

PharmaSuite®



PRODUCTION EXECUTION

RELEASE 8.4 **USER MANUAL**

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. Rockwell Software PharmaSuite $^{\circ}$ - Production Execution

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Production Execution

PharmaSuite for Production Execution is a system designed to control the production on the shop floor by managing its individual processes.

This section contains important information about the basic principles of working with PharmaSuite for Production Execution. 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 work with the system. We assume you are familiar with the conventions described in the following sections and the fundamentals of working with a touch-screen or keyboard-only application.

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	Designates code examples.	

TIP

typeface

Instructions in this manual are based on Windows 7. Select the appropriate commands if you are using a different operating system.

Screen Areas

The basic screen layout of Production Execution with EBR consists of three areas:

- Header bar (page 3)
- Work area (page 5)
- Control bar (page 6)

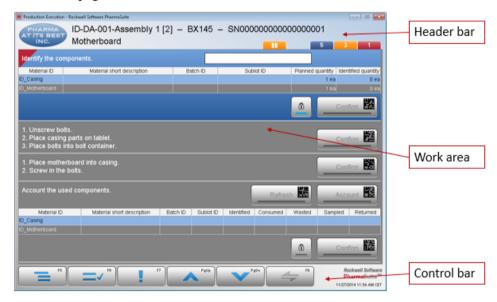


Figure 1: Screen layout

Header Bar

The **header bar** is located at the top of the screen and contains

- a company logo
- a screen title with one or two lines of text that refers to the content of the work area:
 - for the Cockpit (page 22) and the Navigator (page 30)
 - first line: surname and login name of the logged-in user.
 - second line: identifiers of the current work center and station.

for the Execution Window (page 34)

first line for order steps:

identifier of the current order step, with its unit procedure count if it has been reactivated, for batch processing the product batch, for device processing the serial number.

first line for workflows:

identifier of the current workflow with its processing name.

second line:

identifier of the operation with its count if it has been run more than once.

for the Detail Information Window (page 38)

first line for order steps:

identifier of the current order step, with its unit procedure count if it has been reactivated, for batch processing the product batch, for device processing the serial number.

first line for workflows:

identifier of the current workflow with its processing name.

second line:

identifier of the operation, with its count if it has been run more than once, followed by the identifier of the selected phase.

for the phase-specific Exception Window (page 36)

first line:

identifier of the current order step or workflow, with its unit procedure count if it has been reactivated, for order steps the product batch, for devices the serial number.

second line:

identifier of the operation with its count if it has been run more than once and phase identifier.

for the overview Exception Window (page 37)

first line:

identifier of the current order step or workflow, for order steps the product batch, for devices the serial number.

second line:

identifier of the unit procedure from which it has been accessed with its count if it has been reactivated.

for a Selection Window (page 33)

 selection-specific title and optional information, such as identifiers of affected objects or the affected work center and station

a notification bar to display escalation stages (page 71) for the runs of event-triggered operations.

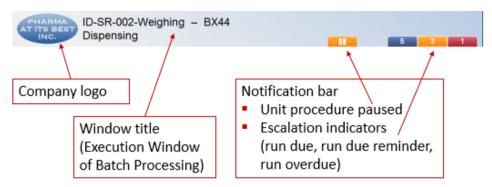


Figure 2: Header bar

Work Area

The work area is the main area in the middle of the screen and displays all dynamic data and controls.

The system indicates the currently focused control in yellow, as background color for input boxes and indicator bar for buttons.

- For the Cockpit (page 22), it contains the lists of **Startable** and **Running** processes and workflows.
- For the Navigator (page 30), it contains the history of executed steps with information and action buttons.
- For the Execution Window (page 34), it contains the phases of the active operation, with display text, input boxes, buttons, and all controls required for processing.
- For the Exception Window (page 36), it displays all exceptions and comments and provides an exception recording panel.
- For the Detail Information Window (page 38), it displays the relevant section of the batch report, along with existing exceptions, comments and an exception recording panel.
- For a Selection Window (page 33), it displays the list of objects available for selection. Above the list, some Selection Windows provide filter functions to restrict the number of listed objects.

Control Bar

The **control bar** is located at the bottom of the screen and contains

- the control buttons for working with the system:
 - Cockpit button to access the Cockpit (page 22)
 - Navigator button to access the Navigator (page 30)
 - **Exception** button to register an exception (page 50) in the process

TIP

In the Cockpit, Navigator, or Exception Windows the respective buttons are replaced by a **Back** button to return to the Execution Window.

- Page up/Page down buttons to page through the content of the work area
- **Switch** button to switch between concurrently running operations

Enabled buttons show a blue indicator bar or graphic, enabled and focused buttons turn their indicators yellow, while disabled buttons are grayed out.

- the PharmaSuite logo
- the current date and time with time zone information

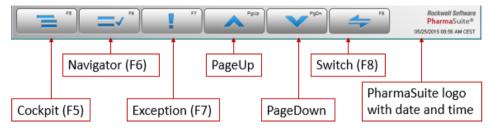


Figure 3: Control bar from Execution Window

Framework for Pre-defined Workflows

The basic layout of the framework for pre-defined workflows consists of:

- status bar with work center information
- work area with access to Cockpit (page 22) and pop-up panel for help
- navigation bar with action buttons



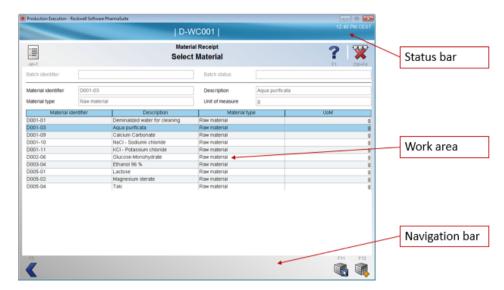


Figure 4: Screen layout

STATUS BAR

The status bar provides workflow-independent information such as the work center identifier and time and time zone information.

WORK AREA

The work area provides all information and controls a user needs for his current workflow step. It may display input boxes and grids for data display and selection, as well as graphics and graphical controls, such as a scale control, etc.

In the upper left corner of the work area, the system provides the **Open cockpit** button to open and close the Cockpit for starting workflows or switching between workflows. The upper right corner holds two buttons, the **Help** button to access the context-sensitive help system and the **Cancel workflow** button to stop processing the current workflow and close the form.

NAVIGATION BAR

The navigation bar provides the controls to move through a workflow. The **Back** button to the far left of the bar takes the user one step back in the workflow, provided this is allowed by the workflow structure. The **Next** button to the far right of the bar confirms the completion of the active step and takes the user one step forward in the workflow. If there are several options available for how to proceed from a workflow step, additional buttons indicate the different options, sometimes even replacing the **Next** button.

In addition to the workflow control buttons, the navigation bar can display indicator icons, which point to specific system statuses or events like "system ready to scan" or "scanning is mandatory".

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Graphical Elements

The following lists contain the graphical buttons and icons used in PharmaSuite for Production Execution.

Framework

The framework provides the following buttons and graphical elements to control and navigate processes and workflows:



Back

In pre-defined workflows, returns to the previous step, if this is permitted by the workflow.



Back (F7)

In the control bar, returns to the window from which you have accessed the currently active window. The **Back** button can replace the **Cockpit**, **Navigator**, or **Exception** buttons, respectively.



Cancel workflow (CTRL+F4)

In pre-defined workflows, cancels the current workflow. This action depends on the workflow step and is not always available.



In the control bar, opens the Cockpit (page 22) to display the lists of **Startable** and **Running** processes and workflows.



In the control bar, opens the Exception Window (page 36) to record an exception to the regular execution process.



Help (F1)

In pre-defined workflows, opens the pop-up window with the context-sensitive help system.





Navigator (f6)

In the control bar, opens the Navigator (page 30) to list the current and completed phases of the operation.



Next

In pre-defined workflows, completes the current step and moves to the next step in the workflow.

Notification bar - due

In the header bar, attached to the top right corner of the work area, indicates the number of runs of an event-triggered operation that are ready for processing.

Notification bar - due reminder

In the header bar, attached to the top right corner of the work area, indicates the number of runs of an event-triggered operation that need to be processed as soon as possible as they have been due for a certain amount of time.

Notification bar - overdue

In the header bar, attached to the top right corner of the work area, indicates the number of runs of an event-triggered operation that are overdue and need to be processed immediately.

Notification bar - paused unit procedure

In the header bar, attached to the top right corner of the work area, indicates that at least one unit procedure running at the current work center is currently paused.



OK

In pre-defined workflows, completes the last step of a workflow and finishes the workflow itself.



Open Cockpit (ALT+T)

In pre-defined workflows, switches to the Cockpit to display the lists of **Startable** and **Running** processes and workflows.



In the control bar, pages down in the content of the work area.



In the control bar, pages up in the content of the work area.



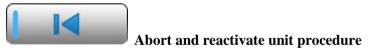
In the **Appendable Workflows** Selection Window, controls if the list of appendable workflows (page 68) only shows the workflows that have been or are running at the current work center. By default the button is selected, thus restricting the number of listed workflows.



In the control bar, switches between concurrently running operations.

Cockpit

The Cockpit provides the following buttons and icons:



On the Actions dialog (page 61) of a unit procedure, aborts and reactivates a unit procedure thus making it available for restarting.



In the list of **Running** processes of the Cockpit (page 22), to the right of a unit procedure, an operation, or template, it opens the Actions dialog to display the additional actions that are available.





Append

On the Actions dialog (page 61) of a unit procedure, opens the Appendable Workflows Selection Window to filter and select a workflow available for appending to the unit procedure.



Cancel all runs

On the Actions dialog (page 64) of an event-triggered operation, cancels all runs of the operation that have not been started yet.



Cancel run

On the Actions dialog (page 64) of an event-triggered operation, cancels the run of the operation.

Only available if the run has not been started yet.



In the list of **Running** processes of the Cockpit (page 22), displays the identifier of the operation, the identifier of the device on which it is running, and the start time of its unit procedure.





Detach



Detach (active operation or unit procedure)

In the list of **Running** processes of the Cockpit (page 22), to the right of a detachable operation or unit procedure, detaches the operation (page 73) from the current station or the unit procedure (page 71) from the current work center, thus holding its processing and making it available for resuming at another station or work center, respectively.



Event-triggered operation run before expiry

In the list of **Running** processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier of the operation with the count of its run, the X marker indicating that the expiry of the run is the next stage in its escalation progress (page 71) with the time when this occurs, and the start time of its unit procedure.

Tableting IPC [1.8] !!! 01:26 PM 11/27/2014 01:25:57 PM CET

Event-triggered operation run before overdue

In the list of **Running** processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier of the operation with the count of its run, the !!! marker indicating that an overdue marker is the next stage in its escalation progress (page 71) with the time when this occurs, and the start time of its unit procedure.



Event-triggered operation run before reminder

In the list of **Running** processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier of the operation with the count of its run, the ! marker indicating that a run due reminder is the next stage in its escalation progress (page 71) with the time when this occurs, and the start time of its unit procedure.



Exceptions

On the Action dialog (page 64) of a unit procedure, opens the overview Exception Window to display all exceptions and comments that have so far been recorded for the operations and phases of the current run of the unit procedure.



New run

On the Actions dialog (page 64) of a template or an event-triggered operation, starts a new run of the operation.



Operation running at different station

In the list of **Running** processes of the Cockpit (page 22), displays the identifier of the operation, the identifier of the device on which it is running, and the start time of its unit procedure.



Pause unit procedure

On the Actions dialog (page 61) of a unit procedure, pauses the execution of a unit procedure by informing all active phases of this fact. Trigger phases react by holding their triggering activities until the unit procedure is resumed.





Remove template

On the Actions dialog (page 64) of a template, removes the template from the list of running processes, thus ending the cycle of the event-triggered operation.



Resume unit procedure

On the Actions dialog (page 61) of a paused unit procedure, resumes the execution of the unit procedure by informing all active phases of this fact. Trigger phases react by resuming their triggering activities.



Run due reminder

In the list of **Running** processes of the Cockpit (page 22), to the left of an event-triggered operation's run button, indicates that the run needs to be processed as soon as possible as it have been due for a certain amount of time.



Run overdue

In the list of **Running** processes of the Cockpit (page 22), to the left of an event-triggered operation's run button, indicates that the run needs to be processed immediately.



In the list of Running processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier of the operation, the identifier of the device on which it is running, and the start time of its unit procedure.



Running unit procedure of Batch Processing

In the list of **Running** processes of the Cockpit (page 22), displays the identifiers of the batch and of the unit procedure started from Batch Processing (page 83). Indented below the unit procedure button, the system lists those of its operations that are ready to be processed.

SN00000000000000001

ID-DA-001-Assembly 1 [2]

Running unit procedure of Device Processing

In the list of **Running** processes of the Cockpit (page 22), displays the identifier of the device and of the unit procedure started from Device Processing (page 85). Indented below the unit procedure button, the system lists those of its operations that are ready to be processed.

AmbientConditionsCheck - WA03

ID-AC-002-Ambient Conditions Check

Running unit procedure of Workflow Processing

In the list of **Running** processes of the Cockpit (page 22), displays the name of the workflow, its identifier and the identifier of the unit procedure started from Workflow Processing (page 89). Indented below the unit procedure button, the system lists those of its operations that are ready to be processed.

Room Cleaning (Prod.)

WF1500000024-Room Cleaning (Production)

Running unit procedure of a one-click startable workflow

In the list of **Running** processes of the Cockpit (page 22), displays the name of the workflow, its identifier and the identifier of the started unit procedure. Indented below the unit procedure button, the system lists those of its operations that are ready to be processed.

