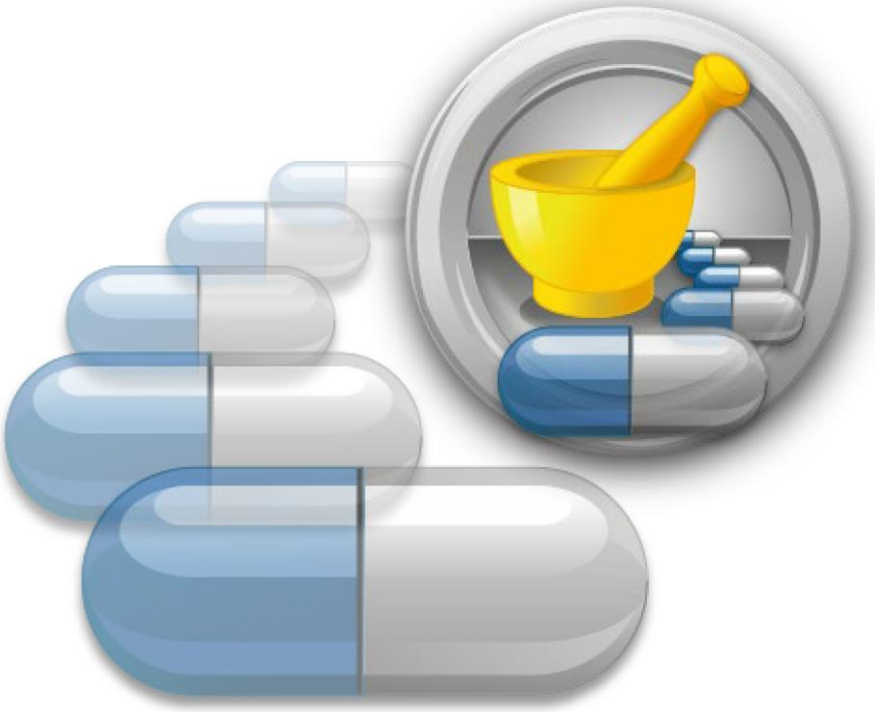
PharmaSuite®



PRODUCTION MANAGEMENT

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USER MANUAL

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Chapter 1

Production Management

PharmaSuite for Production Management is a system designed to control the production preparation process by managing its individual elements, such as orders, materials, inventory, etc.

This section contains important information about the basic principles of working with PharmaSuite for Production Management. Please read this section carefully, because it provides a solid background for all operations you may wish to perform with your system.

Later sections will explain how to perform the specific tasks in the system. We assume you are familiar with the conventions described in the following sections and the fundamentals of working with a personal computer.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface — Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g., status).

Italic typeface — Designates technical background information, such as

- path, folder, and file names
- methods
- classes.

CAPITALS — Designate keyboard-related information, such as

- key names
- keyboard shortcuts.

`Monospaced typeface` — Designates code examples.

Screen Layout and Behavior

The basic screen layout of PharmaSuite for Production Management consists of the following areas:

- status bar (page 3)
- task pane (page 4)
- work area (page 6) with
  - toolbar
  - property pane.

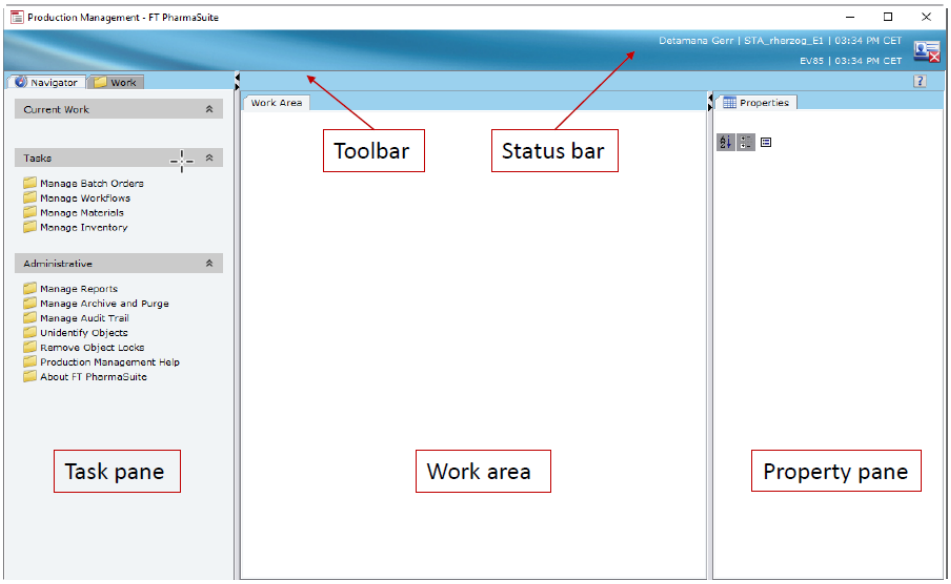

Figure 1: Screen layout

Status Bar

The status bar provides task-independent information such as the logged-in user with his full name, the work station and database name, local and server times, and the time zone information.

The right side of the status bar also holds the **Logout** button.

Task Pane

The task pane consists of two tabs.

It opens with the **Navigator** tab that holds all tasks of the PharmaSuite for Production Management, structured in sections for current work, data management tasks, and administrative tasks.

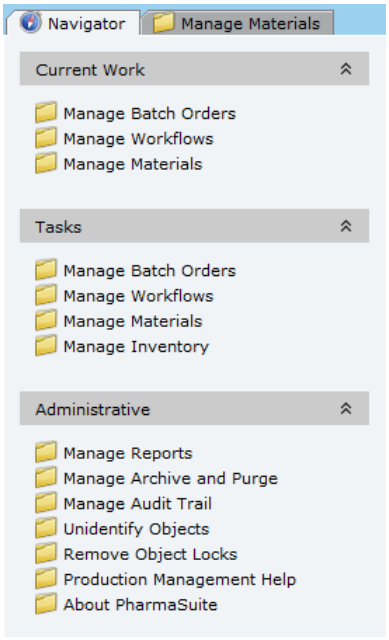

Figure 2: Task pane with Navigator tab

Selecting a task in the **Navigator** tab switches to the **Work** tab and fills it with a tree view of the data relevant to the respective task. Its title then displays the name of the selected task. The **Manage Materials** tab, for instance, holds all objects and data required for maintaining material data, such as material types, risk and safety phrases, etc.

The top node of a task tree view usually is a **Filters** node that contains the available default filters and user-defined filters (page 27) that allow you to restrict the number of object nodes displayed in the tree view.

Consequently, the container nodes that are controlled by a filter display the number of objects shown in the tree view and the number of objects available in the database:

- <Node name> (<number of displayed objects>/<number of available objects in the database>)
- Before a filtered node has been expanded the number of displayed objects has not been established and is thus given as *.

Figure 3: Task pane tree view

The tree view object nodes display the following data (if available):

- Non-version-controlled objects: <identifier> <description>
- Version-controlled objects: <identifier> (<version> <status>) <description>

Click a node in the tree view to update the work area (page 6) with all data pertaining to the node.

Actions for individual tree node objects are available either from the toolbar above the work area (page 6) or from a shortcut menu. To access the shortcut menu, right-click a tree node.

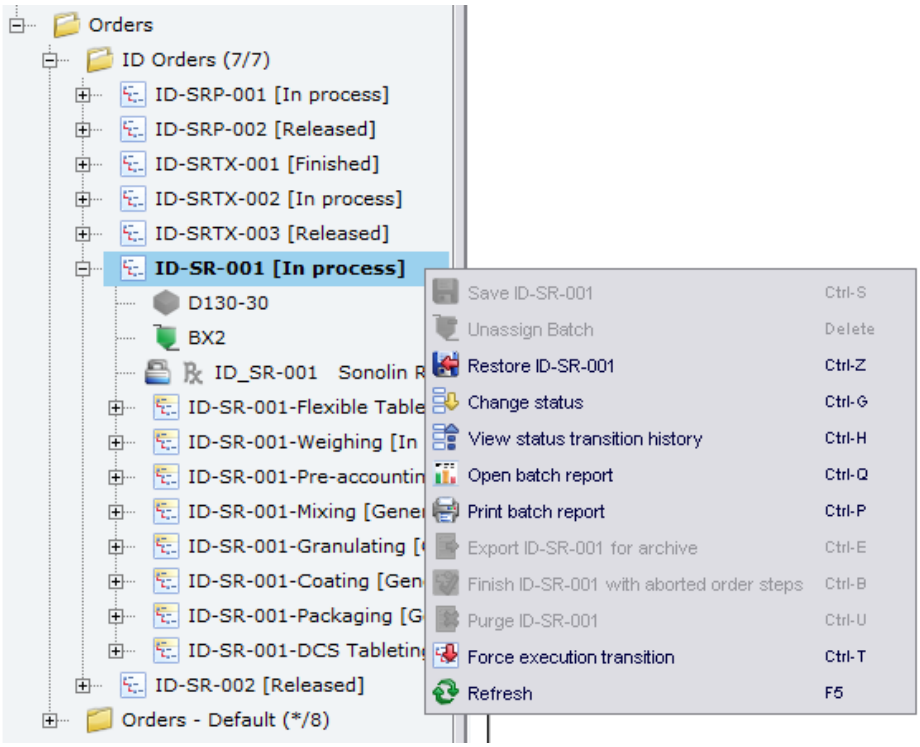

Figure 4: Task pane with shortcut menu

The content of the task pane tree view differs depending on a user's role and privileges. For some users there may be tasks that are not visible at all, and objects comprising other tasks may only be accessible in a read-only mode. This may happen on account of a user's privileges, the object's status, or the object's location (when objects from other tasks are referred to). To indicate that an object is in read-only mode, the object node is grayed out in the tree view.

Work Area

The work area consists of three sub-sections. The toolbar, which spans the entire width of the work area, provides access to the same actions that are available from the respective shortcut menu. The center part of the work area is where the relevant structural data of data objects, such as assignments, can be processed. The third sub-section is the property pane. The **Properties** tab displays all properties of a selected data object in the form of a data sheet.

There is a certain amount of redundancy in the data displayed on the work area and the **Properties** tab:

- The **Basic Data** section is typically identical in the work area and the **Properties** tab.
- Further displayable data is only shown on the **Properties** tab.
- The work area only displays data that cannot be visualized appropriately on the property pane, such as references or images. Labels on the work area have a full-length tooltip to make up for label texts that need to be abbreviated on account of space restrictions.

At the bottom of the **Properties** tab there is a **Description** pane. It provides additional information on the selected property, if available. You can toggle the pane view on and off with the **Show/Hide the Description pane** (page 9) icon located at the top of the **Properties** tab.

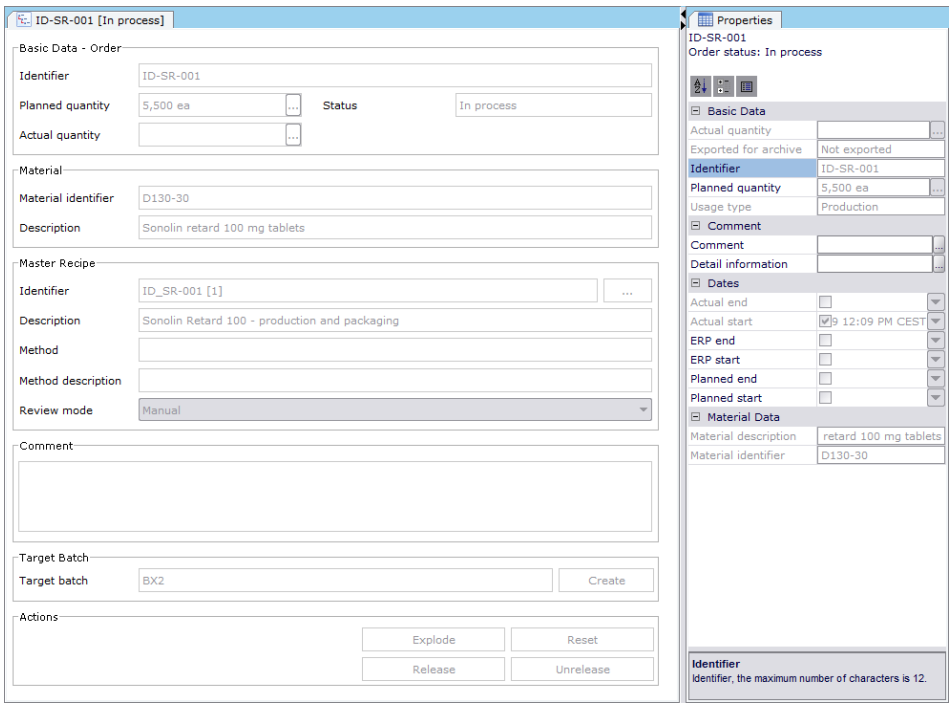

Figure 5: Work area with properties tab and description pane

Panel Management

The task pane, work area and help and property pane are horizontally resizable.

- To change the size of an area, place the mouse cursor on the separator you wish to move and slide the separator to the left or right.
- Use the arrow icons at the top of the separators to collapse the whole pane or expand it to fit the screen width.

Use the scroll bars to access parts of the work area that are not visible on the resized screen.

Graphical Elements

The following lists contain all buttons and icons used in PharmaSuite for Production Management.

Framework Icons

Icons displayed in the general framework of the application:

 **Logout**
Located at the right margin of the status bar. Logs you out of the application and returns you to the webstart page.

 **Navigator**
Indicates the navigator tab of the task pane that contains all tasks.

 **Folder**
Generic icon for object groups.
In the navigator pane it symbolizes the tasks, in the tree view of the work pane it indicates nodes that contain several objects of the same object type.

 **Folder open**
Generic icon for all open tree nodes that contain several objects of the same object type.

 **Properties**
Indicates the properties tab that lists all properties of the object selected in the tree view of the work tab.

 **Help**
Located at the right margin of the toolbar. Opens a web browser to display the context-sensitive help for the object selected in the tree view of the work tab.

 **Locked object**

Located to the left of any object node in the tree view of the work tab. It indicates that an object is locked for editing by another user.

 **Unsaved changes**

Located to the left of any object node in the tree view of the work tab. Indicates that an object has unsaved changes.

 **Sort properties and categories by name**

Located in the property pane. It controls the alphabetic sorting of categories and properties. A gray icon background indicates that alphabetic sorting is switched on.

 **Toggle between category view and flat list view**

Located in the property pane. It controls whether the properties are displayed in their category groups or as flat list without categories. A grey icon background indicates that category grouping is switched on.

 **Show/hide the description pane**

Located in the property pane. It controls whether the description pane to display additional information on a selected property is displayed or not. A gray icon background indicates that the display of the description pane is switched on.

DIALOG ICONS

Indicator icons displayed on dialog boxes:

 **Information**

Displayed with informative messages.

 **Question**

Displayed with interrogative messages.

 **Warning**

Displayed with warning messages.

Error

Displayed with error messages.

OBJECT ICONS

Object icons displayed with the tree nodes in the object tree on the task pane:

 Access privilege

 Auxiliary packaging material

 Auxiliary substance

 Batch

 Bulk material

 Event

 Finished goods

 Intermediate goods

 Intra material

 Master recipe

 Order

 Order/workflow step

 Order/workflow step input or ingoing order/workflow step transfer

 Order/workflow step output or outgoing order/workflow step transfer

 Packaging

 Raw material

 GHS statement

 Secondary packaging material

 Semi-finished goods

 Signature

 Storage area

 Storage location

 Sublot

 Transaction history

 User

 User group

 Warehouse

 Workflow

Action Icons

Action icons displayed in the toolbar and shortcut menus:

 **Abort**
In batch order management, irrevocably aborts an order step that is **Generated** (and startable in PharmaSuite for Production Execution), **In process**, **Held**, or **Reactivated**.

 **Abort for reactivation**
In batch order management, aborts an order step that is **In process** or **Held**.

 **Apply**
Applies filter criteria defined in the work area to the display of the object nodes in the tree view.

 **Change status**
Opens the **Change Status** dialog to perform a status transition on the selected object.

 **Delete**
Deletes the selected object.

 **Export for archive**
In batch order management, it opens the **Export Order for Archive** dialog to export the set of files needed for archiving before an order can be purged.
In workflow management, it opens the **Export Workflow for Archive** dialog to export the set of files needed for archiving before a workflow can be purged.

 **Export list of <data objects>**
In all tasks that display a list in the work area, exports the list entries (page 40) to a file in the CSV format.

 **Finish with aborted order steps**
In batch order management, finishes an order that is **In process**, but all of its order steps are either **Finished** or **Aborted**.

 **Force execution transition**
In batch order management and workflow management, opens the **Force Execution Transition** dialog to force an inactive transition during execution.

 **Increase quantity of order step input**
In batch order management, allows to increase the quantity and batch allocations of the selected order step input of a **Finished** or **Reactivated** order step in an order that is still **In process**.

 **Move all left**
In multi-reference selectors (page 32), moves all objects from the right list to the left list.

 **Move all right**
In multi-reference selectors (page 32), moves all objects from the left list to the right list.

 **Move left**
In single (page 30) or multi-reference selectors (page 32), moves the selected object from the right list to the left list.

 **Move right**
In single (page 30) or multi-reference selectors (page 32), moves the selected object from the left list to the right list.

 **New**
Creates a new object.

 **New alternative order step input**
In batch order management, creates a new alternative order step input for an **Exploded** order, thus replacing the selected order step input.

 **New additional order step input**
In batch order management, creates a new order step input to add a material that is originally no material input of the order to a **Finished** or **Reactivated** order step in an order that is still **In process**.

 **Open batch report**
In batch order management, opens the batch report of the order in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.

 **Open workflow report**
In workflow management, opens the workflow report of the workflow in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.

 **Print batch report**
In batch order management, opens the batch report of the order in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.

 **Print workflow report**
In workflow management, opens the workflow report of the workflow in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.

 **Purge**
In batch order management, opens the **Purge Order** dialog to delete the data of the order from the database.
In workflow management, opens the **Purge Workflow** dialog to delete the data of the workflow from the database.

Reactivate
Order management of non-Dispense orders
Reactivates a **Finished** or **Aborted** order step of an order that is still **In process**.

Order management of Dispense orders
Reactivates a **Finished** Dispense order step of an order that is still **In process** if the order step contains a yet unprocessed material input.
Reactivates an **Aborted** Dispense order step input of a **Finished** or **Reactivated** order step whose order is still **In process**.

Refresh
Updates the selected object node with changes made concurrently by other users.

Replace target sublot
In batch order management, replaces the selected sublot of an order step output of a **Finished** or **Reactivated** order step in an order that is still **In process**.

Restore
Restores the selected object to its last saved version.

