change the release type or incorporate changes in configuration.
regulatory data check	A release check to evaluate the compliance of a batch with country/region-specific regulatory requirements.
release	To certify a batch for a specific release type, for example, for technical release or market release. The release is done by a qualified person or release-responsible person.
release activity	An action related to the preparation, review, or release of a release decision item.
release check	The evaluation of a quality aspect of a batch to determine whether any defects or anomalies exist that require further action before a batch can be released.
release check message	Additional information about the outcome of a release check. A message is shown, for example, if an attribute specified in an assigned business rule does not have the expected value.
release check status	A status that shows the outcome of a release check for a batch release.

Term	Definition
release check type	An attribute that specifies what kind of release check is involved, for example, a batch record review or a component check.
release decision	A release activity that entails the finalizing action in the processing of a release decision item.
release decision item	A worklist item that represents a release decision to be made for a batch or a packaging control number (PCN). In the *My Release Decisions* app, each worklist item represents a release decision to be made for a combination of batch, material, location, release type, and release decision trigger. In the *My PCN Release Decisions* app, each worklist item represents a release decision to be made for a combination of PCN, PCN version, location, release type, and PCN release decision trigger.
release decision trigger	An event that necessitates a new release decision, such as goods issue, for example.
release for distribution	A release type that confirms that a batch can be released for distribution in a specific country/region. Confirmation is provided by the qualified person or release-responsible person in the country/region of destination.
release preparation	A release activity that entails actions required to prepare for a release decision. A user authorized for release preparation can both view and edit a batch but cannot make the final release decision.
release process flow	A defined set of release types and the sequence in which they are to be processed.
release review	A release activity that entails checking a release decision item and the status of its release checks. A user authorized for release review can only view a release decision item and its details.
release type	A set of attributes that define the quality and compliance requirements for the release of a batch or a packaging control number (PCN).
release type sequence	The defined order of release types in a release process flow. The sequence determines the order in which the release types are applied to a batch or a packaging control number (PCN).
release-responsible person Abbreviation: RRP	A business user responsible for a defined release or certification step based on the relevant regulations.

Term	Definition
reprocess	To create a copy of a completed release decision item that requires a new release decision. This may be necessary, for example, due to unplanned changes affecting the batch or if the completed release decision was a preliminary one.
restriction driver	A group of one or more attributes of the supply chain of a pharmaceutical product that are subject to regulatory control. Restriction driver attributes and their authorized reference values are integrated in authorized supply chain maps that are used for jurisdictional control in the batch release process.
serialization commissioning check	A release check to evaluate the consistency of data for a batch that is relevant for serialization, for example, the manufactured quantity and the number of serial numbers commissioned. The serialization commissioning check was introduced as a first step in dividing the existing serialization data check into two distinct checks: one for commissioning and another for reporting.
serialization data check	A release check to evaluate the consistency of data for a batch that is relevant for serialization, for example, the manufactured quantity and the number of serial numbers commissioned.
study	The research conducted on subjects (human volunteers) with the intent to enhance medical knowledge.
supply chain map node	An element of an authorized supply chain map that represents a material and a processing step. Each node documents the authorized reference values of restriction driver attributes that are used for jurisdictional control in the batch release process.
supply chain table	A documentation of the end-to-end supply chain activities related to a specific pharmaceutical material and its destination country/region. It outlines manufacturing, testing, and distribution steps, along with relevant control attributes. While it supports traceability and Qualified Person (QP) certification, it is maintained for documentation purposes only and is not directly used for jurisdictional control checks during batch release decisions.
target material	The final material in the specification of an authorized supply chain map. Usually, the material is a finished good, but it could also be a step before the finished good if the final production and logistics are done outside the company (for example, sellable brite stock).
technical release for external procurement	A release type that confirms that an externally procured batch conforms with Good Manufacturing Practice and complies with its testing requirements.

Term	Definition
technical release for internal production	A release type that confirms that a batch that has been produced internally conforms with Good Manufacturing Practice and complies with its testing requirements.
temperature check	A release check that evaluates characteristics that ensure adherence to temperature control requirements for a batch.
tenant	An onboarded SAP Business Technology Platform (SAP BTP) subaccount. Tenants have separate data and separate identity and access management.
transport check	A release check that covers characteristics that must be evaluated upon goods receipt of a batch.
usage decision	A decision on the further processing of an inspection lot that is made on the basis of the inspection results.

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