Batch Processing

Startable batch orders

In the list of **Startable** processes of the Cockpit (page 22), initiates execution. It opens the list of startable batch order steps for selecting an order step to be processed.

Device Processing

Startable device orders

In the list of **Startable** processes of the Cockpit (page 22), initiates execution. It opens the list of startable device order steps for selecting an order step to be processed.

Material Processing

Startable material for processing

In the list of **Startable** processes of the Cockpit (page 22), initiates execution. It opens the list of materials that are available for processing.



In the list of Running processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier of the operation and the start time of its unit procedure.



Startable workflow

In the list of **Startable** processes of the Cockpit (page 22), initiates the execution of the selected one-click startable or pre-defined workflow.



Startable workflows

In the list of **Startable** processes of the Cockpit (page 22), initiates execution. It opens the list of startable workflow steps for selecting a workflow step to be processed.



Template

In the list of **Running** processes of the Cockpit (page 22), indented below its unit procedure, displays the identifier and description of an event-triggered operation. A template as such cannot be started for processing. Only when a run of the operation has been triggered, either by the system or by manual run creation, is the template button replaced by a tappable operation button.



Unit procedure paused

In the list of **Running** processes of the Cockpit (page 22), to the left of a paused unit procedure, indicates that the unit procedure is paused and some phases, such as trigger phases, may be on hold.

Common

The following buttons and icons are common to several phases or workflows:



For phases that visualize a status, indicates that an alarm status has occurred.



In the exception recording panel of the Exception Window, toggles the bookmark indicator for the exception selected in the list of exceptions.



Cancel order step

In pre-defined workflows, permanently terminates the selected order step.



Checkmark

For phases that visualize a status, indicates that the status is as intended.



Enable

For complex phases that require several actions to be completed before a follow-up action, such as confirming the phase, can be started, an **Enable** toggle button is available to explicitly enable the button that triggers the follow-up action.



Frror

For phases that visualize a status, indicates that an error status has occurred.



Exception at value

In phases that display values as table, indicates that an exception has been recorded for the value given in the marked table cell.



First page

Phases that can display multi-page documents provide a document viewer with navigation buttons. The **First page** button moves to the beginning of the document.



Identify batch manually

In pre-defined workflows, allows the manual identification of a batch as fallback if the batch label cannot be scanned.



Identify load carrier manually

In pre-defined workflows, allows the manual identification of a load carrier as fallback if the load carrier label cannot be scanned.





Identify sublot manually

In pre-defined workflows, allows the manual identification of a sublot as fallback if the sublot label cannot be scanned.



Phases that can display multi-page documents provide a document viewer with navigation buttons. The Last page button moves to the end of the document.



C Loading

For phases that load external data for display, such as a historical data chart, the animated icon indicates that loading is in progress.



Move all down

In pre-defined workflows, used for assignments or for detailed selection between two data tables. All data objects of the upper data table are moved to the lower data table.



Move all up

In pre-defined workflows, used for assignments or for detailed selection between two data tables. All data objects of the lower data table are moved to the upper data table.



Move selected down

In pre-defined workflows, used for assignments or for detailed selection between two data tables. The data objects selected in the upper data table are moved to the lower table.



Move selected up

In pre-defined workflows, used for assignments or for detailed selection between two data tables. The data objects selected in the lower data table are moved to the upper table.



Phases that can display multi-page documents provide a document viewer with navigation buttons. The **Next page** button moves to the beginning of the next page in the document.



For phases that are active for a period of time, such as monitoring phases, the animated icon indicates that the phase activity is ongoing.



Phases that can display multi-page documents provide a document viewer with navigation buttons. The **Previous page** button moves to the beginning of the previous page in the document.



Scanner ready - mandatory

In pre-defined workflows, indicator icon that shows that the connected scanner is ready for use. The identification action is mandatory at this point.



Scanner ready - optional

In pre-defined workflows, indicator icon that shows that the connected scanner is ready for use. The identification action is optional at this point.



Phases that can display multi-page documents provide a document viewer with navigation buttons. The **Scroll down** button scrolls linewise down through the document.



Phases that can display multi-page documents provide a document viewer with navigation buttons. The **Scroll up** button scrolls linewise up through the document.

Selected

In pre-defined workflows, indicator icon used for multi-selection in data tables. The data objects are marked selected for further processing.



Skip step

In pre-defined workflows, skips the current workflow step.



Toggle unit of measure

For input values in phases that can deal with various units of measure, the selected unit is displayed in the center of the button. Clicking the button toggles to the next unit, which shows as preview in the top right corner of the button. The following units are available: **t**, **g**, **kg**, **lb**, **mg**, **oz**.

☐ Unselected

In pre-defined workflows, indicator icon used for multi-selection in data tables. The data objects are no longer marked selected for further processing.

Specific

The following buttons and icons only occur during processing of specific workflows and phases:



Consume sublot

In the **Weigh** phase of a Dispense operation in Recipe Processing (page 83) or Material Processing (page 87), registers a sublot as consumed, thus removing it from all inventory lists.



Even split

In the **Sublot Split** workflow (page 106), provides a form to execute an even split on a sublot.

Manual scale indicator

In the **Select scale** phase of a Dispense or Weighing operation, on a scale button, indicates that the scale is configured as manual scale and that all values have to be entered manually.



New batch

In the **Material Receipt** workflow (page 91), provides a form to create a new batch.





Release scale

In the Weigh phase of a Dispense operation in Recipe Processing (page 83) or Material Processing (page 87), allows an operator to release the scale after an underweight condition during **Net removal** weighing.



Scale loaded indicator

In the **Select scale** phase of a Dispense or Weighing operation, on a scale button, indicates that the scale is loaded, typically with a container, and must not be zeroed.



Scan action indicator for container

In the **Identify container** phase of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a container.



Scan action indicator for printer

In the **Print report** phase of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a printer.



Scan action indicator for scale

In **Tare** and **Release scale** phases of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a scale.



Scan action indicator for scale with value

In the **Weigh** phase of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a scale.





Scan action indicator for sublot

In the **Identify material** phase of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a sublot.



Scan action indicator for undefined scale

In the **Select scale** phase of a Dispense or Weighing operation, in Recipe Processing (page 83) or Material Processing (page 87), indicates that the scan target for phase confirmation is a scale.



Select batch

In the **Material Receipt** workflow (page 91), provides a form to select a batch from the list of existing batches.



Uneven split

In the **Sublot Split** workflow (page 106), provides a form to execute an uneven split on a sublot.

Cockpit

The Cockpit represents an operator's entry point to the execution process. Specific to each station and user, the Cockpit provides a list of all startable, resumable, and running processes, from which the operator can select unit procedures and operations to start or switch to. The running processes also include those operations of the same unit procedure that are running at another station.

In its header bar, the Cockpit displays two lines of text. The first line shows the surname and login name of the logged-in user, the second line shows the identifiers of the current work center and station.

TIP

If you wish to process Dispense operations at your work center, make sure it is assigned to a room of the **Room (RS)** equipment type. Work centers and room equipment entities are maintained in Data Manager.

In the left part of its work area, the Cockpit displays buttons for the **Startable** processes and workflows, sorted by application area in the following sections:

TIPS

Please note that the system can be configured to display additional sections, such as **Quality** or **Maintenance** or to show only selected application sections, processes, and workflows at specific work centers.

Which processes are displayed also depends on the access rights of the logged-in user. Processes that are based on confidential master recipes or master workflows to which the user does not have the required access rights remain invisible.

- Production (page 83)
- Inventory (page 91)
- System
 - **Help** system (page 81)

■ **About** function

It 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.

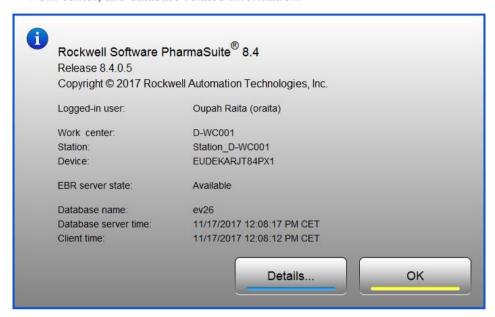


Figure 5: About dialog

TIP

Please note that the dialog also indicates the **EBR server state**. Only when the EBR server is available can you process recipes or EBR workflows with PharmaSuite for Production Execution.

Click the **Details** button to view more specific technical information on the system and its environment. From the **PharmaSuite Installation Details** dialog, you can copy the listed detail data to the clipboard.

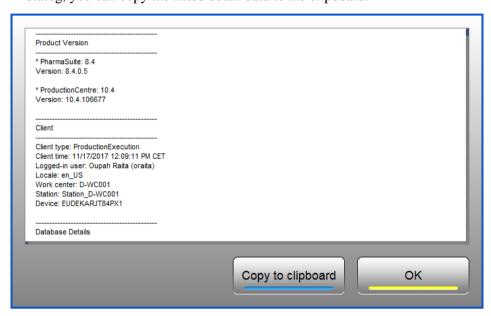


Figure 6: About dialog - Details

TIP

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

■ Register at Station function

It is primarily intended for mobile devices and allows you to register your device at another station. By doing so, the system automatically unregisters your device from where it was previously registered.

On the **Register at Station** dialog you can filter the number of station identifiers displayed in the **Station** option list. The filter becomes effective with the second character you type.

By default, the search is not case-sensitive and the search string may occur anywhere in the station identifiers. Click the magnifying glass icon to set the search criteria to be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

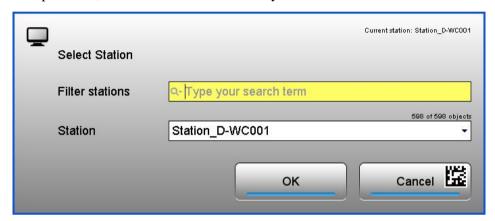


Figure 7: Register at Station dialog

TIPS

Please note that the system supports registration of a device at a station by scanning the station's barcode.

The system rejects a user's registration at the station if there are confidential processes running at the station to which the user does not have the required access rights.

■ Change User function

It allows you to change to another user without having to exit the system, for example at shift change. The **Change User** dialog does not have a **Cancel** button and can only be completed with a valid login name and password. If the function was called unintentionally, it is possible to log in again by typing the login name and password of the currently logged-in user. Thus you can also use the dialog to lock the screen and prevent unauthorized access to the system, while order or workflow processing continues in the background. For this reason, the **Change User** function also serves to provide a configurable auto-lock mechanism that detects if the system is not in active use by an operator and consequently locks the screen after a configurable period of inactivity, typically 15 minutes. Any kind of user interaction with the system by touch, keyboard, scanner, or mouse prevents the system from auto-locking.

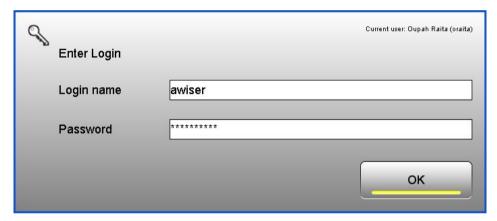


Figure 8: Change User dialog

TIP

Please note that when a user change is initiated while an order or workflow is running, the new user needs to have the access rights required for processing the running order or workflow.

Exit function (page 47)

When you return to the Cockpit while one or more processes are running, the list of startable processes and workflows displays started workflows that cannot be started multiple times is grayed out. Only **Batch Processing**, **Device Processing**, and **Material Processing** can be started multiple times.

TIP

Please note that instead of selecting a batch or device operation from the Cockpit, you can also scan the barcode of its batch or device, respectively. A batch's barcode is typically located on the cover page of its batch report, while a device's barcode is located on the cover page of its DHR report.



Figure 9: Cockpit

The list of **Running** processes and workflows is organized by application area, in the same way as the list of startable processes and workflows. The system displays a running process with its order step or unit procedure as gray header and its startable or running operations as indented tappable buttons.

Unit procedure buttons in Batch Processing show the batch they are producing and their order step identifier with the unit procedure's count if it has been reactivated. Unit procedure buttons in Device Processing show the serial number of the device they are producing and their order step identifier with the unit procedure's count if it has been reactivated.

Unit procedure buttons of workflows show the unit procedure's identifier.

Unit procedures of Batch or Device Processing can provide a button to access further actions (page 61), such as pausing or resuming it (page 65), viewing and processing its exceptions (page 37), aborting and reactivating it (page 72), or appending workflows (page 68).

Some unit procedures can be detached from their current work center (page 71) for being continued at another work center. A detachable unit procedure displays a **Detach** button (page 11) to the right of its unit procedure button.

Operations of the same unit procedure that are already running at another station and are thus unavailable at the current station, are disabled and gray. The currently active operation, from which you have opened the Cockpit, is represented as yellow button, while other startable or running operations have blue buttons.

Event-triggered operations (page 64) first show as template graphics (page 15) and later as tappable operation buttons (page 11) once a run has been created. Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3) and escalation markers to the left of the template or runs of the event-triggered operation.

TIPS

Please note that phases and operations of looped processes can be run and completed several times. In these cases the system appends a count to their identifiers that indicates how often they have been run.

Event-triggered operations display a two-digit count where the first digit represents the number of times the operation has been run and completed, while the second digit represents the count of runs created as long as its template was active.

For some of the listed running operations, the system provides additional actions. They display an **Actions** button (page 10) to their right, which opens their Actions dialog (page 64) to access the available actions.