Save
Saves the selected object along with all of its dependent objects.

Save as
Creates a copy of the selected object or object structure under a different identifier.

Unassign batch from order
In batch order management, cancels the assignment between an order and its assigned target batch.

Unlock order step input
In batch order management, unlocks an order step input that has unintentionally been locked due to an exception situation on the shop floor.

View audit trail
Displays the audit trail data of the selected object.

View status transition history
Displays the status transition history of the current object.

Filter Icons

Filter icons displayed with the filter nodes in the object tree on the task pane:

 Access privilege filter

 Auxiliary packaging material filter

 Auxiliary substance filter

 Batch filter

 Bulk material filter

 Finished goods filter

 Intermediate goods filter

 Intra material filter

 Master recipe filter

 Order filter

 Packaging filter

 Raw material filter

 GHS statement filter

 Secondary packaging material filter

 Semi-finished goods filter

 Transaction history filter

 Storage location filter

 Sublot filter

 User filter

 User group filter

 Workflow filter

INPUT BOXES

Input boxes can have different background colors that assist you with filling in the data of a form. This behavior applies to forms, signature dialogs, and property pane entries.

The different background colors indicate the following:

White
An unfilled input box. A blinking cursor indicates that it has the focus, and you can start to type your entry.

Yellow
A mandatory box that must be filled before the form can be saved or closed with the **OK** button. A blinking cursor indicates that it has the focus, and you can start to type your entry.

Blue
A mandatory box that must be filled eventually but may not be available yet when a new data object is created. It is possible to save the data object without having entered data in the box. A blinking cursor indicates that it has the focus, and you can start to type your entry.

Red
An input box that was filled incorrectly before saving. The system will not allow you to save the data object.

If you try to save a form either by clicking the **Save** button from the toolbar or the **Create** button on intermediate forms, you must have filled in all yellow mandatory boxes with correct entries. Otherwise, the system will display a message that lists all missing entries. If there are unfilled blue mandatory boxes, a system message will list all of those unfilled properties but will allow you to choose whether you wish to save the data as it is.

Keyboard Operation

Control by keyboard is primarily necessary for navigation and editing purposes.

Framework Navigation Shortcuts

Use the following keyboard shortcuts to navigate the general framework of PharmaSuite for Production Management:

- ALT+F4
  Logs you out.
- ALT+N
  Brings the tree view pane to front.
- ALT+P
  Brings the property pane to front.
- ALT+R
  Switches between the main screen areas (task pane, work area, property pane).
- ALT+T
  Brings the navigator pane with tasks to front.
- ALT+W
  Sets the focus in the work area.
- F1
  Opens a web browser to display the context-sensitive help (page 109) of PharmaSuite for Production Management.
- SHIFT+F10
  Opens the shortcut menu in the tree view pane.

Screen Area Shortcuts

Use the following keys and keyboard shortcuts to navigate the screen areas of PharmaSuite for Production Management:

Property pane:

- RIGHT ARROW
  Accesses an edit field.
- UP/DOWN ARROW or TAB/SHIFT+TAB
  Navigates between property rows.

Task pane - navigator tab:

- ENTER
  Triggers a single-click action (opens a use case, expands/collapses a section).

- UP/DOWN ARROW
  Navigates between use cases.

Task pane - object tree tab:

- CTRL+DOWN ARROW
  Scrolls the view down without changing the selection.

- CTRL+UP ARROW
  Scrolls the view up without changing the selection.

- ENTER
  Triggers a click action (updates work area and property pane).

- LEFT ARROW/NUMPAD-
  Collapses the selected tree node or, if the node is collapsed, moves the focus to its next parent object.

- RIGHT ARROW/NUMPAD+
  Expands the selected tree node or, if the node is expanded, moves the focus to its first child object.

- UP/DOWN ARROW
  Navigates between the tree nodes.

Work area:

- ENTER
  Triggers a single-click action (button click, checkbox select/unselect).

- TAB
  Navigates from editable field/enabled button to editable field/enabled button, including tabs such as on a material form.

Action Shortcuts

Use the following keyboard shortcuts to trigger actions available for data objects:

- CTRL+B
  In batch order management, finishes an order that is **In process**, but all of its order steps are either **Finished** or **Aborted**.

- CTRL+D
  In batch order management, for order steps, creates a new additional order step input.

- CTRL+E
  - In batch order management, opens the **Export Order for Archive** dialog to export the set of files needed for archiving before an order can be purged.
  - In workflow management, opens the **Export Workflow for Archive** dialog to export the set of files needed for archiving before a workflow can be purged.

- CTRL+F
  Applies a filter to the tree view.

- CTRL+G
  Opens the **Change Status** form to perform a status transition.

- CTRL+H
  Displays the status transition history of the selected object.

- CTRL+I
  In batch order management, for order step inputs, allows to increase the quantity of an order step input.

- CTRL+L
  - In material management, displays the audit trail of the selected material.
  - In batch order management, for order steps, aborts the order step for subsequent reactivation.
  - In batch order management, for order step inputs, creates a new alternative order step input.

- CTRL+N
  Creates a new object, if there is only one **New** action available.

- CTRL+O
  In batch order management, for order steps, irrevocably aborts an order step.

- CTRL+P
  - In batch order management, opens the batch report of the order in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.
  - In workflow management, opens the workflow report of the workflow in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.

- CTRL+Q
  - In batch order management, opens the batch report of the order in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.
  - In workflow management, opens the workflow report of the workflow in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.

- CTRL+R
  - In batch order management, for sublots of order step outputs, replaces the order step output with a new order step input.
  - In batch order management, reactivates a **Finished** or **Aborted** non-Dispense order step of an order that is still **In process**.
  - In batch order management, reactivates a **Finished** Dispense order step of an order that is still **In process** if the order step contains a yet unprocessed material input.
  - In batch order management, reactivates an **Aborted** Dispense order step input of a **Finished** or **Reactivated** order step whose order is still **In process**.

- CTRL+S
  Saves an object.

- CTRL+T
  In batch order management and workflow management, opens the **Force Execution Transition** dialog to force an inactive transition during execution.

- CTRL+U
  - In batch order management, opens the **Purge Order** dialog, to delete the data of the order from the database.
  - In workflow management, opens the **Purge Workflow** dialog, to delete the data of the workflow from the database.
- CTRL+Z
  Restores an object.
- DEL
  Deletes an object.
- F5
  Refreshes the selected tree node and its sub-nodes.
- F12
  Copies an object to save it under a new identifier.

Dialog Boxes

The system displays information messages, warnings, error messages, and some types of signature requests as modal dialog boxes on top of the application. The following keys are available for navigating and operating dialog boxes:

- ENTER
  For buttons, triggers a single-click action on the default button.
- ESC
  Cancels the dialog and closes the dialog box.
- SPACEBAR
  For buttons, triggers a single-click action on the focused button.
- TAB
  Navigates along the defined navigation path, moving the focus between input boxes and buttons.

Basic Operations

The following sections describe basic and recurring operations and functions in PharmaSuite for Production Management.

Start, Login, Logout, and Password Change

Before you can start working with PharmaSuite your system administrator must have created a user account for you. The PharmaSuite administrator will inform you of your login name and initial password.
Depending on your company policy you may be forced to change your password when you log in for the first time. In this case, the system will display a message that indicates that your password has expired. Then the system will prompt you to change it (page 24).

START PHARMASUITE

To start PharmaSuite double-click the respective icon on the user interface or select it from the start menu. The system displays the webstart page in a browser window, from which you can select to start an application or view either the help system or the documentation.

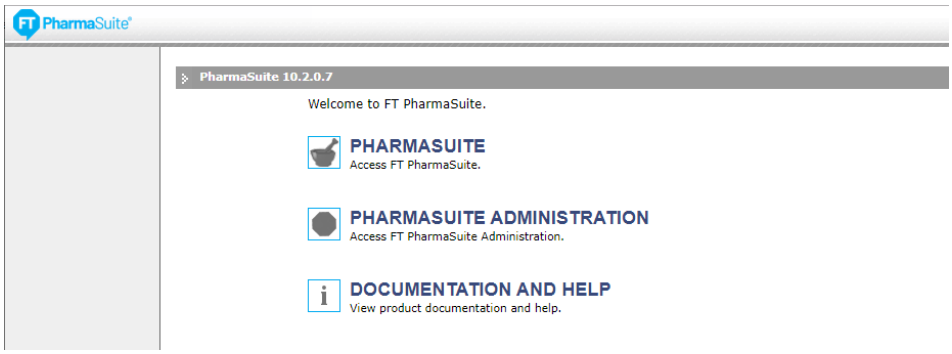

Figure 6: PharmaSuite webstart page

LOGIN

When you select to start PharmaSuite it runs through an initialization phase in the course of which you will also see the splash screen of Shop Operations, which is the internal platform of PharmaSuite. As soon as the initialization phase has been completed, the login form for user login appears.

The login form contains two mandatory fields, one for the login name and one for the password. Your login name and your password are unique for all PharmaSuite applications and are linked to your role and user privileges.

Type your login name and password in the respective boxes. Please note that your password is masked by asterisks (*). Click the **OK** button to complete the login procedure. If your login attempt is not successful, a message appears, and you have to repeat the procedure.

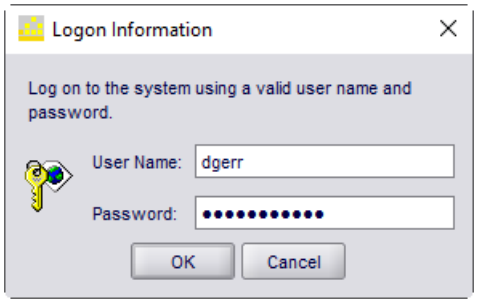

Figure 7: Login form

After you have successfully logged in, the system displays the PharmaSuite welcome page. From here you can start the Production Execution, Production Execution Viewer, Production Management, Data Manager, Recipe and Workflow Designer, and Production Responses applications, change your password and work station, or access the system documentation and help.

Figure 8: PharmaSuite welcome page

TIP

Please note that logins can be linked to access rights, which means that you can only start an application if your system administrator has assigned the suitable access privileges to you.
Some logins, especially in the production execution environment, are directly connected to an application and work station. This means that the welcome page will be skipped, and the application will start directly after you have successfully logged in.

LOGOUT

In PharmaSuite for Production Management, click the **Logout** button in the top right corner to quit PharmaSuite and return to the webstart page.

On the PharmaSuite welcome page, the **Logout** button is also located in the top right corner. Click it to return to the webstart page.

If you decide to log out from a running application, the system will request you to confirm the decision and also warn you if there is any unsaved data you may want to save before you log out.

PASSWORD CHANGE

You can access the function for changing your password from the PharmaSuite welcome page.

1. Click the **Change Password** link to open the **Change Password** form.
   When your password expires the system will open the form automatically. This can also happen when you log in for the first time to force you to change the initial password, which your system administrator defined for you.
2. On the **Change Password** form, the **User Name** box is output-only and contains your login name.
3. Type your current password in the **Old Password** box.
4. Type your new password first in the **New Password** box and then in the **Confirm New Password** box.
   For security reasons, passwords are masked by asterisks (*).

5. Click the **OK** button to close the form.
   From now on, use the new password to log in.

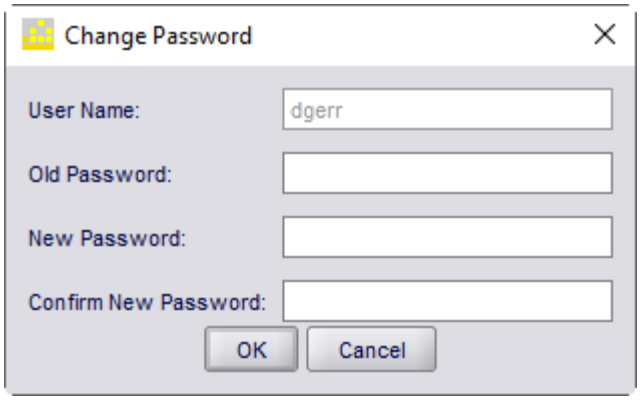

Figure 9: Change password

Required Servers

For providing its full functional scope, PharmaSuite relies on the following servers that are responsible for communication to external systems or between its applications.

- Electronic Batch Recording (EBR) server
  It controls the execution of EBR recipes and workflows and can process incoming messages from a Distributed Control System.
- Triggered Operation Management (TOM) server
  It manages event-triggered operations.
- Operation Execution (OE) server
  It controls the execution of server-run operations.
- Automation Integration (AI) server
  It controls the communication with automation-related systems.
- Transition server
  It performs automatic, system-triggered status changes on objects, such as master recipes, master workflows, batches, orders, workflows, or equipment entities and can process incoming messages from external systems, such as a Quality Management System or Warehouse Management.

PharmaSuite runs a heartbeat check on the servers to monitor their availability. To see if there are any issues, select the **About PharmaSuite** task (page 111), which shows the status of the EBR server. For information on the other servers, open the **Details** dialog and refer to the section that indicates servers with heartbeat issues.

Filter Function

When data objects are displayed in a tree view a filter function is essential to provide a means of organizing the structure of the tree nodes. A successful structure can significantly enhance the ease of handling large data quantities and thus render data management more efficient.

A filter is a defined set of search criteria that is applied to a tree view node and restricts the data objects displayed under the node to those objects that match the search criteria.

There are two types of filters in PharmaSuite, pre-defined default filters (page 26) that are available for each object type and user filters (page 26), which you can define to fit your specific needs and save for later reuse.

Default Filters

PharmaSuite provides a default filter for each object type, which restricts the number of displayed objects to 100 for the respective node.

You can always change and refine the search criteria of default filters, view the list of search results, and even apply the changed filter temporarily to the tree view. A changed default filter, however, cannot be saved. The applied changes are only valid for your current work session and are lost when you log out, unless you save them as user filter.

You cannot delete a default filter.

User Filters

If you wish to retain your search criteria for later sessions, you can save a modified filter as user filter.

User filters provide all the functions default filters have, which means you can modify the search criteria, list the search results, and apply the modifications to the tree view. In addition to that you can save your modification directly in the user filter, thus overwriting the old search criteria. If you repeatedly have the need for specific filters, it may be helpful to prepare a set of adapted filters and save them as user filters, so that they are available to you for work as soon as you log in.

If you do not need a user filter any longer you can delete it.

Working with Filters

To define a new filter, proceed as follows:

1. In the tree view, click the filter, on which you wish to base your new filter, to open it in the work area.
2. Enter search criteria and use the search operators to refine them further. The system provides the following operators to refine your search criteria. Please note that all search criteria are case-sensitive.

   - **Starts with**
     One or more characters or numbers the results will start with.
   - **Containing**
     A sequence of one or more characters or numbers the results will contain.
   - **Ends with**
     One or more characters or numbers the results will end with.
   - **Equal to**
     Only if there is an exact match for the given sequence of characters or numbers will a search result be displayed. If you select this operator and do not type a criterion, no results will be found.
   - **Not equal to**
     All search results other than the exact match for the given sequence of characters or numbers will be displayed.
   - **Greater than**
     For numbers: the search results will be higher than the given number.
     For letters: the search results will consider all letters in the alphabet after the given letter.
     For dates: the search results will be later than the given date.
   - **Greater than or equal**
     For numbers: the search results will be equal or higher than the given number.
     For letters: the search results will consider all letters in the alphabet with and after the given letter.
     For dates: the search results will be identical to or later than the given date.
   - **Less than**
     For numbers: the search results will be lower than the given number.
     For letters: the search results will consider all letters in the alphabet before the given letter.
     For dates: the search results will be earlier than the given date.

- **Less than or equal**
  For numbers: the search results will be equal or lower than the given number.
  For letters: the search results will consider all letters in the alphabet before and with the given letter.
  For dates: the search results will be identical to or earlier than the given date.
- *** (asterisk)**
  Select the asterisk operator without a criterion to see all objects.
- **Distinct only**
  Check this option for the rare occurrence that your search criteria find variants of the same object several times. The respective objects are only displayed once then.
- **Time of day ...**
  For dates that also need to include a timestamp, type the time after the date in the respective box. Use the format that matches your locale (US English example: 08:36:15 AM).

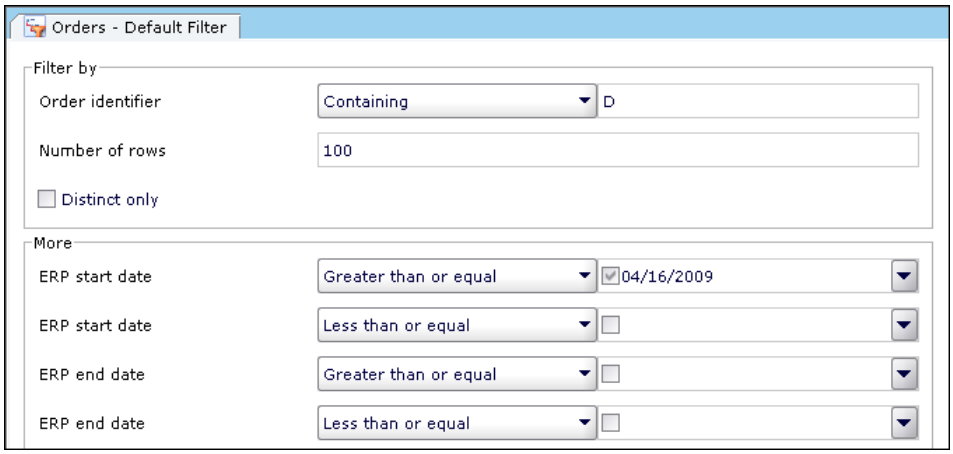

Figure 10: Search criteria

3. Choose the criterion by which you wish to sort the list. The system provides the following sorting operators to influence the order in which your search results are listed:

   - **Ascending**
     For numbers: smallest number first and rising.
     For letters: from A to Z.
   - **Descending**
     For numbers: highest number first and going down.
     For letters: from Z to A.
   - **Disabled**
     No Sorting.

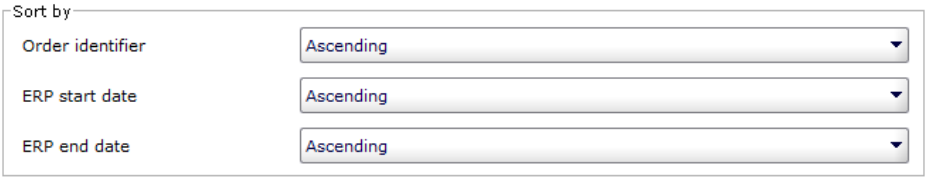

Figure 11: Sorting criteria

4. Click the **Search** button to start the search. The system lists all objects that match your search criteria in the **Results** list.
   Click the **Clear** button to clear all search criteria except the default restriction to 100 rows.