Once you have started an operation on a device, it is attached to the device as well as to the station at which the device is registered. A running operation shows its activity by pulsing its indicator bar. Additionally it displays the identifier of the device on which it is being run in small font in the upper right corner of its operation button.

There are running operations that can be detached (page 73) from their current device and station for being continued at another station. A detachable operation displays a **Detach** button (page 11) to the right of its operation button.

TIP

The list of **Running** processes also contains all operations that have been started in a previous session, have been closed before completion, and can be resumed. This can be especially important if, for example, a power failure causes the system to shut down unexpectedly.

When you process an uninterruptible operation such as a Dispense operation and experience an unexpected shutdown, you must resume and process this operation first after restart. As indicator, the system displays the affected operation as currently active, with its operation button in yellow.

- To page through the listed processes and workflows, tap the **Page up/Page down** buttons in the control bar.
- To start any of the startable processes or workflows, tap it.

 For processing of batch recipes, device recipes, materials, and EBR workflows, the system displays the started unit procedure as running process with its list of startable operations.
 - For pre-defined workflows, the system directly switches to the Execution Window (page 34) for processing the workflow.
- To switch to the Execution Window (page 34) and process the phases of an operation, tap the respective blue operation button.
- To return to the Execution Window (page 34) and proceed with processing the phases of an operation, tap the respective yellow operation button or the **Back** button in the control bar.

- To detach a running unit procedure in order to make it available for being resumed at another work center, tap its **Detach** button (page 11).
- To detach a running operation in order to make it available for being resumed at another device and station, tap its **Detach** button (page 11).
- To access additional actions that are available for an item listed as **Running**, tap its **Actions** button (page 10).
- To return to the form from which you have accessed the Cockpit, tap the **Back** button in the control bar.
- To access the Navigator (page 30) with the execution history, tap the **Navigator** button in the control bar.

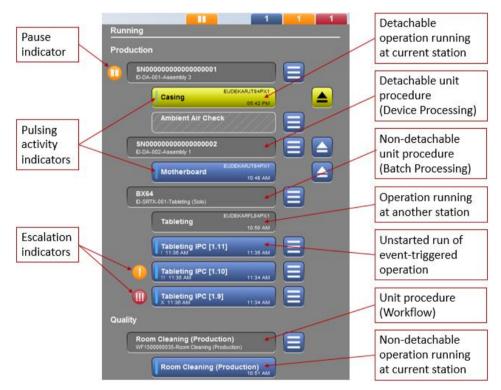


Figure 10: Running processes

as well as additional actions.

Navigator

The Navigator represents an operator's information and service point during the execution process. Specific to each unit procedure, the Navigator provides a historical view of the executed process steps. For each step, the operator can access basic and detail information

In its header bar, the Navigator displays two lines of text. The first line shows the surname and login name of the logged-in user, the second line shows the identifiers of the current work center and station.

Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3).

The work area of the Navigator displays the data panel at the top and three columns below it:

■ For order-related execution, the data panel displays two data frames. The left frame holds the identifiers of the order, the produced batch, and the unit procedure with its count if it has been reactivated. The right frame shows, for device orders only, the serial number of the produced device, while for batch and device orders alike, it shows the identifier and short description of the produced material.

For workflow execution, only the left data frame is filled. It holds the identifier of the workflow, its processing name, and the identifier of the unit procedure. It also provides a **Cancel** button to cancel a running workflow that cannot be completed by regular means.

TIP

Please note that you can only cancel workflows that are not appended to a unit procedure.

■ The left column (phase column) lists all phases of the unit procedure that have been executed so far, ending with the phase or phases of the currently active operation. A phase displays the identifier of the operation to which the phase belongs as well as its phase identifier. Phases that have been fully executed and confirmed are shown with a gray background and can no longer be directly accessed for processing. Phases that have been processed at another station have a dashed phase frame. The currently active phase or phases are represented as tappable, yellow buttons.

TIP

Please note that phases and operations of looped processes can be run and completed several times. In these cases the system appends a count to their identifiers that indicates how often they have been run.

Event-triggered operations display a two-digit count where the first digit represents the number of times the operation has been run and completed, while the second digit represents the count of runs created as long as its template was active.

If a process includes phases that are skipped on the user interface, they are nevertheless included in the count, since the system executes them in the background as hidden phases.

■ The center column (information column) provides buttons to access the Detail Information Window (page 38) for the individual phases that have been fully executed and confirmed. Detail information is provided by a phase-specific report. From here you can also see all exceptions and comments (page 50) that have been recorded for the phase so far and add new exceptions or comments, if necessary.

TIP

Phases for which an exception has been recorded are displayed with a red upper left corner as exception marker.

■ The right column (action column) provides buttons to access up to three actions. For active phases the **Abort** and **Repair** buttons are available to resolve phase definition-related issues (page 58).

For phases that have been fully executed and confirmed, there may be exception situations that require a post completion correction of a value or reprinting of a label are available. Tapping the respective action button will thus take you to the Exception Window (page 36) where you can execute and confirm the action in the same way as when you record a user-triggered, phase-specific exception (page 55).

Phases, on which you have performed an action, display the red exception maker.

- To page through the listed phases, tap the **Page up/Page down** buttons in the control bar.
- To switch to the Execution Window (page 34) for processing a phase, tap the respective yellow phase button in the phase column.
- To switch to the Detail Information Window (page 38) of a phase, tap the respective button in the information column.
- To return to the form from which you have accessed the Navigator, tap the **Back** button in the control bar.
- To open the Cockpit (page 22) with access to other processes, workflows, or system functions, tap the **Cockpit** button.

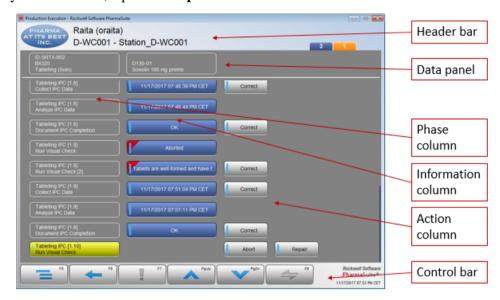


Figure 11: Navigator



Figure 12: Data panel of a non-order-related workflow

Selection Window

A Selection Window supports an operator whenever the process requires him to choose one or several objects, such as order steps for starting (page 87) or workflows for appending (page 67).

In its header bar, a Selection Window displays a selection-specific title and the identifiers of affected objects, if applicable.

Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3)

The work area contains the list of objects that are available for selection. For lists that can potentially have a large number of items the system provides filter tools to restrict the number of listed items. The filter becomes effective with the second character you type. By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

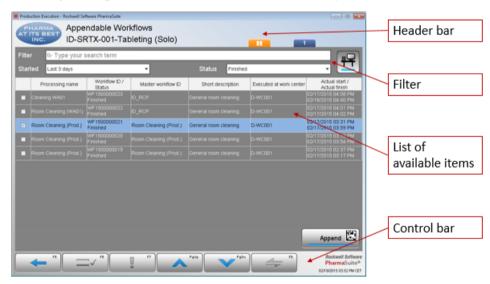


Figure 13: Selection Window

Execution Window

The Execution Window represents an operator's workspace during the execution process. Here, the operator performs the execution-related actions and registers process-relevant data.

In its header bar, the Execution Window displays in the first line for order steps, the identifier of the current order step with its unit procedure count if it has been reactivated. For batch processing it shows the product batch, for devices the serial number. In the first line for workflows, it displays the identifier of the current workflow with its processing name. The second line holds the identifier of the operation with its count if it has been run more than once.

Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3).

The work area represents the dynamic part of the Execution Window and reflects the execution progress:

- 1. Typically, the first operation you perform in processing with EBR is to select what you wish to process. This can either be a specific order step, in **Batch** or **Device Processing**, a workflow step in **Workflow Processing**, or one or several materials, in **Material Processing**.
- 2. After you have selected the order step or materials for processing the system returns you to the Cockpit (page 22) where all executable operations are listed as **Running**. Now you can tap to start the operation you wish to process.
- 3. The system displays the phases of the operation in their order of processing:
 - Previously executed phases are in read-only mode, with a checkmark on their Confirm buttons to indicate that they have been completed.
 - Currently active phases are accessible for processing.
 Some phases may require an electronic signature before they can be completed.
 - Future phases that will only become active after one or all currently active phases have been executed are in read-only mode.

 In a strictly sequential operation, the system displays all phases. If the operation includes one or more decision points, however, it will only show the future phases up to the next decision point.

Exceptions (page 36) that occur during processing can be recorded at all times.

TIP

Please note that some phases may rely on information or input that is not yet available when the preview is created. The preview of these phases only shows a corresponding system message.



Figure 14: Phase representation during execution

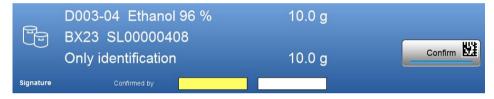


Figure 15: Phase with required completion signature

- 4. Execute an accessible phase and tap its **Confirm** button.
- 5. Move on to the next accessible phase until you have all phases processed and confirmed.
 - When you have tapped the **Confirm** button of the last phase, the system returns you to the Cockpit for selecting a new operation or workflow.
- To page through the listed phases, tap the **Page up/Page down** buttons in the control bar.
- To access the Navigator (page 30) with the execution history, tap the **Navigator** button in the control bar.
- To open the Cockpit (page 22) with access to other processes, workflows, or system functions, tap the **Cockpit** button.

Exception Window

The Exception Window represents an exception handling (page 50) point where an operator can record, comment, and bookmark all exceptions that may occur during execution on the shop floor.

The system provides two variants of the Exception Window:

- the phase-specific Exception Window, which you can access during phase processing by tapping the **Exception** (F7) button (page 8) located in the control bar.
- the overview Exception Window is only available for unit procedures started as order steps with recipe processing. It lists all exceptions that have been recorded for the phases and operations of the unit procedure. You can access the overview of all exceptions from the Cockpit:
 - 1. Tap the **Actions** button (page 10) to the right of a unit procedure. The system opens the Actions dialog of the unit procedure.
 - 2. Select the **Exceptions** button (page 12).

Phase-specific Exception Window

In its header bar, the phase-specific Exception Window has a red triangle in the upper left corner as exception marker and displays the in the first line, the identifier of the current order step or workflow with its unit procedure count if it has been reactivated, for order steps the product batch, for devices the serial number, and in the second line, the identifier of the operation with its count if it has been run more than once and the phase identifier

Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3).

The work area represents the dynamic part of the Exception Window and lists all exceptions and comments that have so far been recorded for the phase. Below the list, the system displays the exception recording panel that provides all controls to record and bookmark exceptions and add comments.

TIP

If the phase provides phase-specific exception (page 55) options, they are displayed above the list of recorded exceptions and the exception recording panel.

- To page through the listed exceptions and comments, tap the **Page up/Page down** buttons in the control bar.
- To return to the form from which you have accessed the Exception Window, tap the **Back** button in the control bar.



Figure 16: Phase-specific Exception Window

Overview Exception Window

In its header bar, the overview Exception Window has a red triangle in the upper left corner as exception marker and displays the in the first line, the identifier of the current order step or workflow, for order steps the product batch, for devices the serial number, and in the second line, the identifier of the unit procedure from which it has been accessed with its count if it has been reactivated.

Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3).

The work area represents the dynamic part of the Exception Window and lists all exceptions and comments that have so far been recorded for the operations and phases of the current run of the unit procedure. Below the list, the system displays the exception recording panel that provides all controls to record and bookmark exceptions and add comments.

TIP

Please note that the list of exceptions does not include the exceptions of workflows that are appended to the unit procedure.

- To page through the listed exceptions and comments, tap the **Page up/Page down** buttons in the control bar.
- To return to the Cockpit, tap the **Back** button in the control bar.



Figure 17: Overview Exception Window

Detail Information Window

The Detail Information Window represents an information point where an operator or reviewer can view phase-specific data of completed phases and comment all exceptions that have been recorded during execution. If necessary, he can also add further comments and exceptions.

In its header bar, the Detail Information Window displays in the first line for order steps, the identifier of the current order step with its unit procedure count if it has been reactivated. For batch processing it shows the product batch, for devices the serial number. In the first line for workflows, it displays the identifier of the current workflow with its processing name. The second line holds the identifier of the operation, with its count if it has been run more than once, followed by the identifier of the selected phase. Event-triggered operations can enforce their timely execution by implementing an escalation scenario (page 71), whose stages are indicated by the notification tabs in the header bar (page 3).

The work area represents the dynamic part of the Detail Information Window. In its upper section, it displays the phase-specific part of the batch report with detailed phase information, such as

- the batch and order identifier to which the phase belongs
- the material that will be produced with the order
- the start and finish timestamps of the phase.

In its lower section, the work area holds the list of exceptions and comments that have been recorded for the phase and the exception recording panel.

- To page through the listed information, tap the **Page up/Page down** buttons in the control bar.
- To return to the form from which you have accessed the Detail Information Window, tap the **Back** button in the control bar.

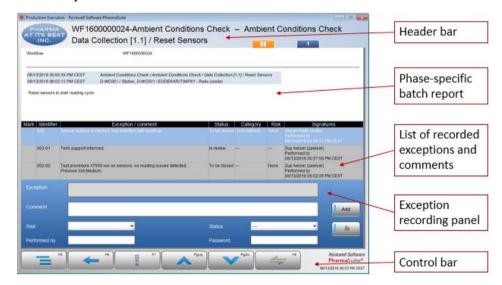


Figure 18: Detail Information Window

Input Devices

Production Execution with EBR is designed for use with various input devices to support the most suitable equipment for all expected application environments.