5. If the search results match your expectations, you can apply the filter to the tree view and/or save the search criteria as new user filter.

   Click the **Apply** button to apply your current search criteria to the respective object node in the tree view.

   Click the **Save as** button to save your current search criteria as new filter. The system will prompt you for a name for your new user filter.

   Click the **Save** button to save your current user filter with changed search criteria.

TIP
Click the **Export list of <data objects>** button to export the entries (page 40) of the **Results** list to an external CSV file.

Reference Selectors

When building complex data structures, it is often necessary to reference one or more objects from the object you are working on. For creating these references, the system supports you with reference selectors. There are two basic types of reference selectors, single-reference selectors (page 30) for assigning one object to a base object and multi-reference selectors (page 32) for assigning or appending two or more objects to a base object.

If the number of objects that are available for selection is very large, the reference selectors include the search and sort options of the filter function (page 27) to restrict the list of objects available for referencing. If you do not specify any search criteria, the system will list all available objects of this type, which can take a while.

Single-reference Selectors

The single-reference selector supports you when you need to assign another object to the base object you are currently working on. Whenever there is a reference to another object required and you know the object's identifier, you can simply type it in the respective box and the assignment is done. To undo the assignment, just clear the box.

If you do not know the identifier, click the **...** button to open the reference selector for the assignment.

Figure 12: Single-reference box with selector button

The **Select Reference** dialog opens on top of the work area.

1. Specify search and sort criteria to reduce the number of objects from which you have to select your assignment object later. The search and sort options are the same as in the filter function (page 27).
2. Click the **Search** button to start the search. The system lists all objects that match your search criteria in the **Results** list.
   Click the **Clear** button to clear all search criteria except the restriction to 100 rows.
3. In the **Results** list, click the row with the object you wish to assign to your base object.

4. Click the **Select** button (or double-click) to select the object, close the reference selector, and return to the work area with the assignment made.
   Click the **Cancel** button to close the reference selector and return to the work area without having assigned an object to your base object.

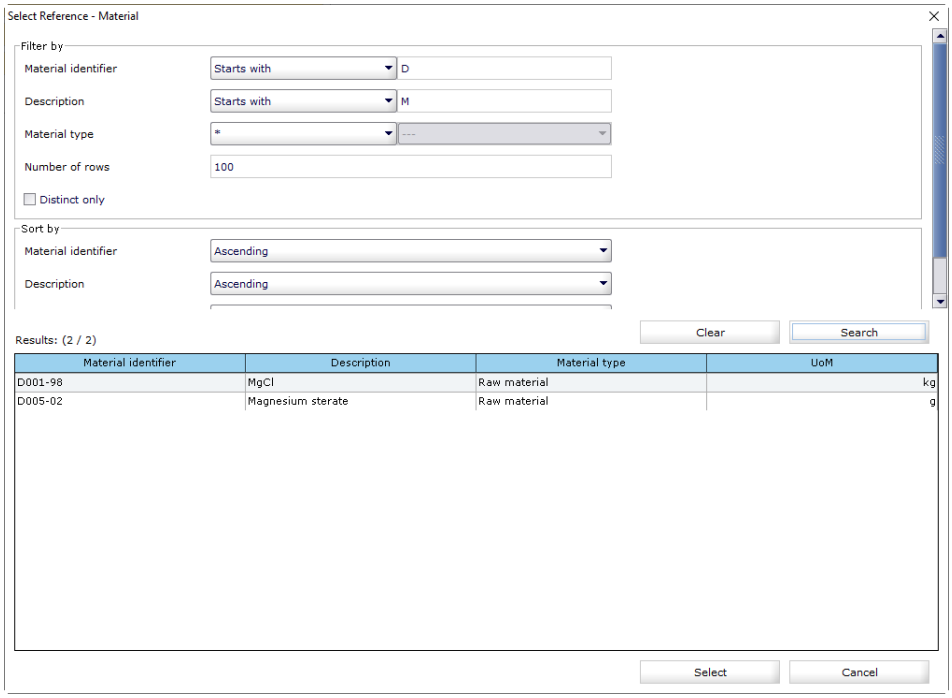

Figure 13: Select reference

MULTI-REFERENCE SELECTORS

The multi-reference selector supports you when you need to assign or append two or more objects to the base object you are currently working on.

APPENDING OBJECTS

The multi-reference selector for appending objects provides functions to find and append several objects to your base object.
After you have clicked the **Append ...** button in the work area, the system opens the **Select References** dialog on top of the work area.

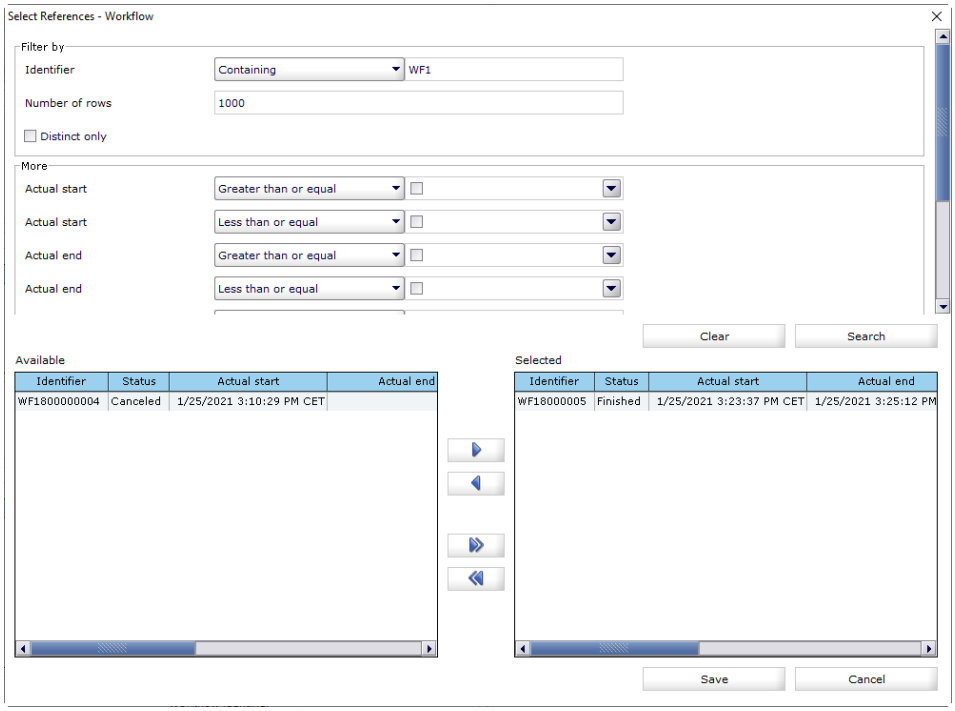

Figure 14: Select References for appending objects

The upper part of the dialog holds the filter to restrict the number of objects displayed in the list on the left, which are available for appending. The list on the right shows all objects that are currently appended or selected for appending.

1. Specify search and sorting criteria to reduce the number of objects from which you have to select your objects to be appended later. The search and sort options are the same as in the filter function (page 27).
2. Click the **Search** button to start the search. The system lists all objects that match your search criteria in the **Available** list.
   Click the **Clear** button to clear all search criteria except the restriction to 100 rows.

3. Use the arrow buttons to move objects between the **Available** and **Selected** lists.

   (or double-click) to move the selected object to the list on the right.

   to move all listed objects to the list on the right.

   (or double-click) to move the selected object to the list on the left.

   to move all listed objects to the list on the left.

4. When you have moved all required objects to the **Selected** list, click the **Save** button to close the dialog and return to the work area. The objects are now appended to your base object.
   Click the **Cancel** button to close the dialog and return to the work area without having changed which the objects are appended to your base object.

TIP

Please note that in the **Select References** dialog for object appending your changes to the list of appended objects are immediately saved and effective once you have clicked the dialog's **Save** button.

ASSIGNING OBJECTS

The multi-reference selector for assigning objects provides functions to find and assign several objects to your base object.
After you have clicked the **Assign ...** button in the work area, the system opens the **Select References** dialog on top of the work area.

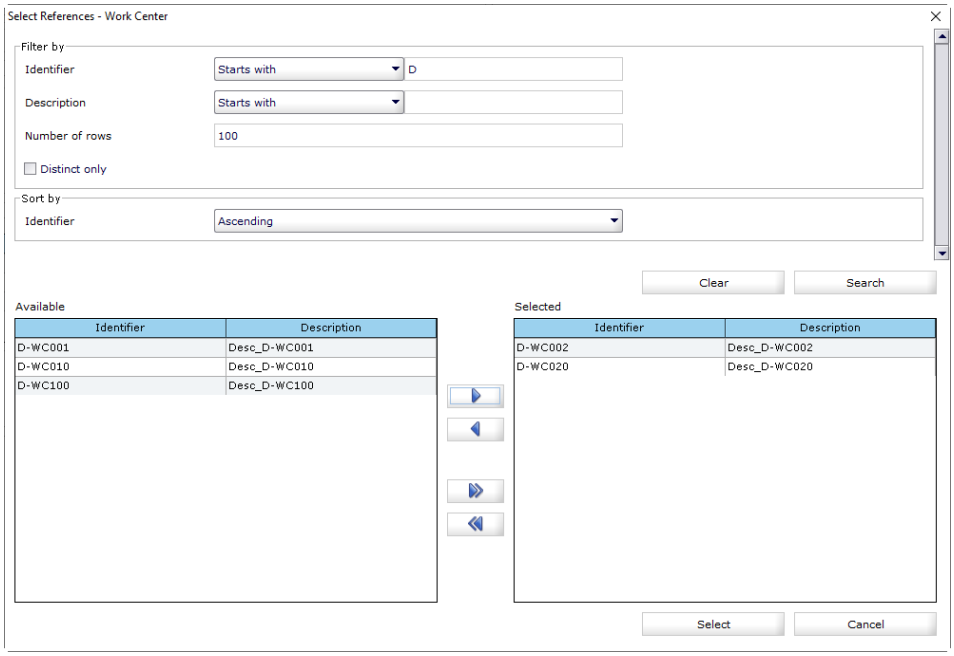

Figure 15: Select References for assigning objects

The upper part of the dialog holds the filter to restrict the number of objects displayed in the list on the left, which are available for assignment. The list on the right shows all objects that are currently assigned or selected for assignment.

1. Specify search and sorting criteria to reduce the number of objects from which you have to select your assignment object later. The search and sort options are the same as in the filter function (page 27).
2. Click the **Search** button to start the search. The system lists all objects that match your search criteria in the **Available** list.
   Click the **Clear** button to clear all search criteria except the restriction to 100 rows.
3. Use the arrow buttons to move objects between the **Available** and **Selected** lists.

    (or double-click) to move the selected object to the list on the right.

    to move all listed objects to the list on the right.

    (or double-click) to move the selected object to the list on the left.

    to move all listed objects to the list on the left.
4. When you have moved all required objects to the **Selected** list, click the **Select** button to close the dialog and return to the work area. The objects are now selected for assignment.
   Click the **Cancel** button to close the dialog and return to the work area without having defined any changes in the assignments to your base object.

TIP

Please note that in the **Select References** dialog for object assignment you only define changes to be made to the assignments to your base object. The defined changes are applied when you save the base object with the **Save** action from the toolbar in the work area.

Status Handling

Several objects in PharmaSuite have a specified life cycle that is governed by a status graph. A status transition is defined for each possible move of a data object from one status to a subsequent status. Status changes often take place implicitly, for example during order processing, when starting an order step automatically changes its status from **Released** to **In process**.

In PharmaSuite for Production Management, status control with explicit status changes (page 35) is available in the **Manage Batch Orders** task for orders, in the **Manage Workflows** task for workflows, and in the **Manage Inventory** task for batches. Depending on your system's configuration, a status transition can require a user to enter a single or double electronic signature as proof of authorization.

Any status transition that an object undergoes is registered in its status transition history (page 37).

Status Transitions

You can trigger a status transition as action of the respective data object.

Click the **Change status** action to open the **Change Status** dialog.

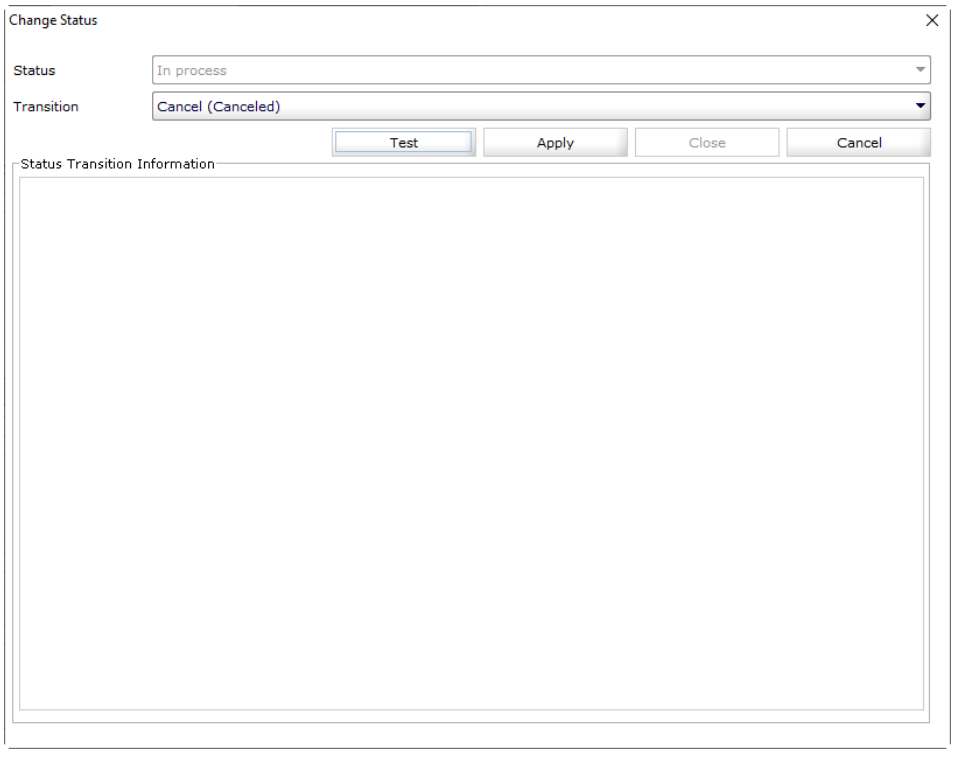

Figure 16: Change Status dialog

1. Select the target transition.
2. Click the **Test** button. The system tests the proposed status transition and updates the **Status Transition Information** list to indicate if the status transition can be performed.
   Click the **Cancel** button to close the window and return to the work area without having performed a status transition.

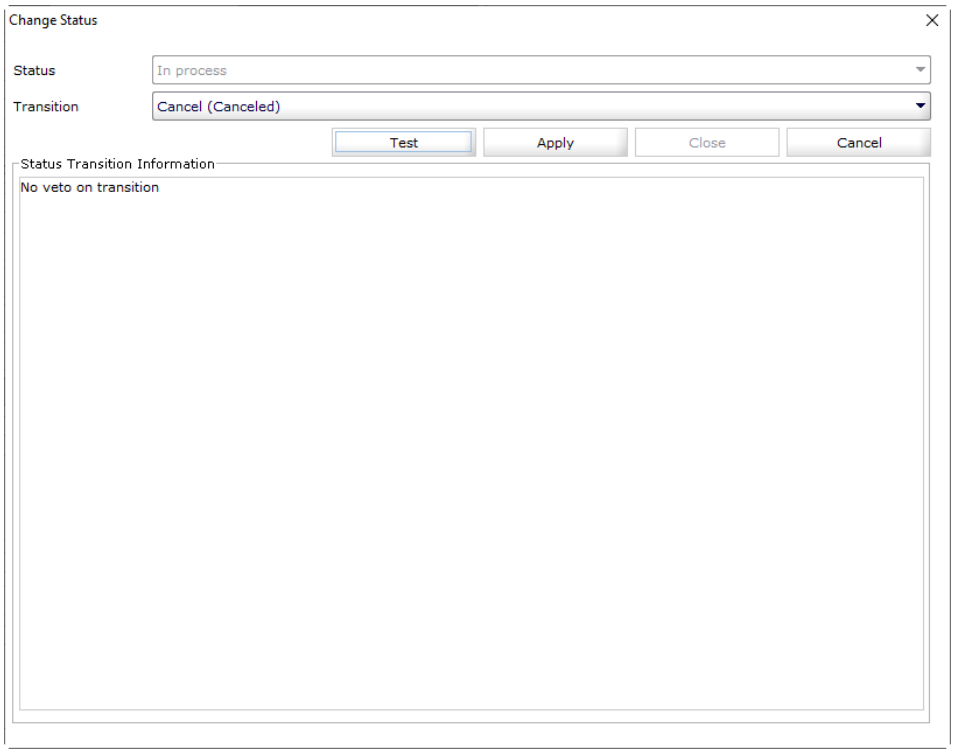

Figure 17: Status transition - test

3. When all prerequisites are met and there are no violations indicated in the list, click the **Apply** button to perform the status transition.
4. After you have performed the status transition, click the **Close** button to close the dialog and return to the work area.

STATUS TRANSITION HISTORY

Status transitions of all status-controlled objects are registered and accessible for viewing at all times as actions of the respective data objects.

Click the **View status transition history** action to open the status transition history of an object.

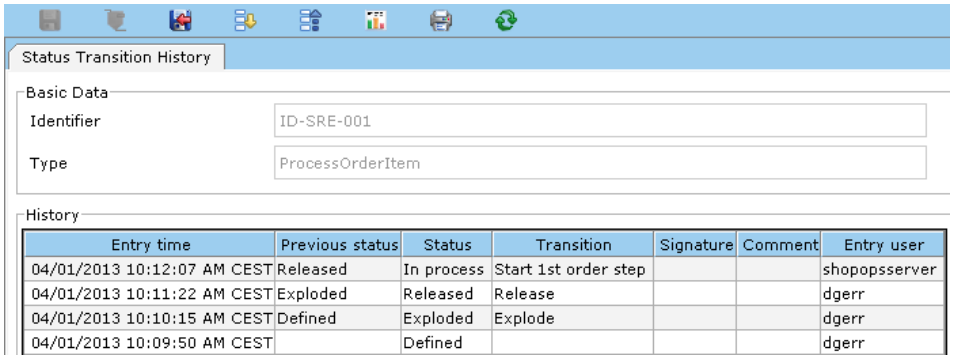

Figure 18: Status transition history

Signature Requests

When performing safety-sensitive or GxP-relevant functions the system may request you to enter an electronic signature, for example during a status change. Signatures are linked to user groups and access privileges, which means that the system will only accept the signature of a user who is qualified to perform the task in question. Unless the required signature data has been entered correctly, subsequent functions cannot be executed.

For situations requiring a witness, the system will ask not only for a single but for a double signature. In these cases, two different users, typically with different qualifications, have to complete the signature form before task processing can continue.

TIP

Please note that the system registers each signature with the timestamp when it has been verified successfully. Thus, the signature timestamps of a double signature will usually be different.

To perform an electronic signature, type your login name and password and click the **OK** button. Free-text comments can be optional or mandatory and may consist of up to 255 characters.
If a list of pre-defined comment texts is configured for a signature, the system displays an option list, which shows the headers of the available text options. Once an option has been selected, the system shows its full text in the read-only text box below the option list. If a pre-defined comment text is configured, it is mandatory. Later on, the pre-defined comment text is added as exception comment to the related exception.

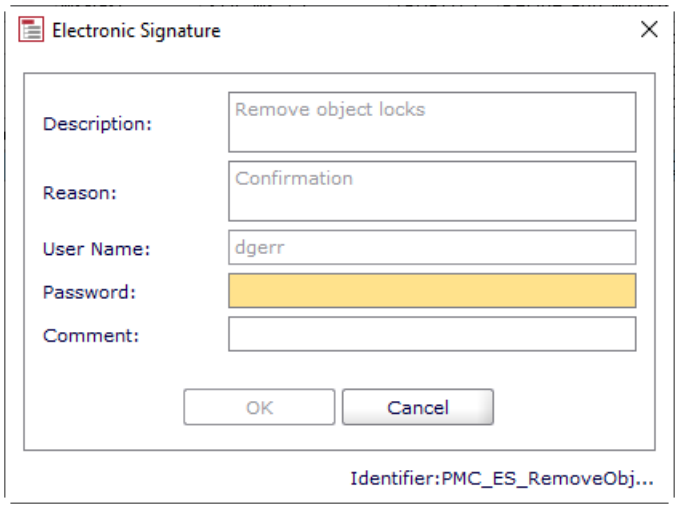

Figure 19: Single electronic signature

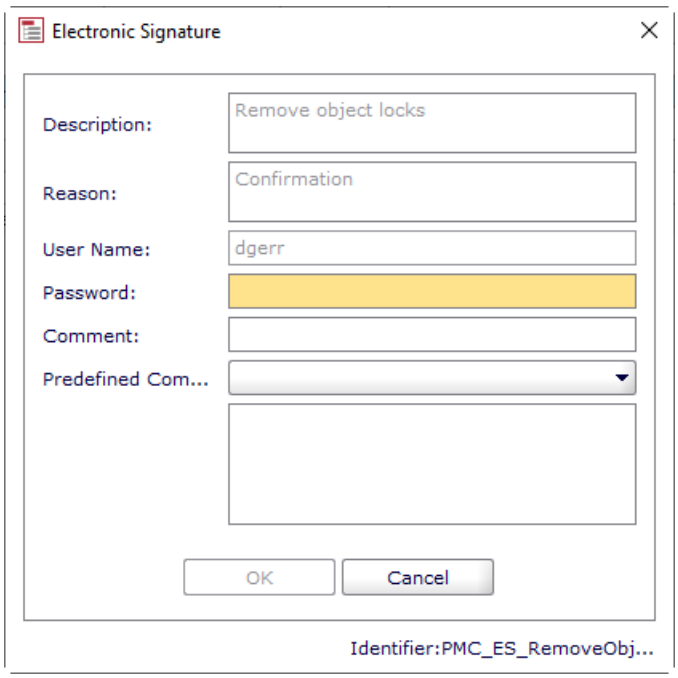

Figure 20: Single electronic signature with pre-defined comment

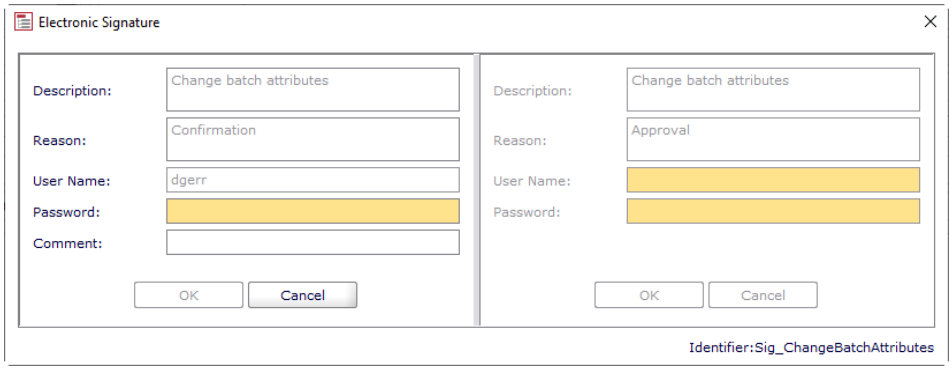

Figure 21: Double electronic signature to support witness role

Execution Transition Forcing

Under specific circumstances, execution in PharmaSuite for Production Execution can come to a halt, since the system cannot determine which path to take after it has evaluated the conditions of all possible transitions. This means that the affected order or workflow cannot proceed to its next step. An issue of this type can be caused by a faulty transition definition in the master recipe or workflow or by a transition condition not receiving an expected output form a preceding phase, which could not be supplied as the phase had to be aborted during processing.

To force an execution transition, proceed as follows:

1. Click the **Force execution transition** action to open the **Force Execution Transition** dialog.
   The dialog lists all execution transitions for which an issue prevents the system from deciding how to proceed.
   The transitions are listed in a nested table where the main table provides the following information for each:
   - the **Path** to the last recipe or workflow component before the faulty transitions,
   - the **Work center** where the affected component is being processed,
   - the date and time when the component completed, and
   - how long the system has been inactive.

   Each sub-table lists the affected transitions with identifier, description and condition expression.
2. Select the transition you wish to force.

3. Click the **Apply** button to force the transition.
   The system performs the transition, which consequently allows processing at the affected work center to continue.

   TIP
   If forcing the transition can be performed successfully, the system requires an electronic signature (page 37) as proof of authorization before it actually performs the action.

   The **Results** panel shows if the transition could be forced successfully or not. Once a transition has been forced successfully, the affected component with its transitions disappears from the list.

4. If necessary, you can now select another transition to force.
   Otherwise, click the **Close** button to close the dialog.

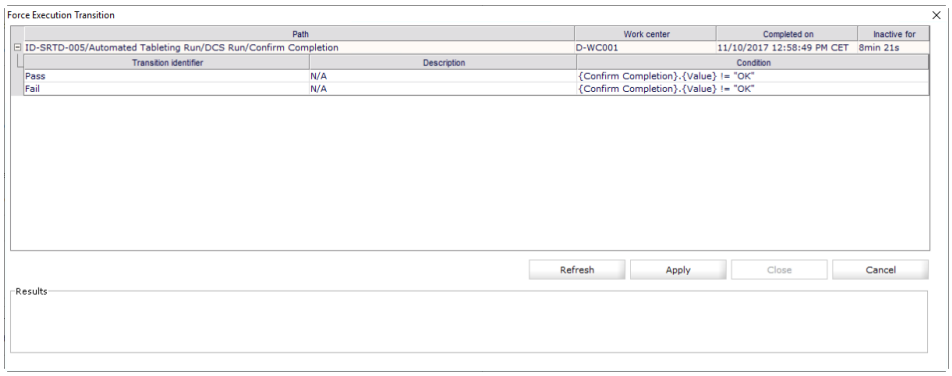

Figure 22: Force Execution Transition dialog

Exporting Data Lists to CSV

When the system lists data objects as table in the work area, it also supports you with the **Export list of data objects** function. It allows you to export all list entries to a file in the CSV format, which you can then view and process in a suitable external application.

TIP
Please note that the file will open automatically if you have a default application defined for opening CSV files in your operating system. If not, the system will ask you to select a suitable application.

Click the **Export list of <data objects>** action to trigger the export of the list of data objects that is currently visible in the work area. The action only refers to the main list of data objects, not to any lists of detail data that are populated when you select an entry in the main list.

TIP

Please note that for the administrative **Remove Object Locks** task (page 108), the function is not triggered by toolbar action but with an **Export** button below the list of locked objects.

Export files receive a generated name that consist of the following components:
PMC_<data object description>_<timestamp>_.csv
Example: PMC_Raw Material - Default_2020-05-08_10-03-30.csv
The files are created in a temporary folder that is cleared when you log off from PharmaSuite for Production Management. So, if you wish to retain an export file, you need to save it to a different location.

TIP

The temporary directory is typically located in your local user directory, such as *C:\users\<your user name>\AppData\Local\Temp\PharmaSuite*.

Chapter 2

Manage Batch Orders

The **Manage Batch Orders** task provides all information and actions you need for processing data related to batch orders. It comprises order filters, orders and order steps, including order step inputs and order step outputs.

TIP

Please note that your access rights determine which orders are listed in the tree view. Orders that are based on confidential master recipes that you are not allowed to access are not shown in the list.

Use the filter function (page 27) to restrict the number of data objects listed in the tree.

What Is a Batch Order?

An order is an instruction concerning the manufacture or delivery of a product, which can be bulk material, semi-finished, or finished goods. It requires a target material, a production quantity, and a master recipe as basic information.

After its creation, an order has to be prepared for the production process:

On the basis of its assigned master recipe, material, and quantity, the order is exploded to generate all order-related objects that are necessary for executing the order.

The generated order steps have to be released for processing at the specified work centers.

Specific circumstances can make it necessary to change an order's material properties, quantities, or status after the order has been exploded or even later than that, when its execution has started. For these incidents the system provides the following actions:

- Abort order step (page 57)
- Reactivate order step (page 57)
- Force execution transition (page 48)
- Finish order with aborted order steps (page 48)
- New additional order step input (page 57)
- New alternative order step input (page 61)
- Increase quantity of order step input (page 61)
- Reactivate order step input (page 61)

- Replace target sublot (page 64)

Batch order-related data is relevant to material (page 81) and master recipe (page 44) objects.

What Is a Master Recipe?

The master recipe is that level of recipe that is targeted to a process cell or a subset of the process cell equipment.
In its role as container for both the what (to manufacture) and the how (to manufacture), the master recipe is the place where the flow of the materials through the production process is specified. Thus, a master recipe typically contains all pharmaceutically relevant data required to support GxP-compliant production. Master recipes are under version and status control.

Master recipes for both production orders and shop floor-defined orders are created and maintained in Recipe Designer. A master recipe for a production order must be fully configured with all parameters, such as process parameters, equipment requirement parameters, and material inputs and outputs. Only then is it available for creating an order, which needs to be exploded and released before it can be selected for processing on the shop floor.
A master recipe for a shop floor-defined order does not require material inputs or outputs, since these can be added in the course of an order definition workflow on the shop floor, during which an operator adds the necessary data, explodes the fully defined order and releases it to execution.

Orders - Data

Under the order nodes you can also view the data of the material (page 84), batch (page 91), and master recipe (page 53) that are assigned to the order.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of an order.
  The maximum number of allowed characters in this box is 12.

  TIP
  Please note that identifiers have to be unique across both batch orders and workflows. An identifier that has been used before can never be reused, not even after the respective order or workflow has been purged.

- Treatment ID
  Only available for editing if the order is **Defined** and the target batch has not been created yet.
  A treatment ID is optional information and is displayed during execution and review of an order. When it is set during order definition, the subsequently created target batch automatically inherits the treatment ID of the order.

  TIP
  Please note that the treatment ID of an order cannot be changed anymore when the target batch of the order has been created. You can, however, change the treatment ID of the batch from the **Change Batch Attributes** node (page 92) in the **Manage Inventory** task (page 89).

- Planned quantity
  During order explosion, the planned quantity for each BOM item is calculated based on the ratio of the planned quantity of the order and the reference quantity of the BOM.

- Actual quantity
  The actual quantity is determined by the system automatically during the order execution.

- Exported for archive
  Indicates the export status of the order. Once an order has been exported, its export status changes from **Not exported** to **Exported**.

  TIP
  Please note that it is not possible to reset the order to **Not exported**.

- Usage type
  Correlates to the master recipe usage type assigned to the order.
  If the order is defined in PharmaSuite for Production Management, its usage type is always **Production** and you can only assign a **Production** master recipe to it.
  If the order is defined, exploded, and released on the shop floor, such as a **Cost center** order, it has a corresponding master recipe assigned. You can unrelease and reset such an order in PharmaSuite for Production Management and then change its master recipe assignment. You cannot, however, change its usage type.

- Master recipe
  Only those master recipes are available for assignment that
  - match the order's usage type,
  - match the assigned target material, and
  - are **Valid**.

TIP
Please note that your access rights determine which master recipes are available for selection. Confidential master recipes that you are not allowed to access are not shown in the list.

- Comment
  Only available for editing if the order is **Defined**, **Exploded**, **Released**, or **In process**.

  TIP
  Please note that changes to the comment of an order that is **Exploded**, **Released**, or **In process** are recorded in the batch report.

- Target batch
  The maximum number of allowed characters in this box is 10.
  The target batch identifier can either
  - be defined manually by typing the identifier in the box,
  - be generated by the system by clicking the **Create** button, or
  - be left empty on the order level. In this case, the system will automatically generate a batch identifier when the order's first order step is started on the shop floor.

  TIP
  If your system is configured to support non-unique batch identifiers, the box will hold not only the batch identifier but also the material identifier. For this configuration, the restriction as to the number of allowed characters does not apply.

- Actual end/start
  The actual start and end dates of processing are determined by the system automatically.

- ERP end/start
  The ERP start date is the default sorting criterion for the list of startable order steps at each work center.
  The ERP start and end dates are order-related attributes typically presented across the system.

- Planned end/start
  For information only. Can be presented across the system as a part of customer-specific extensions.

Order Statuses

During their life cycle, orders can assume the following statuses:

- **Defined**: The first status the order assumes after it has been created. It is the only status in which the order is editable. It must be linked to a master recipe before you can explode it.
- **Exploded**: Can only be reached from the **Defined** status by running the **Explode order** action, which generates order steps, material inputs, and material outputs. By using the **Reset order** action, you can return the order to the **Defined** status thus deleting all generated objects.
- **Released**: Can only be reached from the **Exploded** status by running the **Release order** action. It makes the order selectable for processing in PharmaSuite for Production Execution. By using the **Unrelease order** action, you can return the order to the **Exploded** status.
- **In process**: An order automatically moves to the **In process** status when its first order step is started in PharmaSuite for Production Execution.
- **Finished**: An order automatically moves to the **Finished** status when its last order step has been completed in PharmaSuite for Production Execution.

  TIP
  If potentially quality-relevant changes were made to an order, the system records an exception at the corresponding unit procedure when the order moves to the **Finished** status.

- **Production-reviewed**: Can only be reached from the **Finished** status by using the respective function in PharmaSuite for Production Responses.
- **Reviewed**: Can only be reached from the **Production-reviewed** or **Finished** statuses. Whether an order automatically moves to the **Reviewed** status or has to be moved manually in PharmaSuite for Production Responses is controlled, on the one hand, by its **Review mode** property (page 53) and, on the other hand, if quality exceptions were recorded for it during processing in PharmaSuite for Production Execution.
  An order can only move to the **Reviewed** status if all quality exceptions that were recorded for it have been **Closed** and all of its appended workflows are either **Finished**, **Production-reviewed**, or **Reviewed**.
- **Annulled**: Can only be reached from the **Defined**, **Exploded**, and **Released** statuses and thus indicates that the order was never executed.
- **Canceled**: Can only be reached from the **In process** status. Changing an order's status to **Canceled** causes all of its order steps that are **In process** to be canceled as well. All other order steps retain their statuses.

Depending on the system's configuration, a status change can require a user to enter a single or double electronic signature as proof of authorization.

Orders - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **Unassign batch from order** action
Only available if the order is **Defined** or **Exploded**.
Unassigns the target batch from the order.

 **Change status** action
Opens the **Change Status** dialog to perform a status transition (page 35) on the order.

 **View status transition history** action
Displays the status transition history (page 37) of the order.

 **Open batch report** action
Only available if the order is **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed**.
Opens the batch report of the order in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.

 **Print batch report** action
Only available if the order is **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed**.
Opens the batch report of the order in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.

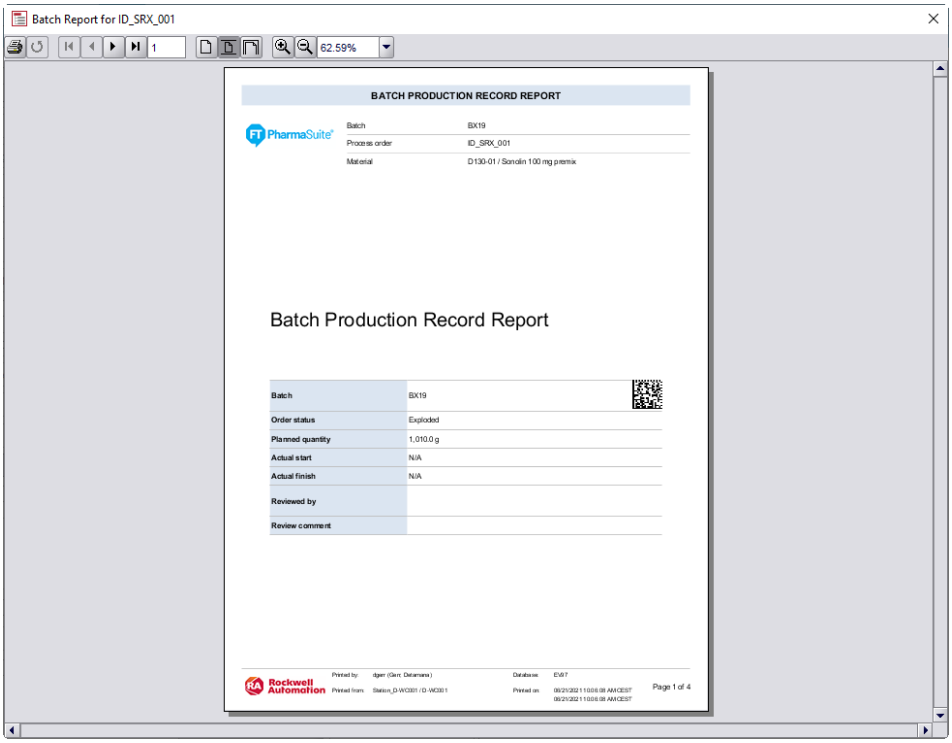

Figure 23: Batch report

TIP

Please note that the cover page of the batch report holds that batch barcode that can be used for scan-starting batch processing in PharmaSuite for Production Execution.