Physical Keyboard

A physical keyboard may be available at your work station for typing data and values in input fields. The system also supports keyboard navigation and control with keyboard shortcuts.

FRAMEWORK SHORTCUTS

Use the following keyboard shortcuts to trigger the functions of the control bar.

■ ALT+F4

Closes a modal window or dialog, such as the help window, that may be open on top of the application.

If there is no other window or dialog open, it logs the current user out and closes the application.

■ ALT+T

In the non-EBR framework, toggles the display of the Cockpit.

CTRI +E/

Cancels the currently active workflow.

F F

Opens the help system (page 81).

F5

In the control bar, toggles the display of the Cockpit (page 22).

F6

In the control bar, toggles the display of the Navigator (page 30).

F7

In the control bar, toggles the display of the phase-specific Exception Window (page 36).

F8

In the control bar, switches between concurrent operations of a running unit procedure.

■ PAGE DOWN

In the control bar, pages the content of the work area down.

PAGE UP

In the control bar, pages the content of the work area up.

NAVIGATION BAR KEYBOARD SHORTCUTS

In the navigation bar of pre-defined workflows, there are no specific assignments of keyboard shortcuts to the individual buttons located on the bar. Instead, the eight available button spaces are mapped to the function key blocks from F5 through F12. Press F5 through F8 to access the four button spaces to left of the center element in the navigation bar or press F9 through F12 to access the four spaces to the right of the center element.

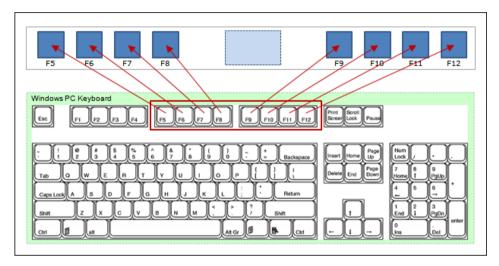


Figure 19: Keyboard mapping of navigation bar buttons

COCKPIT NAVIGATION

Use the following keys to navigate the Cockpit.

- TAB
 Navigates along the defined navigation path, from top to bottom of the **Startable** Workflows list and then of the **Running Workflows** list.
- SHIFT+TAB Navigates back along the defined navigation path from bottom to top of the lists of **Startable** or **Running** processes or workflows.

EXECUTION WINDOW NAVIGATION

Use the following keys to navigate the Execution Window.

CTRL+TAB
 For multi-line text boxes, navigates to the next control in the work area, along the defined navigation path.

ENTER

For tables, moves to the next row and marks it for multi-selection, if applicable. For option lists, selects the highlighted option.

F9

Starts processing in the **Material Processing** workflow.

■ SHIFT+TAB

Navigates back along the defined navigation path from control to control in the work area.

SPACEBAR

For tables, marks the highlighted row for multi-selection. For option lists, selects the highlighted option.

TAB

Navigates along the defined navigation path, typically from the top-left corner to the bottom-right corner of the form, from control to control in the work area.

UP/DOWN ARROW

Navigates between the rows of a table or the options of an option list.

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-tap action on the default button.

■ FSC

Cancels the dialog and closes the dialog box.

SPACEBAR

For buttons, triggers a single-tap action on the focused button.

■ TAB

Navigates along the defined navigation path, moving the focus between input boxes and buttons.

Scanner

The system can process scanner input from both 1D and 2D barcode scanners to support material or equipment identification.

Additionally, you can use a 2D barcode scanner to operate the system itself during processing by scanning the 2D barcodes provided on the buttons in the work area of the Execution Window.

When you operate the system with barcode scans, which is a typical scenario in Dispense operations, the system indicates that it has received an input from a scanner by changing the blue background gradient of the active phase to orange.



Figure 20: Scan in progress

Touch Screen

The system is optimized for running on a touch-screen monitor. The buttons in the work area and the control bar are sized to be large enough for accurate tapping even when you wear protective gear such as gloves.

In addition to the **Page Up** and **Page Down** buttons for paging through the content of the work area, you can also pan the work area manually.

Virtual Keyboard

A virtual keyboard allows an operator to type characters in input boxes when there is no physical keyboard connected to a work station with a touch-screen monitor.

It pops up automatically on top of the Execution Window when the system requires keyboard input.

- 1. Tap the keys to type your input in the edit box of the keyboard.
- 2. Tap the **OK** button to transfer your input to the edit box of the Execution Window.

Or

Tap the **Cancel** button to close the virtual keyboard and return to the Execution Window.

Basic Operations

The following sections describe basic and recurring operations and functions in production execution with PharmaSuite.

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 47).

START PHARMASUITE

To start PharmaSuite double-tap 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 the application or view either the help system or the documentation.

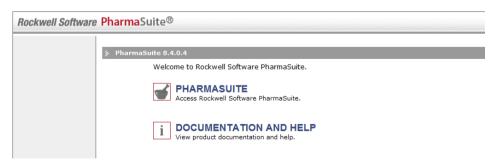


Figure 21: PharmaSuite webstart page

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 (*). Tap 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 22: Login form

After you have successfully logged in, the system displays the PharmaSuite welcome page. From here you can start the Production Execution, 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.

Rockwell Software PharmaSuite Detamana Gerr | Station_D-WC001 | 08:52 PM CET Welcome to PharmaSuite® **Production Execution Production Management** Data Manager Recipe and Workflow Designer **Production Responses** Change Password Register at Station Documentation and Help Rockwell Software

Figure 23: 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, can be connected directly to a work station, an application and, within the application, to one or more processes or workflows. If configured in this way, the system will skip the welcome page and start the application automatically with the specified process or workflow after you have successfully logged in.

LOGOUT

In PharmaSuite for Production Execution, open the Cockpit, navigate to the **System** section, and select the **Exit** function to quit PharmaSuite and return to the webstart page.

On the PharmaSuite welcome page, the **Logout** button is located in the top right corner. Tap 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.

PASSWORD CHANGE

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

- 1. Tap 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 (*).

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

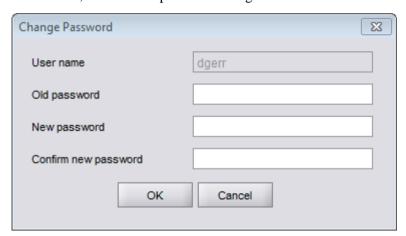


Figure 24: Change password

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, or workflows and can process incoming messages from an external Quality Management System.

PharmaSuite runs a heartbeat check on the servers to monitor their availability. To see if there are any issues, switch to the Cockpit and open the **About PharmaSuite** dialog (page 22), 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.

If one of the servers does not respond to the heartbeat check while execution is active, the system displays a message to indicate this potential issue.

Executing a Unit Procedure

To execute the unit procedure of recipes or EBR workflows, proceed as follows:

- In the Cockpit (page 22), select the order step of the recipe or the EBR workflow you wish to execute from the list of **Startable** processes and workflows.
 From the list of **Running** unit procedures, select the operation you wish to process.
 - The system starts the first phase of the operation and switches to the Execution Window.
- 2. In the Execution Window (page 34), complete and confirm the phases as indicated and available on the screen.
- 3. To monitor your progress and view the history or executed steps, open the Navigator (page 30).
- 4. Use the Exception Window (page 36) to record and view exceptions that may occur or have occurred during processing.
- 5. Continue to execute the phases until you have confirmed the last phase available. The system returns to the Cockpit from where you can
 - start another operation in the current unit procedure, if available.
 - start another unit procedure.
 - resume an operation that was terminated in a previous session.
 - switch to another unit procedure that is running in the background.
- 6. When you have finished your work, select the **Exit** (page 47) function from the **System** section of the Cockpit.

TIP

Please note that you can only exit the system and thus log off from your current station when you have either completed your running processes or detached all running operations (page 73).

Handling Exceptions

Exceptions need to be recorded to document irregular circumstances that have occurred during processing. They are an important element of the processing report (batch, device, workflow). An exception can, on the one hand, be triggered by the phase that is being processed, for example when an operator enters values that exceed the limits defined for the phase. On the other hand, it can be the operator who decides that an exception needs to be recorded, either during processing, through the Exception (page 6) button on the control bar, or after a phase has been completed and confirmed, from the information column of the Navigator (page 30).

Once you have recorded an in-process exception for a phase and return to the Execution Window (page 34), the phase is displayed with a red upper left corner as exception marker. The same red exception marker also shows in the Navigator (page 30) for each phase for which an exception has been registered.

Exceptions can no longer be edited once they have been recorded. If you need to add further information or wish to indicate that the risk or status of the exception should be changed, for example when you have performed a review, you can add comments to any exception.

TIP

Please note that some exceptions include a mandatory comment, which you need to supply before you add the exception.

Exception identifiers are numbered consecutively per batch/order. Comment identifiers consist of the identifier of the exception to which they refer and a two-digit consecutive number.

Additionally, you can bookmark exceptions you wish to find more easily for a later review, for example if you have started the review and could not complete it, or for any other purpose.

System-triggered Exception

When a phase has restrictions or conditions defined for the values it records, deviations from the permitted values cause the system to respond with an information, error, question, or exception dialog. The dialogs indicate their level of severity by a colored frame (blue for information or question, yellow for exception, red for error) and a corresponding markup icon in the upper left corner. The severity itself depends on the inherent capabilities and requirements of each phase as well as the values and limits defined during phase configuration. To indicate the exact context of a message, the dialog displays context information in its upper right corner, which consists of the timestamp of the message's occurrence and the identifiers of the operation and phase to which it refers.

Error dialogs can only be confirmed with the **OK** button but can also display a **Details** button to access further information on the error, such as internal error messages sent by the database or from an external system. If you wish to retain the information listed in the **Details** dialog, click the **Copy to clipboard** button to copy the information and then paste it into a system-external text editor.

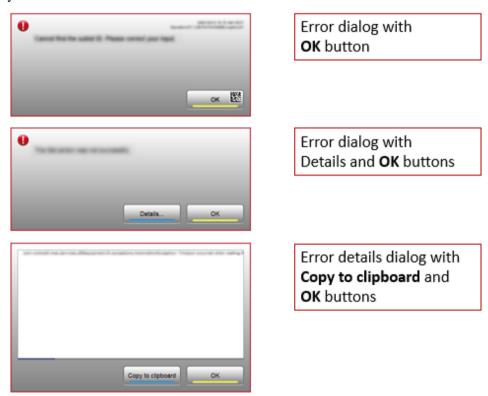


Figure 25: Error and error details dialogs

Information dialogs can only be confirmed with the **OK** button, questions can be answered with **Yes** or **No** and may initiate the recording of an exception. In exception dialogs you always trigger the recording of an exception. If you accidentally triggered the exception, for example due to an input error, you can cancel this specific exception by tapping the **Back** button in the Exception Window. In this case, however,

the system still requires you to sign an **Exception canceled** exception and thus ensures the integrity of all data entered during execution.

Some phases collect several check results to feed them into one dialog. For these cases, the dialogs provide a scrollbar and you can use panning to scroll through the dialog text.

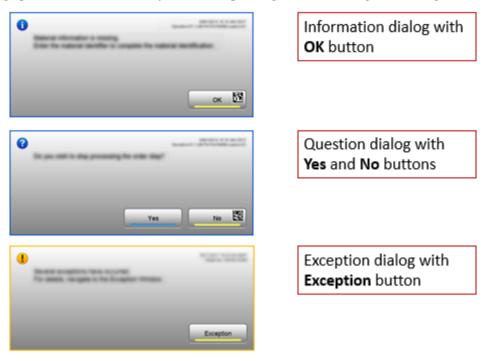


Figure 26: Information, question, and exception dialogs

A system-triggered exception consists of

- a read-only text box that is pre-filled by the system with a description why the current situation represents an exception,
- only if the exception includes a mandatory comment, a text box for entering the comment,
- a read-only option list that is pre-filled by the system with the risk that is attributed to the exception (**None**, **Low**, **Medium**, **High**),
- a read-only option list for the status of the exception (**Open**, **In review**, **To be closed**, **Closed**) that is initially preset with **Open**, and
- a signature panel with **Performed by** and **Password** text boxes to document who recorded the exception.

TIP

Which of the options for **Risk** and **Status** are available depends on user rights and system configuration.

User-triggered Exception

Whenever you encounter an irregular situation during processing you can record it as exception. The system usually provides a free-text description box where you can specify the circumstances of the exception. In addition to free-text exceptions, some situations provide specific exception options to cover recurring irregular events. A typical example of a situation-specific exception could be that a faulty scanner forces you to perform a manual identification instead of the expected barcode scanning.

User-triggered exceptions are recorded from a variety of situations and contexts:

- When you record an exception during phase processing, it is linked to the active phase from which you have triggered the Exception Window. You can access it later for adding comments or bookmarks either from the phase-specific Exception Window (page 36) or after phase completion from the Detail Information Window (page 38).
- When you record an exception for an operation, for instance to document that the operation was detached from its processing device, it affects all active phases of the operation and is thus inserted for each phase. After processing has resumed on another device, you can access the exception later for adding comments or bookmarks either on the phase-specific Exception Window (page 36) of each phase or, after phase completion by way of the Navigator (page 30), on their Detail Information Windows (page 38).
- When you record an exception for a unit procedure, for instance to document that the unit procedure was paused, it is linked to the unit procedure. You can access it later by way of the unit procedure's Actions dialog (page 61), for adding comments or bookmarks on the overview Exception Window (page 37).