Export <order identifier> for archive action

Only available if the order is **Canceled** or **Reviewed**.

Exports a container folder to a pre-defined directory on your file system.

TIP

Please note that exporting an order automatically triggers the export of its appended workflows. Workflows that have been exported already before, however, are skipped. If a workflow is appended to more than one order, all of the affected orders must be **Canceled** or **Reviewed** and the workflow must be **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed**. Otherwise, the order export fails.

The folder name consists of a prefix to indicate the type of the exported object, such as **BR** for batch report, the order identifier, the batch identifier, and the date and time when the export was triggered. It contains the following files and folders:

- PDF file of the batch report
  file name: Batch_Report_<order identifier>_<batch identifier>.pdf
- XML file of the batch record
  file name: Batch_Record_<order identifier>_<batch identifier>.xml
- XML file with meta data of the export event
  file name: LOG_BR_<order identifier>_<batch identifier>_<date>_<time>.xml
- Folder containing the PDF files of all labels and label reprints created in the context of the order.
  - folder name: Labels
  - label file name: Sublot_<sublot identifier>_<label identifier>.pdf
  - for label reprints, if any have been created
    label reprint file name: Sublot_<sublot identifier>_<label identifier>_<copy count>.pdf
- Folder containing the XSD files with the data definitions for the record (folder name: B2MML_V0600)

> **TIP**
> If an identifier that is used to build the name of the export folder contains a character that is not allowed in folder names, such as a backslash, the system replaces it with an allowed character.

To perform the export, proceed as follows:

1. Click the **Export <order identifier> for archive** action to open the **Export Order for Archive** dialog.
   The system displays the pre-defined directory to which it will save the exported files.
2. Click the **Apply** button to start the export.
   The system indicates the progress of the export operation by listing its individual steps as **Result**.
   When the export is completed the system displays the final result as last entry after the list of steps.
   If errors prevent the export from completing successfully, refer to the PharmaSuite log files for further information.
3. Click the **Close** button to close the dialog and return to the work area.

 **Finish <order identifier> with aborted order steps** action

Only available if the order is **In process**, but all of its order steps are either **Aborted** or **Finished**.

Sets the status of the order to **Finished**.

TIP

Since finishing an order with aborted order steps may affect a product's quality, the system records an exception at the corresponding unit procedures when the action is performed.

 **Purge <order identifier>** action

Only available if the order is **Annulled**, **Canceled**, or **Reviewed**. For **Canceled** and **Reviewed** orders, the order data must have been exported with the **Export for archive** action before. An order can only be purged if it is not bound to an equipment object, such as a scale or room.

Deletes all order data including reports and labels from the system. Data objects that contain references to a purged order, such as its appended workflows or equipment used during processing remain unchanged and retain their references to the deleted order.

TIP

Please note that purging an order is an irreversible action and it is thus not possible to restore a purged order.

To purge an order, proceed as follows:

1. Click the **Purge <order identifier>** action to open the **Purge Order** dialog.
2. Click the **Apply** button to start the purge operation.
   The system indicates the progress of the operation by listing its individual steps as **Result**.
   When purging is completed the system displays the final result as last entry after the list of steps.
   If errors prevent the purge operation from completing successfully, refer to the PharmaSuite log files for further information.
3. Click the **Close** button to close the dialog and return to the work area.

 **Force execution transition** action

Only available if the order is **In process**.

Opens the **Force Execution Transition** dialog to force an execution transition (page 39) in order to resolve situations on the shop floor when an order cannot proceed to its next step.

TIP

Since forcing an execution transition may affect a product's quality, the system records an exception at the corresponding operation or unit procedure when the action is performed.

The order work area provides the following actions and order status changes:

Explode
Only available for **Defined** orders that use a **Valid** master recipe.
It explodes the order, thus generating its order steps, material inputs, and material outputs, which are necessary for executing the order.

Reset
Only available for **Exploded** orders.
It resets the order's status from **Exploded** to **Defined**, thus deleting all data objects generated during order explosion (order steps, material inputs, and material outputs).

Release
Only available for **Exploded** orders.
It sets the order status to **Released**, thus making it selectable for processing in PharmaSuite for Production Execution.

Unrelease
Only available for **Released** orders that are not **In process** yet.
It resets the order's status from **Released** to **Exploded**. This means that it is no longer selectable for processing in PharmaSuite for Production Execution.

Additional status changes are available with the **Change status** action (page 35):

Annul order
Only available if the order is not **In process** yet. Terminates the order permanently and irreversibly.

Cancel order
Only available if the order is **In process**. Terminates the order permanently and irreversibly. The work centers in the execution area affected by this action are notified in a system message.

TIPS

Since canceling an order may affect a product's quality, the system records an exception at all active phases of the order when the action is performed.

Please note that order reviews can only be performed in the Exception Dashboard of PharmaSuite for Production Responses.

Master Recipes - Data

IMPORTANT

Master recipes with all their components must be created and maintained in Recipe Designer. Thus, the data shown here has only informational value and cannot be edited.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a master recipe.

- Method
  Very often master recipes are maintained with different methods, which means there are several master recipe objects that only differ with respect to their method. However, in order to allow them to be valid at the same time, a given method must also be reflected within the master recipe identifier. Different versions of the same master recipe identifier cannot be valid at the same time.

- Planned quantity
  This value represents the reference quantity on the basis of which the system will calculate the material quantities when it explodes an order for the master recipe.

- Review mode
  Specifies how an order that is based on the master recipe is moved to the **Reviewed** status in the Exception Dashboard of PharmaSuite for Production Responses.

  - Automatic
    The status of the order automatically moves to **Reviewed** when it is **Finished** and no quality exceptions have been recorded for it or any of its appended workflows while it was being processed and if all of its appended workflows are either **Finished**, **Production-reviewed**, or **Reviewed**.

  - Manual
    The status change to **Reviewed** needs to be performed manually when the order is **Finished** and there are no exceptions left that still need to be reviewed.

Order Steps - Data

Under the order step nodes you can also view the data of the workflows (page 68) that are appended to the order step as well as its material inputs (page 59), transfer inputs and outputs, and the final material output (page 63). The order step work area displays the list of work centers assigned to the order step as well as the list of workflows appended to it.

Please note the additional information on the following properties:

- Identifier
  The order step number is generated automatically and presents a concatenation of the order identifier and the unit procedure identifier defined with the master recipe.

- Description
  It is populated automatically from the respective unit procedure description.

- Type
  It is populated automatically from the respective unit procedure type.

- Comment
  Only available for editing if the order is **Defined**, **Exploded**, **Released**, or **In process**.

  TIP
  Please note that changes to the comment of an order step whose order is **Exploded**, **Released**, or **In process** are recorded in the batch report.

- Work center
  The list of work centers is populated automatically from the respective unit procedure. As long as the order step has not been started yet at a work center, a suitably authorized user can adapt the list of assigned work centers.

  TIPS
  Please note that changes to the work center assignments are recorded in the batch report.
  Changing work center assignments deletes all station assignments that may have been defined for order step dispatching during recipe creation with Recipe Designer. As a result, the order step is startable at all stations of the assigned work centers.
  Restoring the work center assignments to what was defined in Recipe Designer also restores the station assignments as defined in Recipe Designer.

  The functions for changing work center assignments are only available if the order is **Exploded**, **Released**, or **In process** and the order step is **Generated**, **Held**, or **Reactivated**.

- To assign one (additional) work center to the order step, type its identifier in the **Identifier** box and click the **Add** button.
- To revoke the assignment of one work center, select the work center in the list and click the **Remove** button.
- To assign or unassign several work centers, click the **Assign ...** button. The system opens the multi-reference selector (page 33) for work centers, which supports you with a search function and allows for adding or removing several work centers.

> **TIP**
> Please note that in the **Select References - Work Center** dialog you only define which work centers you wish to assign to your order step. The changes you have defined are only applied when you save the order step with the **Save** action from the toolbar in the work area.

- Workflow

  The list of workflows displays all workflows that have been appended to the order step, since they are executed in the context of the order step and should thus be included in the batch report.
  As long as the order step has not been started, the list is empty and cannot be modified. Only after the order step has been started, can a suitably authorized user adapt it by adding or removing workflows.

  The functions for appending workflows to an order step are only available if its order is **In process**, **Finished**, **Production-reviewed**, or **Canceled** and the order step is **In process**, **Held**, **Finished**, **Canceled**, or **Reactivated**.

  > **TIPS**
  > Workflows that have not been started yet or have been **Canceled** cannot be appended.
  > The system requests an electronic signature when an operator appends or removes a workflow.
  > Please note that your access rights determine which workflows are available for appending. Workflows that are based on confidential master workflows that you are not allowed to access are not shown in the list of the multi-reference selector (page 32).

  - To append one (additional) workflow to the order step, type its identifier in the **Identifier** box and click the **Add** button.
  - To revoke the connection of one workflow, select the workflow in the list and click the **Remove** button.
  - To append or unappend several workflows, click the **Append ...** button. The system opens the multi-reference selector (page 32) for workflows, which supports you with a search function and allows for adding or removing several workflows.

TIP
Please note that in the **Select References - Workflow** dialog your changes to the list of appended workflows are immediately saved and effective once you have clicked the dialog's **Save** button.
Since changing the workflow assignments may affect a product's quality, the system records an exception at all active phases of the order when the action is performed.

Order Step Statuses

During their life cycle, order steps can assume the following statuses:

- **Generated**: The first status the order step assumes after its order has been exploded.
- **In process**: An order step automatically moves to the **In process** status when it is started in PharmaSuite for Production Execution.
- **Held**: An order step automatically moves to the **Held** status when its unit procedure is detached in PharmaSuite for Production Execution.
- **Aborted**: Only exists for non-Dispense order steps and can only be reached from the **In process** or **Held** statuses by running the **Abort order step** action.
- **Reactivated**: For Dispense order steps, it can only be reached from the **Finished** status by running the **Reactivate order step** action.
  For non-Dispense order steps, it can be reached from either the **Finished** or the **Aborted** statuses by running the **Reactivate order step**.
  An order step automatically moves to the **Reactivated** status when an operator has performed the **Abort and Reactivate** action on its unit procedure in PharmaSuite for Production Execution.
- **Finished**: An order step automatically moves to the **Finished** status when its last operation has been completed in PharmaSuite for Production Execution.
- **Canceled**: An order step that is **In process** automatically moves to the **Canceled** status when its order has been canceled.

Depending on the system's configuration, a status change can require a user to enter a single or double electronic signature as proof of authorization.

Order Steps - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **View status transition history** action
Displays the status transition history (page 37) of the order step.

 **New additional order step input** action
Creates a new order step input for the order step. It represents a means to react quickly and flexibly to unexpected occurrences on the shop floor, when it turns out that an auxiliary material is required to alter the physical or chemical properties of the materials that are being processed or to perform another order-related activity.
The action is only available for **Finished** or **Reactivated** order steps of orders that are still **In process**. It sets the status of the affected order step to **Reactivated**. The material of the new order step input is of the **Auxiliary substance** weighing material type. If a **Weighing sequence** is defined for the other order step input items of the order step, you also have to define it for the new additional order step input item.

TIP

Since creating an additional order step input may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.

 **Abort** action
Irrevocably terminates the execution of the order step in PharmaSuite for Production Execution. The work centers in the execution area affected by this action are notified in a system message. It is intended for exceptional situations when an order step needs to be aborted but processing of the order can be continued.

TIP

Please note that any inventory objects (such as sublots) that have been identified for and are bound to an aborted order step need to be unbound manually to make them available for identification again. The system provides the **Unidentify Objects** task (page 105) for this purpose.
Intra material sublots that may have been produced already during the aborted order step also need to be cleaned up manually.

The action is only available for order steps that are **Generated** (and listed as startable in the Cockpit of PharmaSuite for Production Execution), **In process**, **Held**, or **Reactivated**. It sets the status of the affected order step to **Final aborted**.

TIP

Since aborting an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure and its active phases when the action is performed.

 **Abort for reactivation** action

Stops the execution of the order step in PharmaSuite for Production Execution. The work centers in the execution area affected by this action are notified in a system message. It is intended for exceptional situations on the shop floor that cause an order step to require rework. Thus, it is possible to **Reactivate** an **Aborted** order step at a later point in time.

TIP

Please note that any inventory objects (such as sublots) that have been identified for and are bound to an aborted order step need to be unbound manually to make them available for identification again. The system provides the **Unidentify Objects** task (page 105) for this purpose.
Intra material sublots that may have been produced already during the aborted order step also need to be cleaned up manually.
After you have **Reactivated** and re-processed an **Aborted** order step you can continue to process its subsequent order steps and thus finish the order.
To cover situations when an order step has been reactivated by mistake and is then aborted but its order is still **In process**, the system provides the **Finish order with aborted order steps** action (page 48) for the order.

The action is only available for non-Dispense order steps that are **In process** or **Held**. It sets the status of the affected order step to **Aborted**.

TIP

Since aborting an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure and its active phases when the action is performed.

 **Reactivate** action

Reactivates the order step, thus making it available for restart in PharmaSuite for Production Execution.
The action is only available for **Finished** or **Aborted** order steps whose order is still **In process**. It sets the status of the affected order step to **Reactivated**.

TIP

The reactivation of an **Aborted** order step usually happens in the context of a rework situation. For this reason, each material input, transfer, and output provides a **Comment to execution** box for typing an instruction that details what needs to be done in order to return to regular processing conditions. When the order step is restarted in PharmaSuite for Production Execution, the system displays the comments to the operator, prefixing each comment with the identifier of the material to which it refers.

For Dispense order steps, it prevents deadlock situations that could occur if an order step has processed all materials, has therefore its concluding **Print report** phase active, and then has an exception recorded to replace a sublot.

TIP

Since reactivating an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.
This only applies to non-Dispense order steps, since in Dispense processes, the system already records a corresponding exception when a sublot is replaced.

Order Step Inputs - Data

Under the order step input nodes, you can also view the data of the batches (page 91) allocated to the material inputs. The work area displays the data of the material (page 84) that is assigned to the order step input as well as the list of batches allocated to it. For Dispense order steps, it also displays the target sublot.

Please note the additional information on the following properties:

- Planned quantity mode
  The planned quantity mode determines how the systems handles the planned quantity value during execution.
  - **As defined**
    During execution, the system uses the quantity defined in Recipe and Workflow Designer. It may, however, apply a prorate factor, for example to material inputs to maintain the intended ratio of materials.
  - **As produced**
    During execution, the system draws the planned quantity from a produced output quantity.
    Thus **As produced** can only be set for ingoing order step transfers, i.e. order step inputs that result from an order step output of a preceding unit procedure.

- **None**
  During execution, the system does not expect a planned quantity value, so the value may have been left blank in Recipe and Workflow Designer. Even if a value has been defined or has been downloaded from an external source, such as an ERP system, PharmaSuite ignores the value.
  Only materials whose weighing material type is **Auxiliary substance** or not set (---), can have **None** as planned quantity mode.

- Planned quantity (original)
  Its display depends on the **Planned quantity mode** of the order step input:
  - **As defined**
    The quantity is taken over from the recipe defined in Recipe Designer and adjusted during order explosion to match the order's planned quantity.
  - **As produced**
    The quantity is not defined, and the box is blank.
  - **None**
    The quantity is not defined, and the box is blank.

- Planned quantity (execution)
  Its display depends on the **Planned quantity mode** of the order step input:
  - **As defined**
    The quantity is taken over from the recipe defined in Recipe Designer and adjusted during order explosion to match the order's planned quantity. Finally, it is updated with a prorate factor before a position is started in PharmaSuite for Production Execution.
  - **As produced**
    Initially, the box is blank. The system calculates the quantity as soon as the quantity of its related transfer output material has been established and updates the box accordingly.
  - **None**
    The quantity is not defined, and the box is blank.

- Batch allocation
  For each order step input item a respective batch can be allocated.
  The functions for changing batch allocations are only available if the order is **Exploded** or **Released** and the order step is **Generated**.
  - To assign one (additional) batch to the order step input, type its identifier in the **Identifier** box and click the **Add** button.
  - To revoke the assignment of one batch, select the batch in the list and click the **Remove** button.

- To assign or unassign several batches, click the **Assign ...** button. The system opens the multi-reference selector (page 33) for batches, which supports you with a search function and allows for adding or removing several batches.

TIP
Please note that changes to the batch allocation of an order are recorded in the batch report.

- Weighing sequence
  If the sequence in which input materials are to be processed during weighing does not coincide with the sort order provided by the positions of the materials, the **Weighing sequence** property allows to explicitly define the order in which the materials are listed for processing during execution.

TIP
Regardless of the defined weighing sequence, the processing sequence with respect to **Active**, **Compensator**, and **Filler** substances that results from the **Weighing material type** of an input item takes precedence

- Comment to execution
  Intended for material-related information to be displayed during execution. The comment will only be shown if the order contains a phase that can deal with comments of this type.

TIP
Please note that changes to the comment to execution of an order are recorded in the batch report.

Order Step Inputs - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **New alternative order step input** action
Creates a new alternative order step input to replace the selected order step input. The identifier of the new order step input is extended by a count.
The action is only available for order step inputs of **Exploded** orders and of one of the following weighing material types: **Active substance**, **Compensation substance**, **Auxiliary substance**, or **Filler substance**. You cannot change the weighing material type of the alternative order step input. If a **Weighing sequence** is defined for the other order step input items of the order step, you also have to define it for the new alternative order step input item.
The new order step input receives the **Created** status, while the replaced order step input is set to **Aborted**.

TIPS

Please note that the system also creates new alternatives for all order step transfers and outputs associated with the replaced order step input.
The batch allocations of the original order step input are deleted.

The creation of a new alternative order step input is recorded in the batch report.

 **Increase quantity of order step input** action

Allows to increase the quantity of an input material by the indicated **Planned quantity** and define other batch allocations than those of the selected order step input. The identifier of the new order step input is extended by a count.
The action is only available for materials in **Completed** order step inputs of **Finished** or **Reactivated** order steps whose order is still **In process**. It sets the status of the affected order step to **Reactivated**.
The weighing material type of the input to be increased and the weighing material types of the yet incomplete order step inputs of the order step determine if the action can be performed:

- To increase the quantity of an **Active** material, there must not be a **Compensation** substance input and no **Filler** substances whose position is higher than that of the **Active**.
- To increase the quantity of an **Auxiliary** material, there must be no **Filler** substances whose position is higher than that of the **Auxiliary**.

TIPS

Please note that you can also use this action to decrease the quantity of an order step input by typing the amount by which you wish to reduce the input quantity as negative value in the **Planned quantity** box.

Since increasing the quantity of an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.

 **Reactivate** action

Reactivates the order step input. It allows you to resolve situations when a Dispense order step input had to be aborted during execution on the shop floor.
The action is only available for **Aborted** order step inputs of **Finished** or **Reactivated** order steps whose order is still **In process**.
It sets the status of the affected order step to **Reactivated**.

TIPS

Please note that it depends on the weighing material type of the **Aborted** order step input whether you need to reactivate other order step inputs by replacing target sublots before you can perform the action:

- For active materials, you need to replace all compensator sublots and all fillers whose position or weighing sequence number is higher than that of the material to be replaced.
- For all other materials (auxiliary, compensator, and filler) you need to replace the fillers whose position or weighing sequence number is higher than that of the material to be replaced.

Since reactivating an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.

 **Unlock order step input** action

Unlocks an order step input that is unintentionally locked due to an exception situation on the shop floor.

TIP

Since unlocking an order step input may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.

Order Step Outputs - Data

In the order step output work area, you can also view the data of its material (page 84).

Please note the additional information on the following properties:

- Planned quantity mode
  The planned quantity mode determines how the systems handles the planned quantity value during execution.
  - **As defined**
    During execution, the system uses the quantity defined in Recipe and Workflow Designer. It may, however, apply a prorate factor, for example to material inputs to maintain the intended ratio of materials.

- **None**
  During execution, the system does not expect a planned quantity value, so the value may have been left blank in Recipe and Workflow Designer. Even if a value has been defined or has been downloaded from an external source, such as an ERP system, PharmaSuite ignores the value.
  Only materials whose weighing material type is **Auxiliary substance** or not set (---), can have **None** as planned quantity mode.

- Planned quantity (original)
  Its display depends on the **Planned quantity mode** of the order step output:
  - **As defined**
    The quantity is taken over from the recipe defined in Recipe Designer and adjusted during order explosion to match the order's planned quantity.
  - **None**
    The quantity is not defined, and the box is blank.

- Planned quantity (execution)
  Its display depends on the **Planned quantity mode** of the order step output:
  - **As defined**
    The quantity is taken over from the recipe defined in Recipe Designer and adjusted during order explosion to match the order's planned quantity. Finally, it is updated with a prorate factor before a position is completed in PharmaSuite for Production Execution.
  - **None**
    The quantity is not defined, and the box is blank.

Order Step Output Sublots - Actions

Specifically for output sublots of Dispense order steps that have been completely processed but are afterwards damaged, contaminated, or otherwise rendered unfit for use, the system provides:

 **Replace target sublot** action
Replaces the selected (unfit) sublot of the order step output by re-creating its order step input. The identifier of the new order step input is extended by a count.
The action is only available for **Finished** or **Reactivated** order steps of orders that are still **In process**. It sets the status of the affected order step to **Reactivated**.

TIPS

Please note that it depends on the weighing material type of the replaced target sublot whether you need to replace additional target sublots before you can perform the action:

- For active materials, you need to replace all compensator sublots and all fillers whose position or weighing sequence number is higher than that of the material to be replaced.
- For all other materials (auxiliary, compensator, and filler) you need to replace the fillers whose position or weighing sequence number is higher than that of the material to be replaced.

Since replacing a target sublot may affect a product's quality, the system records an exception at the corresponding unit procedure when the action is performed.

Chapter 3

Manage Workflows

The **Manage Workflows** task provides all information and actions you need for processing data related to workflows. It comprises workflow filters and workflows.

TIP

Please note that your access rights determine which workflows are listed in the tree view. Workflows that are based on confidential master workflows that you are not allowed to access are not shown in the list.

Use the filter function (page 27) to restrict the number of data objects listed in the tree.

What Is a Workflow?

A workflow is typically intended for multiple executions and has a non-production purpose such as cleaning. Similarly to an order, it is created by in PharmaSuite for Production Management and requires a master workflow as basic information.
On the basis of the assigned master workflow, the workflow is exploded to generate all objects that are required for processing in PharmaSuite for Production Execution, such as workflow steps and material inputs. Afterwards the generated workflow steps have to be released for processing at the specified work centers.

If a workflow is based on a master workflow that is set to **One-click startable**, it does not have to be explicitly created, exploded, and released in PharmaSuite for Production Management, but can be started directly from the Cockpit of PharmaSuite for Production Execution.

Specific circumstances can make it necessary to intervene during the execution of a workflow in PharmaSuite for Production Execution. For this purpose, the system provides the following action:

- Force execution transition (page 70)

What Is a Master Workflow?

A master workflow defines the processing data of workflows, which are often intended for multiple executions and have a non-production purpose, such as cleaning processes. It is structurally similar to a master recipe but only allows one element on the unit procedure level.

Workflows - Data

Under the workflow nodes you can also view the data of the master workflow (page 74) assigned to the workflow and the batch order steps (page 54) to which it is appended.

Please note the additional information on the following properties:

- Identifier
  The identifier of a workflow is either user-defined and set at workflow creation or system-generated.
  The maximum number of allowed characters in this box is 12.
  The system generates a workflow's identifier if it is a one-click workflow and has been created by starting it in the Cockpit of PharmaSuite for Production Execution.
  A system-generated workflow identifier consists of a sequence of characters built from three components: <Prefix><Year><Numbers>. The system generates the value for <year> and <Numbers>, while the two-character prefix can be defined during master workflow definition in Workflow Designer. Unless a prefix has been specified in Workflow Designer, the system uses a pre-defined default (**WF**).

  TIP
  Please note that identifiers have to be unique across both batch orders and workflows. An identifier that has been used before can never be reused, not even after the respective order or workflow has been purged.

- Treatment ID
  Only available for editing if the workflow is **Defined**.
  A treatment ID is optional information and is displayed during execution and review of a workflow.

- Exported for archive
  Indicates the export status of the workflow. Once a workflow has been exported, its export status changes from **Not exported** to **Exported**.

  TIP
  Please note that it is not possible to reset the workflow to **Not exported**.

- Production-relevant
  Indicates that the activities performed in the context of the workflow affect the quality of a product. This could apply to cleaning procedures, for example. A workflow that does not inherit its production-relevance from its master workflow can receive the property if it is appended to an order or if a piece of equipment is used during its execution so that the workflow is listed in the equipment logbook.

- Master workflow
  Comprises the basic data of the workflow, specified at workflow creation in Workflow Designer.
  Only master workflows in a **Valid** status are available for assigning.

  TIP
  Please note that your access rights determine which master workflows are available for selection. Confidential master workflows that you are not allowed to access are not shown in the list.

- Actual end/start
  The actual start and end dates of processing are determined by the system automatically.

- Planned end/start
  For information only. Can be presented across the system as a part of customer-specific extensions.

Workflow Statuses

During their life cycle, workflows can assume the following statuses:

- **Defined**: The first status the workflow assumes after it has been created. It is the only status in which the workflow is editable. It must be linked to a master workflow before you can explode it.
- **Exploded**: Can only be reached from the **Defined** status by running the **Explode workflow** action, which generates workflow steps, material inputs, and material outputs. By using the **Reset workflow** action, you can return the workflow to the **Defined** status thus deleting all generated objects.
- **Released**: Can only be reached from the **Exploded** status by running the **Release workflow** action. It makes the workflow selectable for processing in PharmaSuite for Production Execution. By using the **Unrelease workflow** action, you can return the workflow to the **Exploded** status.
- **In process**: A workflow automatically moves to the **In process** status when its first workflow step is started in PharmaSuite for Production Execution.
- **Finished**: A workflow automatically moves to the **Finished** status when its last workflow step has been completed in PharmaSuite for Production Execution.

  TIP
  If potentially quality-relevant changes were made to a workflow, the system records an exception at the corresponding unit procedure when the workflow moves to the **Finished** status.

- **Production-reviewed**: Can only be reached from the **Finished** status by using the respective function in PharmaSuite for Production Responses.
- **Reviewed**: Can be reached from the **Production-reviewed** or **Finished** statuses. Whether a workflow automatically moves to the **Reviewed** status or has to be moved manually in PharmaSuite for Production Responses is controlled, on the one hand, by its **Review mode** property (page 74) and, on the other hand, if quality exceptions were recorded for it during processing in PharmaSuite for Production Execution.
  A workflow can only move to the **Reviewed** status if all quality exceptions that were recorded for it have been **Closed**.
- **Annulled**: Can only be reached from the **Defined**, **Exploded**, and **Released** statuses and thus indicates that the workflow was never executed.
- **Canceled**: Can only be reached from the **In process** status. Changing a workflow's status to **Canceled** causes all of its workflow steps that are **In process** to be canceled as well. All other workflow steps retain their statuses.

Depending on the system's configuration, a status change can require a user to enter a single or double electronic signature as proof of authorization.

Workflows - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **Change status** action
Opens the **Change Status** dialog to perform a status transition (page 35) on the workflow.

 **View status transition history** action
Displays the status transition history (page 37) of the workflow.

 **Open workflow report** action
Opens the workflow report in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to phases and their exceptions.

 **Print workflow report** action
Opens the workflow report in a preview window, from which you can send it to a connected printer, page through the report, or resize and zoom the displayed pages.

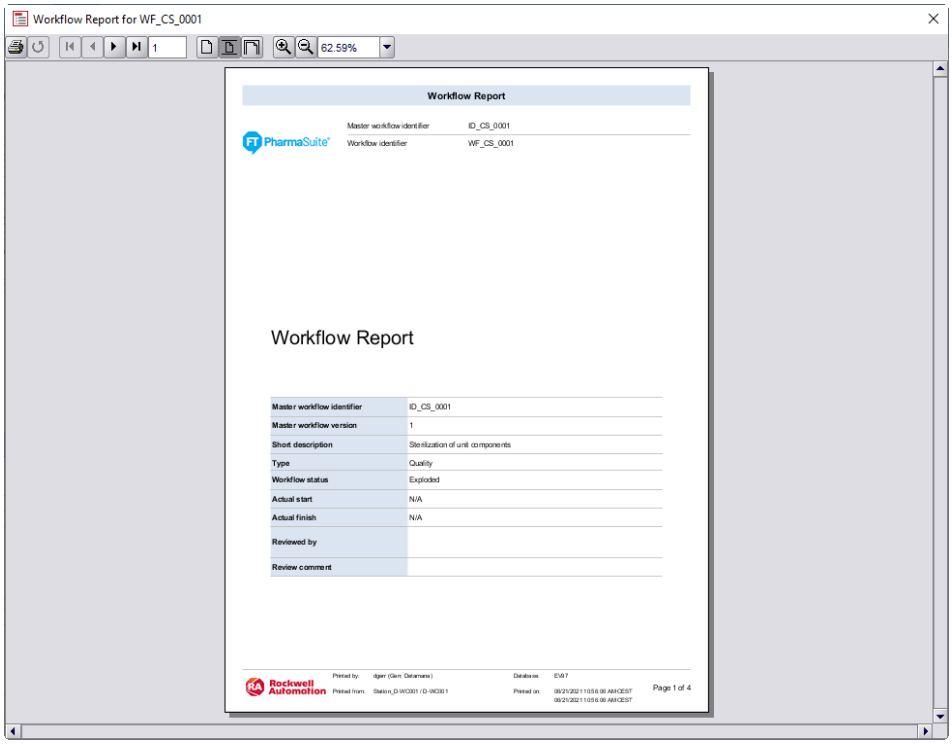

Figure 24: Workflow report

Export <workflow identifier> for archive action

Only available if the workflow is **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed**.

Exports a container folder to a pre-defined directory on your file system.

TIP

Please note that an appended workflow can only be exported if all orders to which it is appended are either **Reviewed** or **Canceled**.

The folder name consists of a prefix to indicate the type of the exported object, such as **WF** for workflow, the workflow identifier, and the date and time when the export was triggered. It contains the following files and folders:

- PDF file of the workflow report
  file name: Workflow_Report_<workflow identifier>.pdf
- XML file of the workflow record
  file name: Workflow_Record_<workflow identifier>.xml)
- XML file with meta data of the export event
  file name: LOG_WF_<workflow identifier>_<date>_<time>.xml
- Folder containing the XSD files with the data definitions for the record (folder name: B2MML_V0600)

TIPS

If an identifier that is used to build the name of the export folder contains a character that is not allowed in folder names, such as a backslash, the system replaces it with an allowed character.

Once a workflow has been exported it cannot be changed any longer. This means it is not possible to append or unappend it or to change its status in PharmaSuite for Production Responses.

To perform the export, proceed as follows:

1. Click the **Export <workflow identifier> for archive** action to open the **Export Workflow for Archive** dialog.
2. Click the **Apply** button to start the export.
   The system indicates the progress of the export operation by listing its individual steps as **Result**.
   When the export is completed the system displays the final result as last entry after the list of steps.
   If errors prevent the export from completing successfully, refer to the PharmaSuite log files for further information.
3. Click the **Close** button to close the dialog and return to the work area.

 **Purge <workflow identifier>** action

Only available if the workflow is **Annulled**, **Canceled**, **Finished**, **Production-reviewed**, or **Reviewed**. For production-relevant workflows that are either **Canceled**, **Finished**, **Production-reviewed**, or **Reviewed**, the workflow must have been exported with the **Export for archive** action before it can be purged. Additionally, all orders to which the workflow is appended must have been purged before the workflow itself can be purged.

TIP

A workflow is considered production-relevant if the **Production-relevant** option is selected in its master workflow, if it is currently appended to an order, or has been appended to an order at some point in its life cycle.

Deletes all workflow data including reports from the system. Data objects that contain references to a purged workflow, such as orders or equipment used during processing remain unchanged and retain their references to the deleted workflow.

TIP

Please note that purging a workflow is an irreversible action and it is thus not possible to restore a purged workflow.

To purge a workflow, proceed as follows:

1. Click the **Purge <workflow identifier>** action to open the **Purge Workflow** dialog.
2. Click the **Apply** button to start the purge operation.
   The system indicates the progress of the operation by listing its individual steps as **Result**.
   When purging is completed the system displays the final result as last entry after the list of steps.
   If errors prevent the purge operation from completing successfully, refer to the PharmaSuite log files for further information.
3. Click the **Close** button to close the dialog and return to the work area.

 **Force execution transition** action
Only available if the workflow is **In process**.
Opens the **Force Execution Transition** dialog to force an execution transition (page 39) in order to resolve situations on the shop floor when a workflow cannot proceed to its next step.

> **TIP**
>
> Since forcing an execution transition may affect a product's quality, the system records an exception at the corresponding operation or unit procedure when the action is performed.

The workflow work area provides the following actions and workflow status changes:

Explode
Only available for **Defined** workflows that use a **Valid** master workflow.
It explodes the workflow, thus generating its workflow steps, material inputs, and material outputs, which are necessary for executing the workflow.

Reset
Only available for **Exploded** workflows.
It resets the workflow's status from **Exploded** to **Defined**, thus deleting all data objects generated during workflow explosion (workflow steps, material inputs, and material outputs).

Release
Only available for **Exploded** workflows.
It sets the workflow status to **Released**, thus making it selectable for processing in PharmaSuite for Production Execution.

Unrelease
Only available for **Released** workflows that are not **In process** yet.
It resets the workflow's status from **Released** to **Exploded**. This means that it is no longer selectable for processing in PharmaSuite for Production Execution.

Additional status changes are available with the **Change status** action (page 35):

Annul workflow
Only available if the workflow is not **In process** yet. Terminates the workflow permanently and irreversibly.

Cancel workflow
Only available if the workflow is **In process**. Terminates the workflow permanently and irreversibly. The work centers in the execution area affected by this action are notified in a system message.

TIPS

Since canceling a workflow may affect a product's quality, the system records an exception at all active phases of the workflow when the action is performed.

Please note that workflow reviews can only be performed in the Exception Dashboard of PharmaSuite for Production Responses.

Master Workflows - Data

IMPORTANT

Master workflows with all their components must be created and maintained in Workflow Designer. Thus, the data shown here has only informational value and cannot be edited.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a master workflow.

- Processing name
  The name with which the workflow is displayed during processing in PharmaSuite for Production Execution. It is especially relevant to workflows that are **One-click startable** since the processing name is displayed on the button that starts the workflow.

- Review mode
  Specifies if and under which conditions the workflow can be reviewed in the Exception Dashboard of PharmaSuite for Production Responses.

- Automatic
  The status of the workflow automatically moves to **Reviewed** when it is **Finished** and no quality exceptions have been recorded for it while it was being processed.
- Manual
  The status change to **Reviewed** needs to be performed manually when the workflow is **Finished** and there are no exceptions left that still need to be reviewed.

- Production-relevant
  Indicates that the activities performed in the context of the workflow affect the quality of a product. This could apply to cleaning procedures, for example.

- Appendable during processing
  Defines if a workflow can be appended to an order while or after being executed in PharmaSuite for Production Execution. Workflows that do not carry the setting can only be appended to orders from PharmaSuite for Production Management.

Appended Order Steps - Data

TIP

The data of the order steps to which the workflow is appended is read-only. Order steps are maintained in the **Manage Batch Orders** task (page 54).

Please note the additional information on the following properties:

- Identifier
  The order step number is generated automatically and presents a concatenation of the order identifier and the unit procedure identifier defined with the master recipe.

- Batch
  The target batch to be produced.

- Order
  The identifier and status of the order step's order and the identifier of its unit procedure.

- Material data
  Identifier and description of the product material.

Workflow Steps - Data

Under the workflow step nodes, you can also view the data of its material inputs (page 59) and the final material output (page 63). The workflow step work area displays the list of work centers assigned to the workflow.

Please note the additional information on the following properties:

- Identifier
  The workflow step number is generated automatically and presents a concatenation of the workflow identifier and the unit procedure identifier defined with the master workflow.

- Description
  It is populated automatically from the respective unit procedure description.

- Work center
  The list of work centers is populated automatically from the respective unit procedure. As long as the workflow step has not been started yet at a work center, a suitably authorized user can adapt the list of assigned work centers.

  TIP
  Please note that changing work center assignments deletes all station assignments that may have been defined for workflow step dispatching during workflow creation with Workflow Designer. As a result, the workflow step is startable at all stations of the assigned work centers.
  Restoring the work center assignments to what was defined in Workflow Designer also restores the station assignments as defined in Workflow Designer.

  The functions for changing work center assignments are only available if the workflow is **Exploded**, **Released**, or **In process** and the workflow step is **Generated** or **Held**.

  - To assign one (additional) work center to the workflow step, type its identifier in the **Identifier** box and click the **Add** button.
  - To revoke the assignment of one work center, select the work center in the list and click the **Remove** button.
  - To assign or unassign several work centers, click the **Assign ...** button. The system opens the multi-reference selector (page 33) for work centers, which supports you with a search function and allows for adding or removing several work centers.