A user-triggered free-text exception consists of

- a text box where you can describe the exception circumstances,
- an option list from which you can select the risk to the process you attribute to the exception (**High**, **Medium**, **Low**, **None**),
- a read-only option list for the status of the exception (**Open**, **In review**, **To be closed**, **Closed**) that is initially preset with **Open**, and
- a signature panel with **Performed by** and **Password** text boxes to document who recorded the exception.

TIP

Which of the options for **Risk** and **Status** are available depends on user rights and system configuration.

A user-triggered situation-specific exception consists of

- a read-only text box that is pre-filled by the system with a description why the current situation represents an exception,
- only if the exception includes a mandatory comment, a text box for entering the comment,
- a read-only option list that is pre-filled by the system with the risk that is attributed to the exception (**None**, **Low**, **Medium**, **High**),
- a read-only option list for the status of the exception (**Open**, **In review**, **To be closed**, **Closed**) that is initially preset with **Open**, and
- a signature panel with **Performed by** and **Password** text boxes to document who recorded the exception

TIP

Which of the options for **Risk** and **Status** are available depends on user rights and system configuration.

RECORDING AN EXCEPTION

Exception recording differs depending on the circumstances that cause the exception, whether it is operator or system-triggered, free-text or phase-specific.

To record a user-triggered free-text exception, proceed as follows:

- Tap the Exception button in the control bar or the respective button in the
 information column of the Navigator to access the exception recording panel. At
 the top, the form displays a list of all exceptions and comments that have so far
 been recorded for the phase. If you are about to enter the first exception, the list
 will be empty.
 - At the bottom it shows the exception recording panel where you can enter the exception.
- 2. In the **Exception** box, type a description of the circumstances that cause you to record the exception.

TIP

Please note that the text box for the description allows a maximum of 2048 characters, which corresponds to approximately ten lines of text.

- 3. Select the suitable risk level you attribute to the exception.
- 4. Type your login name and password in the respective boxes. Please note that your password is masked by asterisks (*).
 - 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.

TIP

Please note that for security reasons the system deletes the typed password if you tap any active box or button other than the **Add exception** button so you need to retype it.

5. Tap the **Add** button to record the exception.

The system will now display it in the list of recorded exceptions.

Once you have recorded the exception, any situation-specific exception options the phase may provide are disabled (grayed out). You can, however, add a comment to the exception or bookmark it.

TIP

Please note that you can only record one exception at a time. To record another exception you have to start the exception recording process from scratch by accessing the Exception Window again.

6. Tap the **Back** button to return to the form from which you have accessed the Exception Window.

You can record user-triggered, situation-specific exceptions for phases, operations, or unit procedures. Proceed as follows:

- 1. Access the Exception Window to record the situation-specific exception.
 - For a phase:

Tap the **Exception** button in the control bar or the respective button in the information column of the Navigator to access the exception recording panel. At the top, you will see one or more pre-defined exception options that cover expected exception cases of the specific phase. Below the pre-defined exception options, the form displays a list of all exceptions and comments that have so far been recorded for the phase. If you are about to enter the first exception, the list will be empty.

Select the suitable exception option, fill in any information that may be required, and tap the **Confirm** button.

The system displays a pre-defined description of the exception situation and its risk level in read-only mode.

TIP

In case none of the pre-defined exception options fit your exception situation, the system also provides the exception recording panel where you can enter a free-text exception (page 54).

For an operation:

Performing an action on an operation that in the current context represents an exception situation, such as detaching the operation, automatically opens the Exception Window, showing only the exception recording panel. The system displays a pre-defined description of the exception situation and its risk level in read-only mode.

For a unit procedure:

Performing an action on a unit procedure that in the current context represents an exception situation, such as aborting and reactivating the unit procedure, automatically opens the Exception Window, showing only the exception recording panel. The system displays a pre-defined description of the exception situation and its risk level in read-only mode.

TIP

Please note that some exceptions include a mandatory comment, which you need to supply before you add the exception.

2. Type your login name and password in the respective boxes. Please note that your password is masked by asterisks (*).

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.

TIP

Please note that for security reasons the system deletes the typed password if you tap any active box or button other than the **Add exception** button so you need to retype it.

3. Tap the **Add** button to record the exception.

The system will now display it in the list of recorded exceptions.

Once you have recorded the exception, the exception options are disabled (grayed out). You can, however, add a comment to the exception or bookmark it.

TIP

Please note that you can only record one exception at a time. To record another exception you have to start the exception recording process from scratch by accessing the Exception Window again.

4. Tap the **Back** button to return to the form from which you have accessed the Exception Window.

To record a system-triggered exception, proceed as follows:

1. Tap the **Exception** button on a warning or exception dialog to open the Exception Window. At the top, the form displays a list of all exceptions and comments that have so far been recorded for the phase. If you are about to enter the first exception, the list will be empty.

At the bottom it shows the exception recording panel where you can enter the exception.

The system displays a pre-defined description of the exception situation and its risk level in read-only mode.

TIP

Please note that some exceptions include a mandatory comment, which you need to supply before you add the exception.

The Exception Window only displays the system-triggered exception you are about to record. If the phase provides phase-specific, user-triggered exceptions (page 55), you cannot access them at this point. However, the list of recorded exceptions shows all exceptions that have been registered so far, regardless of their origin.

2. Type your login name and password in the respective boxes. Please note that your password is masked by asterisks (*).

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.

TIP

Please note that for security reasons the system deletes the typed password if you tap any active box or button other than the **Add exception** button so you need to retype it.

- Tap the **Add** button to record the exception.
 The system will now display it in the list of recorded exceptions.
- 4. Tap the **Back** button to return to the form from which you have accessed the Exception Window.

RECORDING A COMMENT

To record a comment, proceed as follows:

- 1. Tap the **Exception** button in the control bar or the respective button in the information column of the Navigator to access the exception recording panel. At the bottom, it shows the panel where you can enter the comment.
- 2. In the list of recorded exceptions, tap the exception to which you wish to add a comment.
- 3. In the **Comment** box, type a description of the circumstances that cause you to add the comment.
- 4. To change the risk level (**None**, **Low**, **Medium**, **High**) or the status (**Open**, **In review**, **To be closed**) of the exception to which the comment refers, select the new risk level or status. The new value will be propagated to the exception once you have added the comment.

TIP

An exception can only be closed from the Exception Dashboard of PharmaSuite for Production Responses after it has been reviewed.

5. Type your login name and password in the respective boxes. Please note that your password is masked by asterisks (*).

- Tap the **Add** button to record the comment.
 The system will now display it in the list of recorded exceptions.
- 7. Tap the **Back** button to return to the form from which you have accessed the Exception Window.

BOOKMARKING AN EXCEPTION

To bookmark an exception, proceed as follows:

- 1. Tap the **Exception** button in the control bar or the respective button in the information column of the Navigator to access the exception recording panel. At the bottom it shows the panel where you can bookmark the exception.
- 2. In the list of recorded exceptions, tap the exception you wish to bookmark.
- Tap the **Bookmark** button to bookmark the exception.
 The system will now display the marker it in the list of recorded exceptions.

TIP

Tapping the **Bookmark** button for a bookmarked exception will remove the marker.

4. Tap the **Back** button to return to the form from which you have accessed the Exception Window.

Aborting and Repairing Phases

To resolve processing issues that can result from a faulty or inconsistent process parameter definition during recipe or workflow creation, the system provides functions to abort or abort and repair a phase.

When a user aborts a phase the system terminates its execution and moves on to the next phase in the process. An aborted phase does not record data or provide phase outputs, which means that all subsequent phases that reference an output of the aborted phase will be impacted.

When a user aborts and repairs a phase, the system enters a specific repair mode in which it displays the phase's process parameters and allows the user to change them with suitable editors. Expressions, however, cannot be changed and there is no Expression editor available. This means that it is not possible to change an equipment object reference specified with an equipment requirement parameter. Apart from this restriction, however, the system provides the same editors that are used for defining recipes or workflows in the Process Parameter Panel of Recipe and Workflow Designer.

For further information, please refer to "Editors" in Vol. 1 "Introduction and Basics" of "PharmaSuite User Manual Recipe and Workflow Designer".

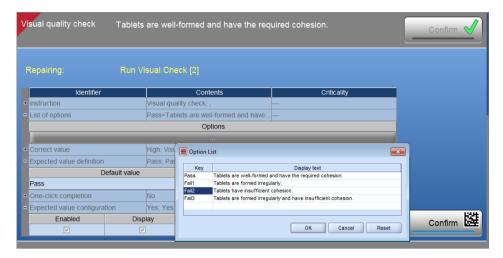


Figure 27: Phase repair mode with Option List editor

TIPS

Please note that the repair mode may not be available for all phases, the system can be configured to exclude specific phases from being repairable.

The repair mode is only available for phases for which no exceptions other than those related to aborting and repairing have been recorded yet.

To abort a phase, proceed as follows:

- 1. In the right column of the Navigator (page 30), tap the **Abort** button. The system displays a confirmation dialog.
- Tap Yes to confirm the dialog.
 The system displays the Exception Window (page 36).
- 3. Sign and add the **Phase execution aborted** exception.
- 4. In the Control Bar (page 6), tap the **Back** button to return to the Execution Window, where the aborted phase is shown as completed with the exception marker in the top left corner.

To abort and repair a phase, proceed as follows:

- 1. In the right column of the Navigator (page 30), tap the **Repair** button. The system displays a confirmation dialog.
- Tap Yes to confirm the dialog.
 The system displays the Exception Window (page 36).
- 3. Sign and add the **Phase repair mode started** exception.

4. In the Control Bar (page 6), tap the **Back** button to return to the Execution Window, where the phase is shown as aborted with the exception marker in the top left corner.

The system displays the phase in the repair mode with yellow phase text. It shows the identifier of the phase in the top row and below that, the list of the phase's process parameters. In the list, each process parameter is displayed as a nested table, with the common parameter attributes as main table and each parameter's specific attributes in a collapsible sub-table.

To edit the values of the parameter attributes, proceed as follows:

- 1. Tap the table cell you wish to edit. The system displays a text cursor or a button to access a suitable editor for the required value type.
- 2. Enter the value of the parameter attribute.
- 3. Tap in another cell or the ENTER key to conclude the edit action.

When you have made all required changes, tap the **Confirm** button. The system displays the Exception Window (page 36).

- 5. Sign and add the **Phase parameters repaired** exception.
- 6. In the Control Bar (page 6), tap the **Back** button to return to the Execution Window where the phase is shown as active with the exception marker in the top left corner. It is ready for processing with the changed values.

Accessing Cockpit Actions

From the Cockpit, you can access additional actions that may be available to items listed as **Running**, such as the actions required for managing event-triggered operations and their runs.

To access the additional actions of a running item, proceed as follows:

- Open the Cockpit where the template or operation is displayed in the list of Running processes.
- 2. Tap its **Actions** button (page 10).

The system displays the respective **Actions** dialog that holds a tappable button for each action available.

Depending on the context from which you call the **Actions** dialog, some of the actions may be disabled.

3. Tap the action you wish to perform.

The system closes the dialog and performs the action.

To close the dialog and return to the Cockpit without performing an action, tap the **Close** button.

ACTIONS OF UNIT PROCEDURES

The Actions dialog of a unit procedure holds the following actions:

Pause

Only for running unit procedures, pauses the unit procedure (page 65), thus preventing trigger phases from generating triggers.

Resume

Only for paused unit procedures, resumes a unit procedure, which returns to operating and informs all affected phases of this fact.

Exceptions

Opens the overview Exception Window (page 37) to display all exceptions and comments that have so far been recorded for the unit procedure.

Abort and reactivate

Terminates processing of the unit procedure and makes it available for restart (page 72).

Append

Opens the Selection Window for **Appendable Workflows** to filter and select a workflow (page 68) that needs to be appended to the unit procedure.

TIPS

Please note that you can append workflows only to unit procedures of batch or device processing, but not to unit procedures of workflows. On the **Actions** dialog of a workflow's unit procedure, the **Append** button is hence disabled. Workflows that are based on a confidential master workflow to which you do not have the required access rights are not listed and are thus not available for selecting and appending.

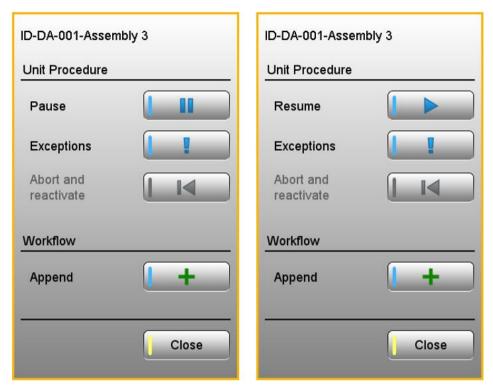


Figure 28: Actions dialogs of a running/paused unit procedure



Figure 29: Actions dialog of a unit procedure available for abort and reactivate

ACTIONS OF EVENT-TRIGGERED OPERATIONS

During processing, an event-triggered operation only exists as non-executable template until an external trigger or an operator action creates an executable run of the template. Once a run has been created, an operator can start it like any other operation to process its phases. When the operator confirms the last phase of the run, the template remains available for creating further runs. It is also possible to create additional runs of the template while there are already startable runs or runs that are being processed. As long as a template is displayed during processing and thus available for creating new runs, an operator cannot start succeeding operations for processing. For this reason, the system provides a function to remove the template, so that the operator can continue with processing.

Event-triggered operations are especially suited for processes that need to be performed repeatedly at definable intervals, such as in-process controls (IPC). They show in the Cockpit either as templates or as runs.

Their Actions dialog holds the following actions:

- New run
 - Available for both templates and runs. Starts a new run of the operation.
- Cancel run
 - Only available, if the run has not been started yet. Cancels the run of the operation.
- Cancel all runs
 - Only available if there is more than one run available. Cancels all runs of the operation that have not been started yet.
- Remove template
 - Only available for templates.
 - Removes the template from the list of running processes, thus ending the cycle of the event-triggered operation.



Figure 30: Actions dialog of an event-triggered operation

Pausing Unit Procedures

Some unit procedures allow an operator to pause their execution. When the operator sets a unit procedure to paused, the system informs all currently active phases of this fact. Phases that run without user interaction, such as trigger phases, react to this information by holding their triggering activities. This prevents the system from stacking runs of event-triggered operations while the execution itself is paused.

To pause a unit procedure, proceed as follows:

- 1. Open the Cockpit where the unit procedure is displayed in the list of **Running** processes.
- 2. Tap the **Actions** button of the unit procedure.

 The system displays the Actions dialog of the unit procedure (page 61).

3. Tap the **Pause unit procedure** button (page 12).

If defined so in the recipe, the system opens the Exception Window to record the pausing as exceptional situation.

If not, the system immediately marks the unit procedure as paused by displaying the **Paused unit procedure** icon (page 15) to the left of its unit procedure button and by showing a corresponding marker tab (page 9) in the notification bar.

- If pausing the unit procedure is not critical to the process and is thus permitted without restrictions, the system immediately marks the unit procedure as paused by displaying the **Paused unit procedure** icon (page 15) to the left of its unit procedure button and by showing a corresponding marker tab (page 9) in the notification bar.
- If pausing the unit procedure represents an exception situation, the Exception Window opens and displays a corresponding exception, which you need to sign with an electronic signature.

 The exception description is pre-defined and read-only, but you can add a comment if you need to provide additional information. You can also access it later by way of the unit procedure's Actions dialog (page 61), for adding comments or bookmarks on the overview Exception Window (page 37).

 Tap the **Back** button to return to the Cockpit.

To resume a paused unit procedure, proceed as follows:

- 1. Tap the **Actions** button of the paused unit procedure you wish to resume. The system displays the Actions dialog of the unit procedure (page 61).
- 2. Tap the **Resume unit procedure** button.

 The system removes the marker icon and the marker tab. The unit procedure resumes its execution, including the generation of triggers.
- 3. Tap the **Back** button to return to the Cockpit.

TIP

Please note that pausing a unit procedure does not interfere with the escalation scenario defined for existing runs of an event-triggered operation. An existing run still passes through all stages of its escalation scenario, even if its unit procedure is paused.

Appending Workflows to Orders

Some workflows are executed within the context of an order, such as specific cleaning or preparation procedures. For this reason they need to be included in the order's batch report. By appending a workflow to those unit procedures of an order to which their execution applies, you establish the connection and thus include the processing details of the workflow in the order's batch report.

TIPS

Please note that only those workflows whose master workflow is marked as **Production-relevant** and **Appendable during processing** are available for being appended to unit procedures of batch or device processing.

The system can be configured to request an electronic signature when an operator appends a workflow to a unit procedure.

Workflows that are based on a confidential master workflow to which you do not have the required access rights are not listed and are thus not available for selecting and appending.

When appending workflows to unit procedures, PharmaSuite for Production Execution supports several scenarios:

- At workflow start, the workflow can be appended to the only unit procedure that is currently running at the work center.

 The system displays a corresponding question dialog. After you have selected whether or not you wish to append the workflow to the unit procedure, the appended or unappended workflow is available for processing in the list of **Running** processes of the Cockpit.
- At workflow start, the workflow can be appended to one of several unit procedures that are currently running at the work center.
 - The system displays a corresponding question dialog.
 Tap Yes, to open the Selection Window for Appendable Unit Procedures that lists all unit procedures that are currently running at your work center.
 - To reduce the number of listed unit procedures, use the **Filter** box to type the characters you are looking for. The filter becomes effective with the second character you type.
 - By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.
 - 3. Tap to select the unit procedure to which you wish to append the workflow.

4. Tap the **Append** button to append the workflow to the selected unit procedure.

The system returns to the Cockpit where the appended workflow is available for processing.

Tap the **Back** button of the Control Bar to return to the Cockpit and process the workflow without having appended it to the unit procedure.

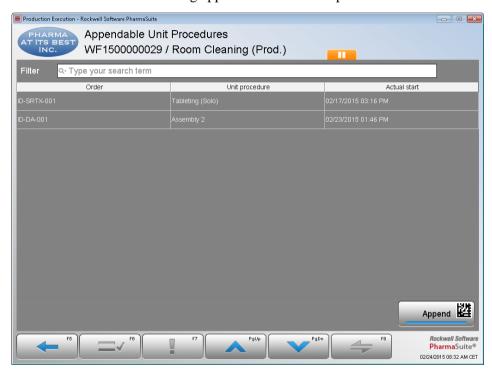


Figure 31: Appendable Unit Procedures

- During unit procedure processing, a workflow for appending can be selected from the list of workflows that are running or have been completed at any work center.
 - 1. Tap the **Actions** button of the unit procedure to which you wish to append a workflow.

The system displays the Actions dialog of the unit procedure (page 61).

TIP

Please note that you can append workflows only to unit procedures of batch or device processing, but not to unit procedures of workflows. On the **Actions** dialog of a workflow's unit procedure, the **Append** button is hence disabled.

2. Tap the **Append** button (page 11). The system opens the Selection Window for **Appendable Workflows** that displays a filtered list of workflows available for appending. In the leftmost column of the list, a checkbox indicates for each workflow if it is already appended to the unit procedure.

TIP

Please note that with this action you can only append workflows, but not unappend workflows that have been appended before. Modifications of this kind can only be done in PharmaSuite for Production Management.

- 3. You can use the filter tools to restrict the number of listed workflows:
 - In the **Filter** box, type the characters you are looking for. The filter becomes effective with the second character you type.

 By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.
 - From the **Started** option list, select how long ago the workflow may have been started.
 - The default option is **Last 8 hours**.
 - From the **Status** option list, select the status the workflow you wish to append needs to have (**Canceled**, **Finished**, **In process**, **Production-reviewed**).

The default option is **Finished**.

workflows of your current work center.

- Use the **Running at current work center** button (page 10) to toggle between listing only the workflows that were or are running at your work center or at all work centers.

 By default, the button is toggled on and thus the list contains only the
- 4. Tap to select the workflow you wish to append to the unit procedure.
- 5. Tap the **Append** button to append the selected workflow to the unit procedure.

The system returns to the Cockpit.

Tap the **Back** button of the Control Bar to return to the Cockpit without having appended a workflow to the unit procedure.

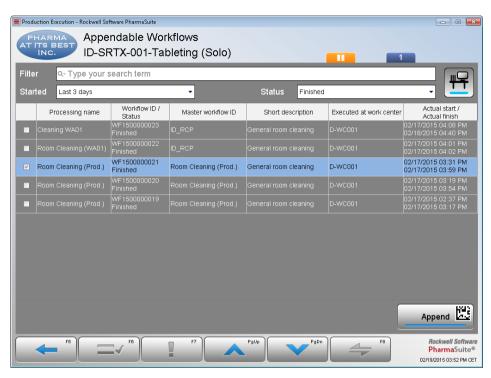


Figure 32: Appendable Workflows

Handling Escalations

Event-triggered operations (page 64) can enforce their timely execution by implementing a four-level escalation scenario, with the following stages:

1. Run due

When a run becomes due, the system displays its tappable operation button (page 12), which also indicates the next stage of the escalation progress and when it will occur. Additionally, the center-left (blue) tab of the notification bar (page 3) reflects this stage.

Run due reminder

After a run has been due for a certain amount of time, the system alerts its operator to this fact by displaying the **Run due reminder** icon (page 13) to the left of its tappable operation button (page 12), which also indicates the next stage of the escalation progress and when it will occur. Additionally, the center-right (orange) tab of the notification bar (page 3) reflects this stage.

3. Run overdue

When a run has been due for too long and needs to be processed immediately, the system displays the **Run overdue** icon (page 13) to the left of its tappable operation button (page 11), which also indicates the next stage of the escalation progress and when it will occur. Additionally, the rightmost (red) tab of the notification bar (page 3) reflects this stage.

4. Run expired

After a run has been in the overdue stage for some time, it eventually expires and disappears from the list of **Startable** operations.

Detaching Unit Procedures

The system allows an operator to detach a running unit procedure from its work center if

- the unit procedure is not paused and
- none of its operations are running.

Detaching a unit procedure puts it on hold until an operator selects it again for processing at another work center to which it is consequently attached. The operator resumes processing where it was left off, by starting the unit procedure, which continues at the next available operation. As putting a running unit procedure on hold can represent a critical situation that may compromise the quality of the materials that are being processed, a detach action may need to be recorded as exception or may even not be available at all.

To detach a unit procedure, proceed as follows:

- 1. Open the Cockpit where the unit procedure is displayed in the list of **Running** processes.
- 2. Tap its **Detach** button (page 11).
 - If detaching the unit procedure is not critical to the process and is thus permitted without restrictions, the button disappears, thus indicating that the system has detached the unit procedure from both the device and the station where the device is registered.
 - If detaching the unit procedure represents an exception situation, the Exception Window opens and displays a corresponding exception, which you need to sign with an electronic signature.
 The exception description is pre-defined and read-only, but you can add a comment if you need to provide additional information. You can also access it later by way of the unit procedure's Actions dialog (page 61), for adding comments or bookmarks on the overview Exception Window (page 37).
 Tap the Back button to return to the Cockpit.
- 3. Now the unit procedure is available again for selection and processing from another work center.

When a unit procedure with detach exception is resumed again, the system automatically adds a comment to that effect to the exception.

Aborting and Reactivating Unit Procedures

The system allows an operator to abort and reactivate a running unit procedure. A new run of the unit procedure is then available for restart from the Selection Window for processing all of its operations and phases.

This action is intended for rework situations when an entire unit procedure needs to be repeated. Any equipment identified and bound to the unit procedure during its aborted run is unbound and available for identification again. As aborting and reactivating a running unit procedure can represent a critical situation that may compromise the quality of the materials that are being processed, the action may need to be recorded as exception or may even not be available at all.

To abort and reactivate a unit procedure, proceed as follows:

- Open the Cockpit where the unit procedure is displayed in the list of **Running** processes.
- Tap the Actions button of the unit procedure.
 The system displays the Actions dialog of the unit procedure (page 61).

- 3. Tap the **Abort and reactivate** button (page 10).
 - If aborting and reactivating the unit procedure is not critical to the process and is thus permitted without restrictions, the button disappears, thus indicating that the system has detached the unit procedure from the work center.
 - If aborting and reactivating the unit procedure represents an exception situation, the Exception Window opens and displays a corresponding exception, which you need to sign with an electronic signature.

 The exception description is pre-defined and read-only, but you can add a comment if you need to provide additional information.

 Tap the **Back** button to return to the Cockpit.

Now a new run of the unit procedure is available again for selection and processing.

When a reactivated unit procedure is selected for processing, the system displays its instance count along with its identifier.

Detaching Operations

The system allows an operator to detach a running operation from its device and station, thus putting it on hold until it is selected for processing from another device and thereby attached to it and resumed. As putting a running operation on hold can represent a critical situation that may compromise the quality of the materials that are being processed, a detach action can for some phases lead to a user-triggered exception (page 53) or may even not be available from PharmaSuite for Production Execution at all.

To detach an operation, proceed as follows:

- Open the Cockpit where the operation is displayed in the list of **Running** processes.
- 2. Tap its **Detach** button (page 11).
 - If detaching the operation is not critical to the process and is thus permitted without restrictions, the button disappears, thus indicating that the system has detached the operation from both the device and the station where the device is registered.

If detaching the operation represents an exception situation, the Exception Window opens and displays a corresponding exception, which you need to sign with an electronic signature.

The exception description is pre-defined and read-only, but you can add a comment if you need to provide additional information. The exception is added to each phase of the operation that is active when the operation is detached. You can access it later for adding comments or bookmarks either on the phase-specific Exception Window (page 36) of each phase or, after phase completion by way of the Navigator (page 30), on their Detail Information Windows (page 38).

Tap the **Back** button to return to the Cockpit.

3. Now the operation is available again for selection and processing from another device or station.

TIP

Please note that the system provides an emergency detach function for non-detachable operations from the **Unlock Objects** task in PharmaSuite for Production Management.

When an operation with detach exception is resumed again, the system automatically adds a comment to that effect to the respective exceptions of each affected phase.

Signature Requests

When performing safety-sensitive or GxP-relevant functions the system may request you to enter an electronic signature, for example during material identification. 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.

To perform an electronic signature, type your login name and password and tap the **OK** button. Comments can be optional or mandatory and may consist of up to 255 characters.