TIP
Please note that in the **Select References - Work Center** dialog you only define which work centers you wish to assign to your workflow step. The changes you have defined are only applied when you save the workflow step with the **Save** action from the toolbar in the work area.

Workflow Step Statuses

During their life cycle, workflow steps can assume the following statuses:

- **Generated**: The first status the workflow step assumes after its workflow has been exploded.
- **In process**: A workflow step automatically moves to the **In process** status when it is started in PharmaSuite for Production Execution.
- **Held**: A workflow step automatically moves to the **Held** status when its unit procedure is detached in PharmaSuite for Production Execution.
- **Finished**: A workflow step automatically moves to the **Finished** status when its last operation has been completed in PharmaSuite for Production Execution.
- **Canceled**: A workflow step that is **In process** automatically moves to the **Canceled** status when its workflow has been canceled.

Depending on the system's configuration, a status change can require a user to enter a single or double electronic signature as proof of authorization.

Workflow Steps - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **View status transition history** action
Displays the status transition history (page 37) of the workflow step.

Workflow Step Inputs - Data

Under the workflow step input nodes, you can also view the data of the batches (page 91) allocated to the material inputs. The work area displays the data of the material (page 84) that is assigned to the workflow step input as well as the list of batches allocated to it.

Please note the additional information on the following properties:

- Planned quantity mode
  The planned quantity mode determines how the systems handles the planned quantity value during execution.
  - **As defined**
    During execution, the system uses the quantity defined in Recipe and Workflow Designer. It may, however, apply a prorate factor, for example to material inputs to maintain the intended ratio of materials.
  - **None**
    During execution, the system does not expect a planned quantity value, so the value may have been left blank in Recipe and Workflow Designer. Even if a value has been defined or has been downloaded from an external source, such as an ERP system, PharmaSuite ignores the value.
    Only materials whose weighing material type is **Auxiliary substance** or not set (---), can have **None** as planned quantity mode.
- Planned quantity (original)
  Its display depends on the **Planned quantity mode** of the workflow step input:
  - **As defined**
    The quantity is taken over from the workflow defined in Workflow Designer.
  - **None**
    The quantity is not defined, and the box is blank.
- Planned quantity (execution)
  Its display depends on the **Planned quantity mode** of the workflow step input:
  - **As defined**
    The quantity is taken over from the workflow defined in Workflow Designer and adjusted during workflow explosion to match the workflow's planned quantity. Finally, it is updated with a prorate factor before a position is started in PharmaSuite for Production Execution.
  - **None**
    The quantity is not defined, and the box is blank.

- Batch allocation
  For each workflow step input item a respective batch can be allocated.
  The functions for changing batch allocations are only available if the workflow is **Exploded** or **Released** and the workflow step is **Generated**.
  - To assign one (additional) batch to the workflow step, type its identifier in the **Identifier** box and click the **Add** button.
  - To revoke the assignment of one batch, select the batch in the list and click the **Remove** button.
  - To assign or unassign several batches, click the **Assign ...** button. The system opens the multi-reference selector (page 33) for batches, which supports you with a search function and allows for adding or removing several batches.

- Comment to execution
  Intended for material-related information to be displayed during execution. The comment will only be shown if the workflow contains a phase that can deal with comments of this type.

Workflow Step Outputs - Data

In the workflow step output work area, you can also view the data of the material (page 84) that is assigned to the workflow step output.

Please note the additional information on the following properties:

- Planned quantity mode
  The planned quantity mode determines how the systems handles the planned quantity value during execution.
  - **As defined**
    During execution, the system uses the quantity defined in Recipe and Workflow Designer. It may, however, apply a prorate factor, for example to material inputs to maintain the intended ratio of materials.
  - **None**
    During execution, the system does not expect a planned quantity value, so the value may have been left blank in Recipe and Workflow Designer. Even if a value has been defined or has been downloaded from an external source, such as an ERP system, PharmaSuite ignores the value.
    Only materials whose weighing material type is **Auxiliary substance** or not set (---), can have **None** as planned quantity mode.

- Planned quantity (original)
  Its display depends on the **Planned quantity mode** of the workflow step output:
  - **As defined**
    The quantity is taken over from the master workflow defined in Workflow Designer and adjusted during workflow explosion to match the workflow's planned quantity.
  - **None**
    The quantity is not defined, and the box is blank.
- Planned quantity (execution)
  Its display depends on the **Planned quantity mode** of the workflow step output:
  - **As defined**
    The quantity is taken over from the workflow defined in Workflow Designer and adjusted during workflow explosion to match the workflow's planned quantity. Finally, it is updated with a prorate factor before a position is completed in PharmaSuite for Production Execution.
  - **None**
    The quantity is not defined, and the box is blank.

Chapter 4

Manage Materials

The **Manage Materials** task provides all information and actions you need for processing data related to materials. It comprises material filters, and materials.

Use the filter function (page 27) to restrict the number of data objects listed in the tree.

What is a Material?

Materials are defined as all substances that are directly or indirectly related to or utilized in the manufacturing process, that are relevant to the pharmaceutical production process, and must thus be taken into consideration for all planning purposes. Materials can be classified by their types.

Material objects are subject to audit trail (page 99).

RAW MATERIALS

A raw material is defined as each substance used during the manufacturing of a drug that is not a packaging material.

AUXILIARY SUBSTANCES

An auxiliary substance is a component of a drug. Auxiliary substances do not have a therapeutical effect but are used as flavor or to improve a product's stability.

BULK MATERIALS

A bulk material is defined as the finished but not yet packaged pharmaceutical product, such as loose, uncounted tablets, that is used in producing finished goods, e.g. blistered and packaged tablets. In this sense, a bulk material is a specific case of a semi-finished good.

SEMI-FINISHED GOODS

Semi-finished goods are materials that are yet unfit for sale or shipment. They can either be produced internally or purchased externally and are usually utilized in further production phases for manufacturing other products - typically finished goods.

FINISHED GOODS

Finished goods (also known as finished products) are all products that are ready for shipping. A variety of different starting materials and/or semi-finished goods is typically involved in the production of finished goods.

PACKAGING MATERIALS

Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product (e.g. blisters vs. folding cartons).

SECONDARY PACKAGING MATERIALS

Secondary packaging materials are all materials used for outer packaging, such as folding cartons, brochures, package leaflets, films, etc.

AUXILIARY PACKAGING MATERIALS

Auxiliary packaging materials are materials that are required for additional packaging of trade packs, such as wrapping film, adhesive tape etc.

INTERMEDIATE GOODS

Intermediate goods are partially processed materials that must go through additional production stages before they become semi-finished goods, such as tablet bodies prior to coating.

INTRA MATERIALS

Intra materials are materials that occur only temporarily between two processing steps. They are related to MFC transfer items.

What Is GHS?

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is an internationally agreed-upon system that was created by the United Nations. It addresses the classification and labeling of chemicals by types of hazards.
The system comprises the following components:

- Signal words that indicate the basic hazard level of a material, such as **Danger** or **Warning**.
- Hazard pictograms that provide a graphical representation of the hazards inherent to a material.
- Hazard statements
  Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard.
- Precautionary statements
  A precautionary statement is a phrase, which describes recommended measure that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product.

GHS signal words, pictograms, and statements are relevant to material (page 81) objects.

What Is a Risk and Safety Phrase?

TIP

Please note that the system needs to be specifically configured to display risk and safety phrases instead of GHS statements.

Risk and safety phrases are a system of hazard codes and phrases for labeling dangerous chemicals and compounds.

Risk phrases specify hazards arising from dangerous properties of a material. Safety phrases give advice on necessary precautions that need to be taken during handling of the material, such as indicating the required protective gear.

There are several safety phrases that contain an ellipsis symbol (...) to indicate that they need to be extended by specific material information before they can be used, for example S14 "Keep away from ...".

Risk and safety phrases are relevant to material (page 81) objects.

Materials - Data

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a material.
  Once it has been defined it becomes read-only and cannot be changed any more.
  The maximum number of allowed characters in this box is 18.

- Description
  For information only. The description supports easier identification of a material. It is displayed together with the identifier throughout the system, for example in lists and tree views, as a reference to a given material.

- Material type
  It is the specific type of a material (page 81).

- Unit of measure
  The quantity of each sublot (page 90) that is created in the system must have the same unit of measure assigned as it is defined on the material level.

- Conversion
  Material-specific conversions of units of measure are typically used for converting the weight value of a material to its amount of material per piece (ea). The material quantity in the target unit of measure is calculated with the following formula:
  `value of source UoM * conversion factor + conversion offset`

  Example:

  - Target UoM: ea
    Source UoM: g
    Conversion factor: 0.25
    Conversion offset: 0
  - Calculation for 100 g of the material:
    `100 [g] * 0.25 + 0 = 25 [ea]`

- Template equipment entity
  Template equipment entities are required for materials such as filter liners or hoses, which are used as equipment during processing and thus need to be tracked. The template entity assigned to a material specifies the properties that generated equipment entities of the material will have. Template equipment entities are maintained in Data Manager.
  Only those template equipment entities are available for assignment that
  - have a property with **Hybrid (RS)** as its equipment type
  - are not **Archived**.

- GHS tab
  The GHS data will be displayed on sublot labels and consists of a signal word and a set of hazard symbols.
  The system can be configured to display ECB hazard class data instead of GHS data.

- Allowed weighing methods tab
  Defines which weighing methods are allowed for the material.
  During execution, only the weighing methods that have been selected as allowed can be used for processing.
  If the allowed weighing methods are defined on the material level, they are populated automatically as parameter attributes to the material parameter panel of Recipe Designer.

  TIP
  Allowing only one weighing method may lead to deadlock situations on the shop floor, when either Pallet weighing or Only identification have been set as only allowed weighing methods but require a follow-up Net or Gross weighing to complete a weighing item in tolerance.
  Please note that the **Gross** weighing method covers both **Gross** and **Gross removal** weighing.

- Hazard statements
  Lists all hazard statements assigned (page 33) to the material.

- Precautionary statements
  Lists all precautionary statements assigned (page 33) to the material.

  TIP
  Hazard and precautionary statements can be displayed during order execution on the shop floor by suitable phases, such as the Show GHS Data phase.
  The system can be configured to display Risk and safety phrases instead of GHS statements.

- Access privilege (recipe)
  When a master recipe is created that will produce the material, the access privilege selected for the product material is automatically passed on to the master recipe.

- ERP data
  For information only. Depending on the specific ERP integration, the fields may be renamed and used to present the material-related information maintained on the ERP level.

- Packaging levels
  Define the packaging structure of the material with up to six levels. Level 0 indicates the basic dosage form of the material while levels 1 through 5 represent the layers of packaging required for the material. Each level is identified by its meaning, such as **Tablet** or **Vial** for level 0 and **Blister**, **Tray**, **Bundle**, or **Shipping carton** for levels 1 through 5. For each of the packaging levels 1 through 5, it is possible to define the number of units (of the next lower level) it contains.

  Example:

  - Level 0:
    Meaning: **Tablet**
  - Level1:
    Meaning: **Blister**
    Contained number: **10**
  - Level 2:
    Meaning: **Folding carton**
    Contained number: **5**
  - Level 3:
    Meaning: **Box**
    Contained number: **15**
  - Level 4:
    Meaning: **Shipping carton**
    Contained number: **20**
  - Level 5:
    Meaning: **Pallet**
    Contained number: **50**

- Tolerance
  If defined on the material level, tolerances are populated automatically during the BOM item data entry as default properties.

- Warehouse data
  Defines picking relevance, default batch status, default sublot status, and sampling-related data that is required if PharmaSuite is configured to communicate with Warehouse Management in order to clarify procedures during goods receipt and picking order operations.

  TIP
  Please note that all settings except for the default sublot status are only considered for operations performed in Warehouse Management. The default sublot status is also relevant to sublot creation operations in PharmaSuite, such as material receipt, material production, or dispensing processes.

- Default weighing method
  Defines a default weighing method for the dispensing process, which is consequently pre-selected during execution. Depending on the allowed weighing methods, it can be overridden later on the shop-floor level during execution.
  If a default weighing method is selected, it is populated automatically to the Parameter Panel of Recipe Designer when the material is drawn as parameter into a recipe or building block.

Materials - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **View audit trail** action
Displays the audit trail data (page 101) of the material.

Chapter 5

Manage Inventory

The **Manage Inventory** task provides all information and actions you need for processing data related to the inventory. It comprises batch, sublot, storage location, and transaction history filters, as well as batches, sublots, the transaction history, and the storage topology with warehouses, storage areas, and storage locations.

Use the filter function (page 27) to restrict the number of data objects listed in the tree.

What Is Inventory?

Inventory is a repository that serves for storing and managing goods and materials. In PharmaSuite for Production Management it has a hierarchical structure and consists of the following three components:

- warehouse
- storage area, and
- storage location.

The inventory is managed on the batch and sublot level. A batch can contain any number of sublots. Each sublot can hold any quantity of a material. The unit of measure that defines the quantities of a batch and its sublots is usually the same as the one defined with the master data of its material.

Inventory data is used and processed during Production Execution workflows such as material receipt and issue, relocation, sublot split, or inventory correction.

What Is a Warehouse?

A warehouse is a physical location, in which materials and goods used in the production process are stored and managed. It is the highest level in the inventory structure.

Warehouse-related data is relevant to storage area (page 89) and storage location (page 90) objects.

What Is a Storage Area?

A storage area defines a physical area in a warehouse and is relevant to goods receipt and goods issue transactions. It occupies the middle level in the physical hierarchy of a PharmaSuite-controlled inventory.
Each storage area consists of a specified number of storage locations. This number depends on the warehouse type (e.g. high-rack warehouse).

What Is a Storage Location?

A storage location is identified by topological data, which defines the exact spatial position of the storage location in the warehouse. It occupies the lowest level of the physical hierarchy in a PharmaSuite-controlled inventory.

What Is a Batch?

A batch is a quantity of substance, packaging materials, or product manufactured during one step or in a series of steps that is expected to be homogeneous.
In the pharmaceutical industry it refers to pharmaceuticals that are produced and packaged during the same production sequence with identical raw materials.

Batches are used to control material flow, starting at goods receipt, in the production process. To ensure the proper quality of materials, batches typically go through several statuses, such as **Blocked** or **Quarantined**, before they are **Released** and can be used for production.

Batch-related data is relevant to sublot (page 90), material (page 81), and batch order (page 43) objects.

What Is a Sublot?

A sublot is the smallest material unit in a PharmaSuite-controlled warehouse. Optionally, it can assume its own status, such as **Blocked**, **Quality Inspection**, or **Unrestricted**, which is independent from the batch to which the sublot belongs. It can be necessary to update the quantity of a sublot. One reason for a quantity update, for example, can be that material was lost during transport or was damaged.

Several Production Execution workflows implicitly affect the sublot data, visible in Production Management. This applies, for example, to the consumption during production, splits and merges during dispensing, or automatic relocations.

Sublot-related data is relevant to material (page 81) and batch (page 90) objects.

What Is a Transaction History?

Transaction history stores data on any events that result in modifying the properties of batches and sublots in their life cycles. It helps to trace material-related activities on the batch and sublot level, such as the batch creation, change of potency, change of batch status, generation and consumption of sublots, goods issue, etc.
In PharmaSuite, all inventory transactions are recorded in the transaction history.

Transaction history-related data is relevant to batch (page 90) and sublot (page 90) objects.

Batches - Data

Under the batch nodes you can also view the data of the sublots that belong to the batch. Typically, batches and their identifiers are created along with order creation (page 46) in the **Manage Orders** task or generated in PharmaSuite for Production Execution during Material Receipt or order execution.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a batch.

- Treatment ID
  A treatment ID is optional information and is displayed during execution and review of an order. When it is set during order definition (page 44) in the **Manage Batch Orders** task (page 43), the subsequently created target batch automatically inherits the treatment ID of the order.

  TIP
  Please note that you can change the treatment ID of the batch from the **Change Batch Attributes** node (page 92). This does, however, not affect the treatment ID of the order from which the batch was created.

Batches - Actions

In addition to standard actions the shortcut menu and toolbar provide:

 **View status transition history** action
Displays the status transition history (page 37) of the batch.

Sublots - Data

Typically, sublots and their identifiers are generated in PharmaSuite for Production Execution during Material Receipt or order execution.
Sublots that are consumed during order processing are no longer visible in PharmaSuite for Production Management.

Please note the additional information on the following properties:

- Sublot identifier
  The identifier is the unique key of a sublot.

- Quantity
  The quantity of material that is currently contained in the sublot.

- Sublot status
  The current status of the sublot (**Blocked**, **Quality Inspection**, **Unrestricted**).

TIP
You cannot change the status of a sublot in PharmaSuite for Production Management, but if PharmaSuite is configured to communicate with Warehouse Management, a change can be performed there.

Sublots - Actions

In addition to standard actions the shortcut menu and toolbar provide:

View status transition history action
Displays the status transition history (page 37) of the batch to which the sublot belongs.

Batches - Change Attributes

In addition to standard actions the tree view node provides:

Change Batch Attributes action
Modifies the following attributes of a batch:

- batch status by selecting a change action
- potency
- expiry date
- retest date
- production date
- treatment ID
- comment

To change batch attributes, proceed as follows:

1. Click the batch node from the **Change Batch Attributes** node to open the batch data form.
2. Modify the batch attributes in the **New Data** group box.
3. Right-click the batch node and select the **Change batch attributes** action from the shortcut menu to save the changes.
4. Authorize the action with an electronic signature.
5. Click the **OK** button to acknowledge the informative message.

Warehouses - Data

Under the warehouse nodes you can also view the data of the storage areas (page 93) and storage locations (page 93) that are assigned to the warehouse.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a warehouse.
  The maximum number of allowed characters in this box is 12.

Warehouses - Actions

In addition to standard actions the shortcut menu and toolbar provide:

New storage area action
Creates a new storage area (page 93) for the warehouse.

Storage Areas - Data

Under the storage area nodes, you can also view the data of the storage locations (page 93) that are assigned to the storage area.

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a storage area.
  The maximum number of allowed characters in this box is 12.

Storage Areas - Actions

In addition to standard actions the shortcut menu and toolbar provide:

New storage location action
Creates a new storage location (page 93) for the storage area.

Storage Locations - Data

Please note the additional information on the following properties:

- Identifier
  The identifier is the unique key of a storage location.
  The maximum number of allowed characters in this box is 12.

Chapter 6

Manage Reports

The **Manage Reports** task provides all information and actions you need for processing data related to reports. It comprises filters for dispensing, scale test, and scale calibration reports as well as for labels.