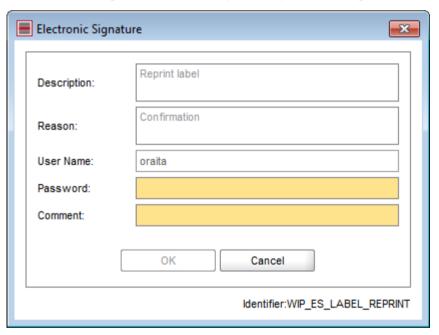


Figure 33: Single electronic signature

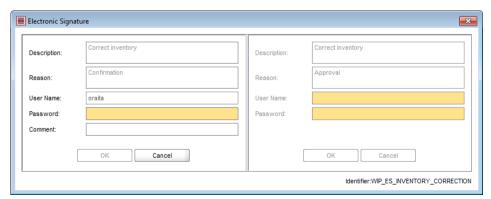


Figure 34: Double electronic signature to support witness role

INPUT BOX COLORS IN SIGNATURE DIALOGS

Input boxes can have different background colors that assist you with filling in the data of a form.

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 \mathbf{OK} button. A blinking cursor indicates that it has the focus and you can start to type your entry.

EBR processes can include mandatory, phase-specific phase completion signatures, which are displayed below the respective phases. You can only confirm such a phase when you have performed the signature.

After phase completion, the system displays the full name and login name of the person who performed the signature, along with the timestamp when it was performed. Phase completion signatures can be defined as single or as double signatures.

TIP

Please note that for security reasons the system deletes an already entered password unless you tap the confirm button within a reasonable amount of time after having entered the password.



Figure 35: Single phase completion signature - active



Figure 36: Single phase completion signature - completed

In addition to the phase completion signature for a specific phase, the system also provides a sequential phase completion signature to be performed as confirmation after one or more phases with completion signatures have been completed. The system requires a sequential phase completion signature to be performed by another user than its preceding plain phase completion signatures. Sequential signatures can only be defined as single signatures.



Figure 37: Sequential phase completion signature - active



Figure 38: Sequential phase completion signature - completed

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 single-reference selectors (page 77), for assigning one object to a base object.

If the number of objects that are available for selection is very large, the reference selectors include search and sort options (page 77) 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, simply clear the box.

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



Figure 39: Single-reference box with selector button

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

Specify search and sort criteria to reduce the number of objects from which you
have to select your assignment object later. 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.

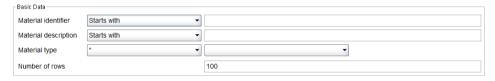


Figure 40: Search criteria

2. Choose the criterion you want to sort the list by. 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 41: Sorting criteria

3. Tap the **Search** button to start the search. The system lists all objects that match your search criteria in the **Results** list.

Tap the **Clear** button to clear all search criteria except the restriction to 100 rows.

4. In the **Results** list, tap the row with the object you wish to assign to your base object.

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

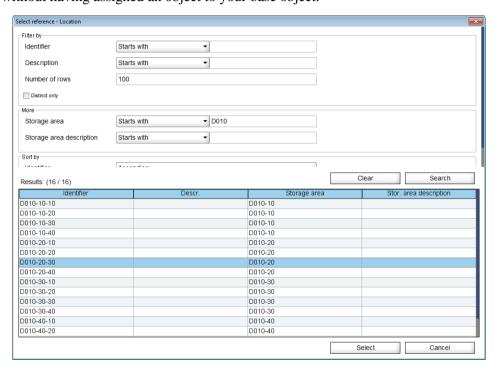


Figure 42: Single-reference selector

Help Access

The help system is accessible from the Cockpit via the **Help** button located in the **System** section of the **Startable** processes and workflows.

For keyboard use, press the F1 key to open the help window.

In pre-defined workflows the **Help** button is also located in the upper right corner of the work area. The help system is context-sensitive on step level, which means that the active workflow step triggers the content of the help window.

The help window is displayed in a modal dialog box on top of the application.

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
 - tap 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, tap 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.

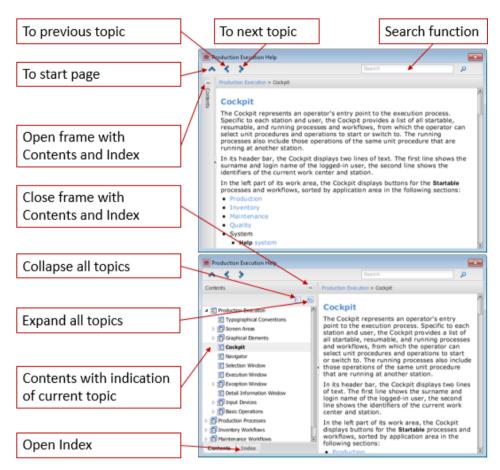


Figure 43: Help window navigation

Production Processes

The **Production** processes of PharmaSuite for Production Execution are accessible from the Cockpit (page 22).

TIP

Please note that the following list holds standard processes and workflows that are available unless configured to be hidden for this work center. Additional workflows for this application area type that can be created in the Workflow Designer application of PharmaSuite are added at the bottom of the list.

- Batch Processing (page 83)
- Device Processing (page 85)
- Material Processing (page 87)
- Workflow Processing (page 89)

Batch Processing

Batch Processing provides all functions and actions you need for executing the processes of a batch order.

It begins with the **Start Batch Processing** Selection Window where the system lists all order steps that are startable at your current work center.

TIP

Which order steps are displayed depends on the access rights of the logged-in user. Order steps of orders that are based on confidential master recipes to which the user does not have the required access rights remain invisible.

To restrict the number of listed order steps, you can filter for any string of characters in any column of the table of order steps. The filter becomes effective with the second character you type.

By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

By default, the order steps are sorted alphabetically by their identifiers. It is, however, possible to reverse the sort order or sort by another column.

- To adjust the sorting, proceed as follows:
 - 1. Tap any column header to sort the table by this column in ascending order. The system indicates the sort order with a triangle pointing up.
 - 2. Re-tab the same column header to switch the sort order to descending. The system indicates the sort order with a triangle pointing down.
 - CTRL-tap a yet unmarked column header to add this column as further sort level in ascending sort order, indicated by the triangle pointing up and a count number indicating the sort level.
 - 4. Re-CTRL-tap the same column header to switch the sort order to descending without changing its sort level.

When you have located the order step you wish to process, proceed as follows:

To start the order step, double-tap it.
 The system returns you to the Cockpit (page 22) where it lists all executable operations as Running.

TIPS

Please note that batch processes allow you to start processing by scanning the barcode of the batch that is going to be produced. A batch's barcode is typically located on the cover page of its order's batch report.

Scanning a batch barcode takes you directly to the Execution Window for phase processing if the order step's first operation is auto-startable.

- 2. Tap the operation you wish to execute.
 - The system displays the phases of the operation in their order of processing:
 - Previously executed phases are in read-only mode, with a checkmark on their
 Confirm buttons to indicate that they have been completed.
 - Currently active phases are accessible for processing.
 Some phases may require an electronic signature before they can be completed.
 - Future phases that will only become active after one or all currently active phases have been executed are in read-only mode.

 In a strictly sequential operation, the system displays all phases. If the operation includes one or more decision points, however, it will only show the future phases up to the next decision point.

Exceptions (page 36) that occur during processing can be recorded at all times.

- 3. Execute an accessible phase and tap its **Confirm** button.
- 4. Move on to the next accessible phase until you have all phases processed and confirmed.

When you have tapped the **Confirm** button of the last phase, the system returns you to the Cockpit for selecting a new operation or workflow.

Device Processing

Device Processing provides all functions and actions you need for executing the processes of a device order.

It begins with the **Start Device Processing** Selection Window where the system lists all order steps that are startable at your current work center.

TIP

Which order steps are displayed depends on the access rights of the logged-in user. Order steps of orders that are based on confidential master recipes to which the user does not have the required access rights remain invisible.

To restrict the number of listed order steps, you can filter for any string of characters in any column of the table of order steps. The filter becomes effective with the second character you type.

By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

By default, the order steps are sorted alphabetically by their identifiers. It is, however, possible to reverse the sort order or sort by another column.

- To adjust the sorting, proceed as follows:
 - 1. Tap any column header to sort the table by this column in ascending order. The system indicates the sort order with a triangle pointing up.
 - 2. Re-tab the same column header to switch the sort order to descending. The system indicates the sort order with a triangle pointing down.
 - CTRL-tap a yet unmarked column header to add this column as further sort level in ascending sort order, indicated by the triangle pointing up and a count number indicating the sort level.
 - 4. Re-CTRL-tap the same column header to switch the sort order to descending without changing its sort level.

When you have located the order step you wish to process, proceed as follows:

To start the order step, double-tap it.
 The system returns you to the Cockpit (page 22) where it lists all executable operations as Running.

TIPS

Please note that device processes allow you to start processing by scanning the barcode of the serial number of the device that is going to be produced. A device's serial number barcode is typically located on the cover page of its DHR report.

Scanning a serial number barcode takes you directly to the Execution Window for phase processing if the order step's first operation is auto-startable.

2. Tap the operation you wish to execute.

The system displays the phases of the operation in their order of processing:

- Previously executed phases are in read-only mode, with a checkmark on their Confirm buttons to indicate that they have been completed.
- Currently active phases are accessible for processing.
 Some phases may require an electronic signature before they can be completed.
- Future phases that will only become active after one or all currently active phases have been executed are in read-only mode.

 In a strictly sequential operation, the system displays all phases. If the operation includes one or more decision points, however, it will only show the future phases up to the next decision point.

Exceptions (page 36) that occur during processing can be recorded at all times.

- 3. Execute an accessible phase and tap its **Confirm** button.
- 4. Move on to the next accessible phase until you have all phases processed and confirmed.

When you have tapped the **Confirm** button of the last phase, the system returns you to the Cockpit for selecting a new operation or workflow.

Material Processing

Material Processing provides all functions and actions you need for processing the materials of several order steps together, thus building a weighing campaign. It is only available for Dispense work centers.

TIP

The materials of which order steps are displayed depends on the access rights of the logged-in user. Order steps of orders that are based on confidential master recipes to which the user does not have the required access rights remain invisible.

To restrict the number of listed materials, you can filter for any string of characters in any column of the table of order steps. The filter becomes effective with the second character you type.

By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

Material processing begins with the **Select Materials** Selection Window where the system lists all materials of all order steps that are available for processing at your current work center.

By default, the materials are sorted alphabetically by their identifiers. It is, however, possible to reverse the sort order or sort by another column.

- To adjust the sorting, proceed as follows:
 - 1. Tap any column header to sort the table by this column in ascending order. The system indicates the sort order with a triangle pointing up.
 - 2. Re-tab the same column header to switch the sort order to descending. The system indicates the sort order with a triangle pointing down.
 - CTRL-tap a yet unmarked column header to add this column as further sort level in ascending sort order, indicated by the triangle pointing up and a count number indicating the sort level.
 - 4. Re-CTRL-tap the same column header to switch the sort order to descending without changing its sort level.

To support you with optimizing the sequence of materials you will process at your work center, the **Cleaning** column in the list displays the room cleaning demand, which the system determines for each material input item on the basis of the predecessor material processed at the work center. When you have located the material input items you wish to process together, proceed as follows:

1. Tap the checkbox in the leftmost column of a material to select it.

TIP

When order steps are available for processing at several work centers, some of the listed materials may already have been selected for processing at other work centers and are thus unavailable to you. These materials display their **Status** column with the identifier of the work center where they are being processed instead of their status.

2. When you have selected all materials you wish to process, tap the **Process** button. The system returns you to the Cockpit where it lists all operations that contain the materials you have selected from the **Running** processes.

TIP

Please note that you can use the **Back** button from the Cockpit to return to the **Select Materials** window and change your selection. The operations listed as **Running** will change accordingly.

- 3. Tap the operation you wish to execute.

 The system displays the phases of the operation in their order of processing:
 - Previously executed phases are in read-only mode, with a checkmark on their Confirm buttons to indicate that they have been completed.
 - Currently active phases are accessible for processing.
 Some phases may require an electronic signature before they can be completed.
 - Future phases that will only become active after one or all currently active phases have been executed are in read-only mode.

 In a strictly sequential operation, the system displays all phases. If the operation includes one or more decision points, however, it will only show the future phases up to the next decision point.

Exceptions (page 36) that occur during processing can be recorded at all times.

- 4. Execute an accessible phase and tap its **Confirm** button.
- 5. Move on to the next accessible phase until you have all phases processed and confirmed.

When you have tapped the **Confirm** button of the last phase, the system returns you to the Cockpit for selecting a new operation or workflow.

Workflow Processing

Workflow Processing provides all functions and actions you need for executing the processes of a workflow.

It begins with the **Start Workflow Processing** Selection Window where the system lists all workflow steps that are startable at your current work center.

TIP

Which workflow steps are displayed depends on the access rights of the logged-in user. Workflow steps of workflows that are based on confidential master workflows to which the user does not have the required access rights remain invisible.

To restrict the number of listed order steps, you can filter for any string of characters in any column of the table of order steps. The filter becomes effective with the second character you type.

By default, the search applies to all table columns, is not case-sensitive, and the search string may occur anywhere within the content of a cell. Click the magnifying glass icon to set the search criteria to search only in specific columns, be case-sensitive, allow the use of wildcards or regular expressions, or match from start or exactly.

By default, the workflow steps are sorted alphabetically by their identifiers. It is, however, possible to reverse the sort order or sort by another column.

- To adjust the sorting, proceed as follows:
 - 1. Tap any column header to sort the table by this column in ascending order. The system indicates the sort order with a triangle pointing up.
 - 2. Re-tab the same column header to switch the sort order to descending. The system indicates the sort order with a triangle pointing down.
 - 3. CTRL-tap a yet unmarked column header to add this column as further sort level in ascending sort order, indicated by the triangle pointing up and a count number indicating the sort level.
 - 4. Re-CTRL-tap the same column header to switch the sort order to descending without changing its sort level.