What Is a Report?

A report is a textual or graphical representation of operational data for the purpose of evaluation or documentation. This means that labels printed during processing are also considered reports.
In PharmaSuite for Production Management the following report types are available:

- reports on **dispensing** performed for a given order
- **batch production record** reports for a given order, which you can print from the Manage Batch Orders task as an action of the order (page 48)
- **workflow** reports for a given workflow, which you can print from the Manage Workflows task as an action of the workflow (page 70)
- **labels** created for a given sublot

TIP

If your system contains report data that was created in a pre-PharmaSuite 8.1 release and migrated to your current system, it may also contain **scale test** and **scale calibration** reports and allow them to be reprinted.

Reports - Data

The data form for reports and labels displays a combined view of the filter form with the **Results** list and the **Report History Entries** list, which provides further information and actions for the report or label selected in the **Results** list.

Reports - Actions

In addition to standard actions the system provides:

Report details button
to view the list of history entries generated by the system for a report or label.

1. From the **Results** list populated with the reports or labels that match the defined selection criteria, select the report or label whose history you wish to view.
2. Click the **Report Details** button.
   The system displays all history entries pertaining to the selected report or label in the **Report History Entries** list.

Reprint button
to reprint a report or label.

1. From the **Results** list populated with the reports or labels that match the defined selection criteria, select the report or label whose history you wish to view.
2. Click the **Reprint** button. Depending on your system's configuration you may be asked for an electronic signature.
   The system opens a preview of the report or label you have selected to reprint.
   The reprint shows a dark bar as reprint marker indicating the full name and login name of the user who has triggered the reprint action, the timestamp when the reprint action was performed, and a counter with the copy number.

Chapter 7

Manage Archive and Purge

The **Manage Archive and Purge** task provides all information and actions you need for processing data related to archive and purge events (page 97).

What Are Archive and Purge Events?

When a user triggers the **Export for archive** action for either a batch order (page 48) or a workflow (page 70) or purges one of these objects, PharmaSuite for Production Management logs the action and all of its relevant data as event.

Archive and Purge Events - Data

The system displays a filter form and the **Results** list for all archive and purge events that have been performed for orders or workflows. The list columns provide relevant data of the respective events:

- Event identifier
  It consists of a prefix to indicate the type of the affected object (**BR**, **WF**), the object's identifier, and the date and time when the event started.
- Event type
  Available event types: **Export for archive**, **Purge**.
- Execution type
  Available execution types:
  - **Manual**: the event was triggered manually from PMC.
  - **Automated**: the event was triggered by another system.
- Processing status
  Current processing status of the event:
  - **Preparing**: the data affected by the event is being collected.
  - **In progress**: the export for archive or purge operation is running.
  - **Success**: the export for archive or purge operation completed successfully.
  - **Failure**: the export for archive or purge operation failed and can be retried once the reasons for the failure have been resolved.
- Start timestamp
  Date and time when the event started.

- Finish timestamp
  Date and time when the event completed.
- Object type
  Available object types: **Order (batch)**, **Workflow**.
- Object identifier
  Identifier of the affected object.
- Object status
  Status the affected batch order or workflow had when the event was started.
- Object context
  It provides contextual data of the affected object:
  - For batch orders, it displays the identifier of the produced material (part) and the identifier and version of its master recipe.
  - For workflows, it displays the workflow's processing name and the identifier and version of its master workflow.
- Logged-in user
  User who was logged in to the system when the event was started.
- Signature data
  Displays two items per signature (page 37):
  - User and login names of the user who performed the signature.
  - Timestamp when the signature was recorded.
- Signature comment
  It displays the comment recorded for each signature. For double signatures, each comment is prefixed with **Comment 1** or **Comment 2** to indicate with which signature the comment was recorded.

Chapter 8

Manage Audit Trails

The **Manage Audit Trail** task provides all information and actions you need for processing data related to audit trail. It comprises audit trail filters, and audit trail types. With this task you can also view access-related data (page 101), such as access privileges of users and user groups, the system access history, and the history of removed object locks.

Use the filter function (page 27) to restrict the number of data objects listed in the tree.

What Is Audit Trail?

Audit trail means preparation of data in a logical structure that images the sequence of events and thus guarantees that all procedures may be traced back. This also includes the chronological recording of system activities that permits reconstruction, verification, and examination of a sequence of activities and their environment conditions.

Whenever data objects that are under audit trail are created or modified, an audit trail data set is written automatically by the system. The audit trail data contains several attributes, which have the purpose to identify the circumstances and the context of the performed actions.
The system does not write an explicit data set at deletion of a data object that is under audit trail. In this case, the period of validity (which is different from the period of validity in the context of version control) is shortened. That means that the timestamp of the period of validity changes from "not limited" (e.g. 9999-12-31 23:59:59) to the exact time of deletion (e.g. 2008-10-30 09:48:56).

TIP

Please note that your access rights determine which data is displayed. Transaction data related to orders or workflows that are based on confidential master recipes/workflows that you are not allowed to access are not shown in the list.

The following audit trail types are available in the system:

Materials Audit Trail

Displays all changes made to a given material (page 81).

Users Audit Trail

Displays all changes made to a given user.

> **TIP**
> Please note that users can be maintained in PS Administration.

User Groups Audit Trail

Displays all changes made to a given user group.

> **TIP**
> Please note that user groups can be maintained in PS Administration.

Access Privileges Audit Trail

Displays all changes made to a given access privilege.

> **TIP**
> Please note that access privileges can be maintained in PS Administration.

Applications Audit Trail

Displays all changes made to a given application.

> **TIP**
> Please note that applications can be maintained in PS Administration.

Lists Audit Trail

Displays all changes made to a given list.

> **TIP**
> Please note that lists can be maintained in PS Administration.

Audit Trails - Actions

In addition to standard actions the system provides:

View Audit Trail History

To view the audit trail history of an object, proceed as follows:

1. Use the filter function (page 26) to find the object, whose history you wish to view, or select the object from the relevant audit trail object node in the tree view.
2. Click the object node to access the object data form.
3. Define the selection criteria for the audit trail data and click the **Search** button.
4. The **Audit Trail Entries** list populates with the audit trail records matching the defined selection criteria. If no selection criteria have been defined, all audit trail data available for the given object is displayed. The audit trail search results are displayed as well in the form of **Revisions** in the tree view, under the selected object node.
5. To view the details of the selected audit trail record, either
   - click the audit trail item in the **Audit Trail Entries** list to display the record properties in the property pane, or
   - click the revision under the object node to display both the basic data and properties of the given revision.

View Access Data

It is possible to view the following access-related data:

- Access Privileges of Users
  All access privileges displayed per user.
- Access Privileges of User Groups
  All access privileges displayed per user group.
- Users of Access Privileges
  Users assigned to a given access privilege, displayed per privilege.
- User Groups of Access Privileges
  User groups assigned to a given access privilege, displayed per privilege.
- System Access History
  Displays the history of login and logout events.
- History of Removed Object Locks
  Displays all occurrences when locked objects were unlocked.

TIP
Please note that objects can be unlocked by an administrator with the **Remove Object Locks** task (page 107).

View Access Privileges of Users or User Groups

To view the access privileges of users or user groups, proceed as follows:

1. Use the filter function (page 26) to find the object, whose access privileges you wish to view, or select it from the relevant access object node in the tree view.
2. Click the object node to access the object data form.
3. Define a timestamp as selection criterion for the access privilege data and click the **Search** button.
4. The search result list populates with the records matching the defined timestamp. If no timestamp has been defined, all access-related records available for the given object are displayed.
5. Click the access-related item in the list to display the record properties in the property pane.

View Users or User Groups of Access Privileges

To view the users or user groups of access privileges, proceed as follows:

1. Use the filter function (page 26) to find the access privilege, whose users or user groups you wish to view, or select it from the relevant access object node in the tree view.
2. Click the object node to access the object data form.
3. Define a timestamp as selection criterion for the user/user group data and click the **Search** button.
4. The search result list populates with the records matching the defined timestamp. If no timestamp has been defined, all user/user group-related records available for the given access privilege are displayed.
5. Click the user/user group-related item in the list to display the record properties in the property pane.

View System Access History

To view the system access history, proceed as follows:

1. Click the **System Access History - Default** sub-node under the **System Access History** node in the tree view, to access the sub-node data form.
2. Define the selection criteria for the system access history data and click the **Search** button.
3. The **System Access History** list populates with the system access history records matching the defined selection criteria. If no selection criteria have been defined, all system access history data available for the system access history function is displayed.
4. Click a system access history record in the **System Access History** list to display its properties in the property pane.

View History of Removed Object Locks

To view the history of removed object locks, proceed as follows:

1. Click the **History of Removed Object Locks - Default** sub-node under the **History of Removed Object Locks** node in the tree view, to access the sub-node data form.
2. Define the selection criteria for the history of removed object locks data and click the **Search** button.
3. The **History of Removed Object Locks** list populates with the history records matching the defined selection criteria. If no selection criteria have been defined, all available history data on removed object locks is displayed.

   TIP
   Please note that, by default, the system restricts the number of displayed entries to 100. You can change this by adapting the **Number of rows** in the selection criteria. The list header displays both the number of filtered entries and the number of available entries in parenthesis.

4. Click a record in the **History of Removed Object Locks** list to display its properties in the property pane.

Chapter 9

Unidentify Objects

The **Unidentify Objects** task provides all information and actions you need for revoking the identification of sublots that have previously been identified during processing.

What Is Object Unidentification?

When an object such as a sublot is identified during processing, the system links it to the order step that is being processed. Under specific circumstances, it may become necessary to revoke this link and make the object available for identification again elsewhere. With **Unidentify Objects** you can revoke the order step links of an object and make it available for re-identification.
This administrative function should be used with care and only as last resort as it can impact the material flow of an order.

Identified Objects - Actions

In addition to standard actions the system provides:

Unidentify an Object

To unidentify a sublot, proceed as follows:

1. In the tree view, click the respective object node to access the filter data form.
2. Define the selection criteria for the object and click the **Search** button.
3. The **Results** list populates with the object records matching the defined selection criteria. If no selection criteria have been defined, all object data available for the given object filter is displayed.
4. Click the **Unidentify** button to revoke the identification of the selected object for the order step for which it had been identified, thus unbinding it from the order step and making it available for identification elsewhere.

Chapter 10

Remove Object Locks

The **Remove Object Locks** task provides all information and actions you need for processing locked objects.

What Is an Object Lock?

An object is locked when it is currently being edited or processed elsewhere. It is available then for read-only output to prevent a situation where users or the system access the same object simultaneously and overwrite changes made by the other party. Under specific circumstances, however, it may become necessary to unlock such an object manually and make it available for work again.
With Remove Object Locks you can unlock the locked objects.

This administrative function should only be used as a last resort for scenarios such as

- A user runs Data Manager, Recipe and Workflow Designer, or PharmaSuite for Production Management, opens data objects, such as equipment classes, stations, master recipes, or master workflows, and omits to close them before locking his computer and being absent or otherwise unavailable. If the objects need to be accessed by another user or the system for performing a status change or in the course of executing a change request, they need to be unlocked. This means, however, that unsaved changes that were made by the user who has initially locked the objects are lost and cannot be restored.
- A user comments an exception in PharmaSuite for Production Execution or runs the exception dashboard of PharmaSuite for Production Responses to review exceptions and does not release the exception before locking his computer and being absent or otherwise unavailable. If the review needs to be finished by another user to release a batch, the exception needs to be unlocked.
- Similarly, a user is logged in on a device running PharmaSuite for Production Execution with operations in progress, locks the device while leaving it unattended, and is prevented from returning to continue processing from the device. Before another user can step in and take over processing from another device, the operations need to be unlocked, i.e. detached from the locked device so that the new user can pick them up at the new device and proceed with execution.

- A hardware failure occurs on a device running PharmaSuite for Production Execution on the shop floor and causes it to crash irrevocably. In order to proceed with the processing of running operations a replacement device needs to be installed and the running operations need to be unlocked, i.e. detached from the dead device so that they can be resumed at the replacement device.

TIP

Please note that the system records an exception for all active phases of an operation that is unlocked with this function.

Object Locks - Actions

In addition to standard actions the system provides:

Remove Object Locks

To remove a lock from an object, proceed as follows:

1. In the navigator pane, click the **Remove Object Locks** task to open the data form. The system displays the list of all objects that are currently locked.
2. Select the object from which you wish to remove the lock, and click the **Unlock** button. The unlocked object is removed from the list.
3. Click the **Refresh** button to refresh the list of locked objects.

TIPS

Please note that the system tracks all object lock removal actions in the **History of Removed Object Locks** node (page 103) of the **Manage Audit Trail** task (page 99).

Click the **Export** button to export the list (page 40) of locked objects to an external CSV file.

Chapter 11

Production Management Help

The **Production Management Help** task opens a web browser to display the start page of the help system of PharmaSuite for Production Management.
To display the context-sensitive help for the currently selected node of the tree view, click the Help button at the right margin of the toolbar or press the F1 function key.

In order to access other topics than the one directly related to the current context, use the navigation arrows located at the top of the help page, or related topic links located at the bottom of the page, if available.

The following additional features support your use of the help system:

- To access an overview of all available topics, open the **Contents** tab in the **Contents and Index** frame. The system additionally provides **Expand all** and **Collapse all** buttons to facilitate easier navigation in the contents tree.
- To access the index, open the **Index** tab in the **Contents and Index** frame.
- To use the **Search** function
  1. type the term you are looking for in the **Search** box and
  2. click the **Search** button or press the ENTER key.
     The system will display all occurrences of the search term in a third tab in the **Content and Index** frame.
- To print the page that is currently displayed in the help window, click the **Print this page** button. The system displays a print preview of the page along with the default Windows **Print** dialog.

> **TIP**
> Please note that printing is only available from the stand-alone format of the help system and not from within the application.

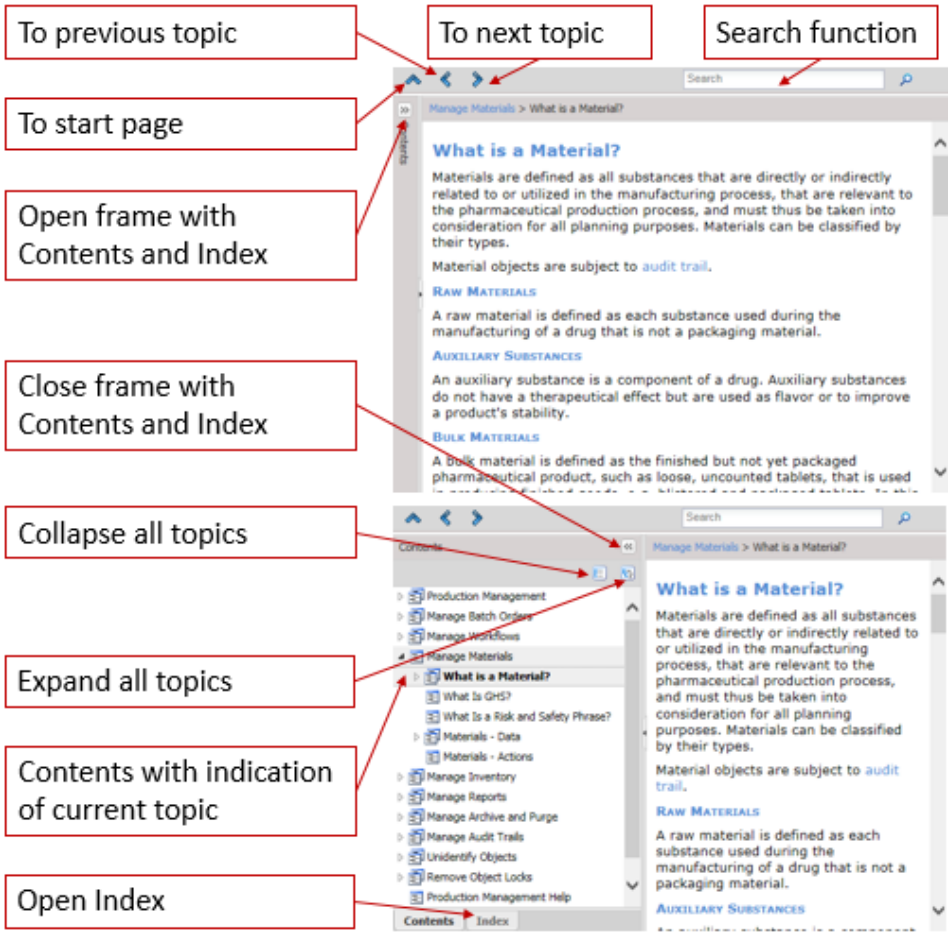

Figure 25: Help window navigation

Chapter 12

About PharmaSuite

The **About PharmaSuite** task opens the **About PharmaSuite** dialog to display system-related information, such as the current system version and build, the logged-in user, work center, and database-related information.

TIP

Please note that the dialog also indicates the **EBR server state**. Only when the EBR server is available can orders or workflows be processed in PharmaSuite for Production Execution.

Click the **Details** button to view more specific technical information on the system and its environment.

Figure 26: About PharmaSuite

Details

From the **PharmaSuite Installation Details** dialog, you can copy the listed detail data to the clipboard.

TIP

Please note that the path to the PharmaSuite log files is given in the last section of the listed detail data.

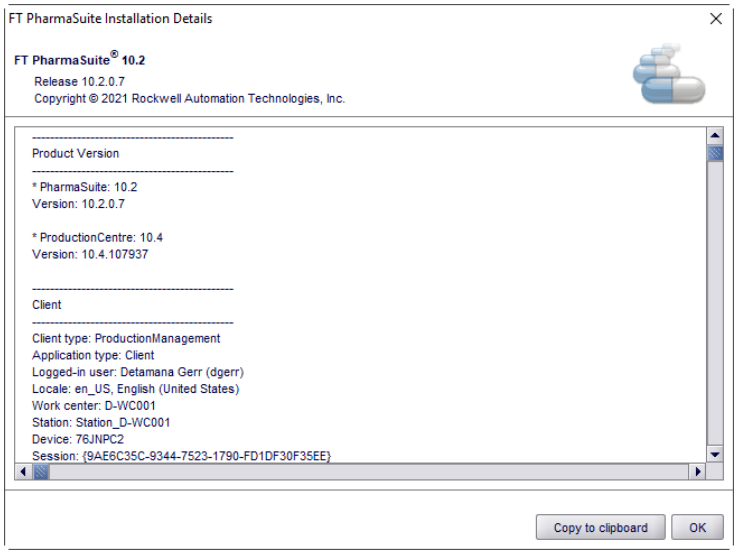

Figure 27: PharmaSuite Installation Details

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