When you have located the workflow step you wish to process, proceed as follows:

- To start the workflow step, double-tap it.
 The system returns you to the Cockpit (page 22) where it lists all executable operations as Running.
- Tap the operation you wish to execute.
 The system displays the phases of the operation in their order of processing:
 - Previously executed phases are in read-only mode, with a checkmark on their
 Confirm buttons to indicate that they have been completed.
 - Currently active phases are accessible for processing.
 Some phases may require an electronic signature before they can be completed.
 - Future phases that will only become active after one or all currently active phases have been executed are in read-only mode.

 In a strictly sequential operation, the system displays all phases. If the operation includes one or more decision points, however, it will only show the future phases up to the next decision point.

Exceptions (page 36) that occur during processing can be recorded at all times.

- 3. Execute an accessible phase and tap its **Confirm** button.
- 4. Move on to the next accessible phase until you have all phases processed and confirmed.

When you have tapped the **Confirm** button of the last phase, the system returns you to the Cockpit for selecting a new operation or workflow.

Inventory Workflows

The pre-defined **Inventory** workflows of PharmaSuite for Production Execution are accessible from the Cockpit (page 22).

TIP

Please note that the following list holds pre-defined workflows that are available unless configured to be hidden for this work center. Additional one-click startable workflows for this type of application area, which you can create in the Workflow Designer application of PharmaSuite, are added at the bottom of the list.

- Material Receipt (page 91)
- Material Issue (page 99)
- Relocation (page 103)
- Sublot Split (page 106)
- Inventory Correction (page 110)

Material Receipt

The **Material Receipt** workflow provides all functions and actions you need for introducing materials into an inventory.

What Is Material Receipt?

Material receipt is the pre-defined workflow for introducing materials into small storage areas in a shop-floor environment, such as buffer or line warehouses. It can be used for adding materials to existing batches or to generate new batches. At the end of a successful material receipt the fully identified and labeled material sublots are available for further processing on the shop floor. The material receives a batch identifier (page 94), the target storage location (page 96) is specified, its sublots (page 98) are registered individually, and one or more labels (page 99) are printed for sublot identification.

Material Receipt: Filter Materials

In order to receive your material into the system you have to pick it from the list of available materials. Since the number of materials in the system can be very large, it is often useful to apply a filter and thus reduce the number of materials listed.

1. 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.

2. 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.



Tap the **Next** button to complete the workflow step and move to the

Material Receipt: Select a Material

The system lists the materials according to your search and sorting criteria.

- 1. Select the material you are about to receive.
- 2. Decide whether you need to create a new batch for your material or add the material to an existing batch.



Tap the **New batch** button to create a new batch.



Tap the **Select batch** button to select a batch from the list of available batches.

Select or Create a Batch

When materials are received into the system they are assigned to a batch. Typically, a new batch is created to receive a new material. In some cases, however, you will receive material that belongs to an already existing batch. Then you can select the batch and add the received material to it.

MATERIAL RECEIPT: CREATE A NEW BATCH

You have decided to create a new batch. To define the batch data, proceed as follows:

- 1. Type the potency if it is relevant for the material.
- 2. Select retest and expiry dates, if necessary.
- 3. Tap the **Create batch** button to have the system generate an identifier for the new batch.



Tap the **Next** button to complete the workflow step and move to the

TIP

If you need to use a pre-defined batch identifier instead of a system-generated one, type it in the **Batch identifier** box.

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.

MATERIAL RECEIPT: FILTER BATCHES

You have decided to add your material to an existing batch. Since the number of batches in the system can be very large, it is often useful to apply a filter and thus reduce the number of batches listed.

1. 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.

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.



Tap the **Next** button to complete the workflow step and move to the

MATERIAL RECEIPT: SELECT A BATCH

The system lists the batches according to your search and sorting criteria.

1. Select the batch to which you want to add the material.



next.

2.

Tap the **Next** button to complete the workflow step and move to the

Material Receipt: Filter Storage Locations

In order to define the target storage location for your material you have to pick it from the list of available storage locations. Since the number of storage locations in the system can be very large, it is often useful to apply a filter and thus reduce the number of storage locations listed.

1. 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.

2. 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.



Tap the **Next** button to complete the workflow step and move to the

Material Receipt: Select a Storage Location

The system lists the storage locations according to your search and sorting criteria.

1. Select the storage location where the material will be stored.



Tap the **Next** button to complete the workflow step and move to the

Material Receipt: Create Sublots

You have selected a target storage location for your material. Now you need to specify the how many sublots you will store there and how much material they contain.

- 1. Type the number of sublots and the quantity per sublot with its unit of measure in the respective boxes. Type a comment, if necessary.
- 2. Tap the **Create sublots** button.
- 3. If you need to add further sublots, repeat the first two steps.



Tap the **Next** button to complete the workflow step and move to the

Material Receipt: Print Labels

You have specified all sublots you are about to store. The last step in the Material Receipt process is to print the labels for your sublots.

- 1. Type the number of labels you need to print per sublot in the respective box.
- 2. If you print more than one label per sublot, select whether you want to collate them or not.

TIP

Please note that the default system only allows one label per sublot. For this reason, the **Number of labels per sublot box** is preset with 1 and read-only. The **Printing Sequence** options are consequently disabled.

- 3. Tap the **Print labels** button.
- 4. If there was a problem during label printing that renders the printed labels unusable, tap the **Reprint labels** button to print again.



Tap the **OK** button to complete the step and finish the workflow.

Material Issue

The **Material Issue** workflow provides all functions and actions you need for removing materials from an inventory.

What Is Material Issue?

Material issue is the pre-defined workflow for removing materials, in the form of individual sublots, from the inventory. This can happen either because the material is required for processing and thus issued for a specific cost center or because the material is not fit for utilization and needs to be destroyed. The sublots are selected (page 101) individually and are issued (page 102) after the reason for their issue has been indicated.

Material Issue: Filter Sublots

In order to issue material you have to pick the sublots concerned from the list of available sublots. Since the number of sublots in the system can be very large, it is often useful to apply a filter and thus reduce the number of sublots listed.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will move on to the **Select Sublots** step.

1. 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.

2. 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.



Tap the Next button to complete the workflow step and move to the

next.

Material Issue: Select Sublots

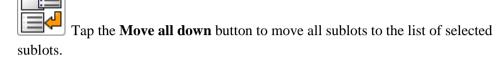
The system lists the sublots according to your search and sorting criteria.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will display the sublot in the list of selected sublots.

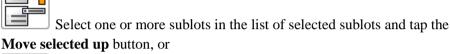
Select one or more sublots from the filtered list.

2. Tap the **Move selected down** button to move the sublots to the list of selected sublots.

If you have set your filter criteria to only list the sublots you want to issue:

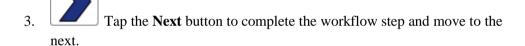


To undo your selections and move sublots back up to filtered list of sublots:





Tap the **Move all up** button to move the sublots all back up.



Material Issue: Issue Sublots

You have selected the sublots you wish to issue.

- 1. Select the reason for the issue, **Destruction** or **Cost center**. If the issue is cost center-related, type the **Cost center identifier**.
- 2. Tap the **Issue sublots** button.



Tap the **OK** button to complete the step and finish the workflow.

Relocation

The **Relocation** workflow provides all functions and actions you need for moving materials within an inventory.

What Is Relocation?

Relocation is the pre-defined workflow for moving material, in the form of sublots, from one storage location to another. The sublots are selected (page 105) individually and then relocated (page 106) together.

Relocation: Filter Sublots

In order to relocate material you have to pick the sublots from the list of available sublots. Since the number of sublots in the system can be very large, it is often useful to apply a filter and thus reduce the number of sublots listed.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will move on to the **Select Sublots** step.

1. 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.

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.





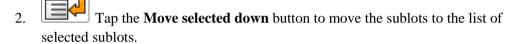
Tap the **Next** button to complete the workflow step and move to the

Relocation: Select Sublots

The system lists the sublots according to your search and sorting criteria.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will display the sublot in the list of selected sublots.

1. Select one or more sublots from the filtered list.



If you have set your filter criteria to only list the sublots you want to issue:



Tap the **Move all down** button to move all sublots to the list of selected

To undo your selections and move sublots back up to filtered list of sublots:



Select one or more sublots in the list of selected sublots and tap the **Move selected up** button, or



Tap the **Move all up** button to move the sublots all back up.



Tap the **Next** button to complete the workflow step and move to the next.

Relocation: Relocate Sublots

You have selected the sublots you wish to relocate.

1. In the **Target location** box, type the identifier of the storage location to which you wish to move the sublots. If you do not know the identifier, tap the ... button to open the reference selector (page 77) for storage locations that will support you with this workflow.

TIP

Please note that you can only relocate sublots that have the same source storage location.

If you need to relocate sublots from different source storage locations, please run the workflow for each of the source storage locations.

2. Tap the **Relocate sublots** button to book the sublots to their new storage location.



3. Tap the **OK** button to complete the step and finish the workflow.

Sublot Split

The **Sublot Split** workflow provides all functions and actions you need for splitting sublots into even or uneven parts.

What Is Sublot Split?

Sublots occasionally need to be split, for example to make material available simultaneously at two different locations. Splits can be even or uneven. An even split means that the base sublot is split in two or more new sublots with identical quantities, thus using up the base sublot. In an uneven split one or more sublots are split off from the base sublot, which itself also continues to hold material. The sublot to be split is selected (page 108), the number and quantities of the new sublots are specified (page 109) and registered, and one or more labels are printed (page 110) for sublot identification.

Sublot Split: Filter Sublots

In order to split a sublot you have to pick the sublot concerned from the list of available sublots. Since the number of sublots in the system can be very large, it is often useful to apply a filter and thus reduce the number of sublots listed.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will move on to the **Select Sublot** step.

1. 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.

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.



Tap the **Next** button to complete the workflow step and move to the

Sublot Split: Select a Sublot

The system lists the sublots according to your search and sorting criteria.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. The system will show the scanned sublot as selected in the list.

- 1. Select the sublot you are about to split.
- 2. Decide whether you need to perform an even or an uneven split.



Tap the **Even split** button to split the sublot into even parts.



Tap the **Uneven split** button to split some parts off the base sublot.

Perform an Even or Uneven Split

When you split a sublot you need to decide how many new sublots you will require and how much material the new sublots are to contain. On the basis of these requirements you can either perform an even or an uneven split on your selected sublot.

SUBLOT SPLIT: PERFORM AN EVEN SPLIT

You have decided to split your base sublot into even parts. Proceed as follows:

- 1. In the **Count** box, type the number of new sublots into which you wish to split your base sublot.
- 2. Tap the **Split** button. The system now lists the new sublots.

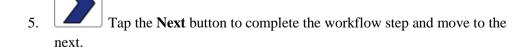


3. Tap the **Next** button to complete the workflow step and move to the next.

SUBLOT SPLIT: PERFORM AN UNEVEN SPLIT

You have decided to split your base sublot into uneven parts. Proceed as follows:

- 1. In the **Count** box, type the number of new sublots you wish to split from your base sublot.
- 2. In the **Split quantity** box, type the quantity and unit of measure you wish each of the new sublots to have.
- 3. Tap the **Split** button. The system lists the new sublots. The **Quantity** box now displays the quantity of material that remains in your base sublot.
- 4. If you need to create further sublot splits, repeat the first three steps.



Sublot Split: Print Labels

You have created one or more new sublots. The last step in the **Sublot Split** process is to print the labels for your sublots.

- 1. Type the number of labels you need to print per sublot in the respective box.
- 2. If you print more than one label per sublot, select whether you want to collate them or not.

TIP

Please note that the default system only allows one label per sublot. For this reason, the **Number of labels per sublot box** is preset with 1 and read-only. The **Printing Sequence** options are consequently disabled.

- 3. Tap the **Print labels** button.
- 4. If there was a problem during label printing that renders the printed labels unusable, tap the **Reprint labels** button to print again.



5. Tap the **OK** button to complete the step and finish the workflow.

Inventory Correction

The **Inventory Correction** workflow provides all functions and actions you need for correcting the quantities of inventoried sublots.

What Is Inventory Correction?

An inventory correction becomes necessary if, during an inventory check for example, it turns out that a sublot contains more or less material than registered in the system. In these cases the sublot quantity can be changed to the actual quantity of material contained in the sublot. The sublot whose quantity needs to be correct is selected (page 112) and its actual quantity (page 113) is registered.

Inventory Correction: Filter Sublots

In order to correct the quantity of a sublot you have to pick the sublot from the list of available sublots. Since the number of sublots in the system can be very large, it is often useful to apply a filter and thus reduce the number of sublots listed.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will move on to the **Change Quantity** step.

1. 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.

2. 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.



Tap the **Next** button to complete the workflow step and move to the next.

Inventory Correction: Select a Sublot

The system lists the sublots according to your search and sorting criteria.

The **Scanner ready** icon in the navigation bar indicates that your scanner is ready for use. After you have successfully scanned a label the system will move on to the **Change Quantity** step.

1. Select the sublot you are about to correct.



Tap the **Next** button to complete the workflow step and move to the next.

INVENTORY CORRECTION: CHANGE THE QUANTITY

You have selected a sublot to correct its quantity. Proceed as follows:

- 1. In the **Quantity** box, type the actual quantity and unit of measure of the sublot.
- 2. Tap the **Set quantity** button. The system now registers the new quantity for the sublot.



Tap the **OK** button to complete the step and finish the workflow.

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