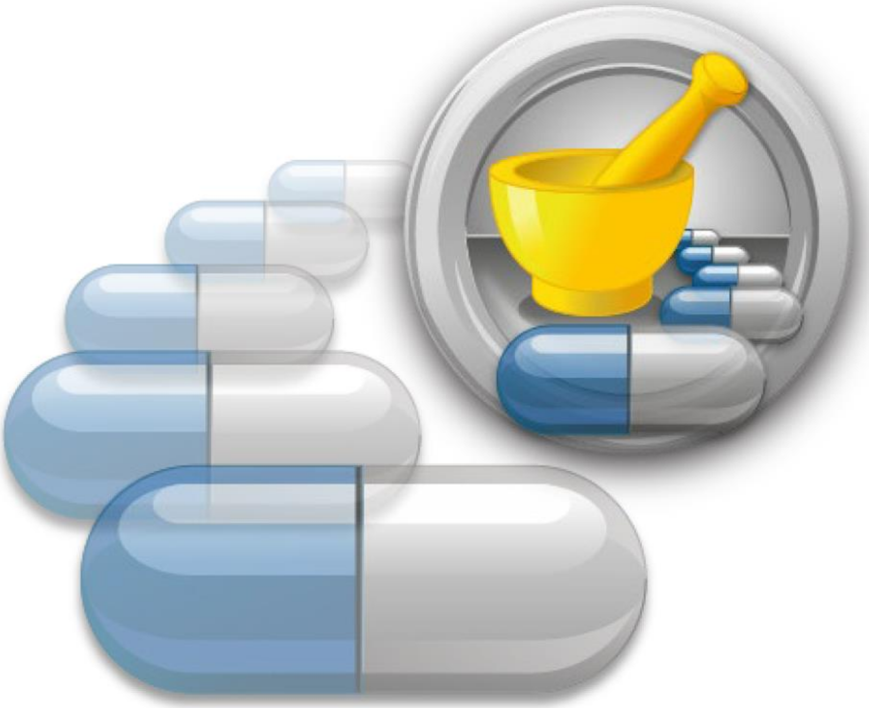
FT PharmaSuite®



PRODUCTION RESPONSES

RELEASE 10.02.00

USER MANUAL

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Rockwell Automation

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Production Responses

PharmaSuite for Production Responses is a system framework designed to support production managers or QC personnel in monitoring and processing production responses that are collected in the course of the execution process.

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

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

Typographical Conventions

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

Bold typeface	Designates user interface texts, such as ■ window and dialog titles ■ menu functions ■ panel, tab, and button names ■ box labels ■ object properties and their values (e.g., status).
Italic typeface	Designates technical background information, such as ■ path, folder, and file names ■ methods ■ classes.
CAPITALS	Designate keyboard-related information, such as ■ key names ■ keyboard shortcuts.
`Monospaced typeface`	Designates code examples.

Screen Layout

The basic screen layout of the PharmaSuite for Production Responses holds the following components:

- Menus and toolbars (page 16) for accessing the functions of PharmaSuite for Production Responses.
- Filter Selection panel (page 24) for selecting the filter to be applied to the pool of orders and workflows available in the system.
- Filter Definition panel (page 25) for editing or refining the selection criteria of the applied filter.
- Overview panel (page 31) for displaying all filtered orders and workflows along with information on the statuses of their unit procedures and their progress.
- Details panel (page 37) for displaying execution details of a selected order or workflow with
  - Object Information panel (page 38) for a graphical representation of an order or workflow and its related objects.
  - Exception Explorer (page 40) for a structural representation of an order or workflow in the form of a tree view.
  - Exception List (page 43) for displaying all exceptions and comments recorded for an order or workflow and its related objects.
  - Toolbar (page 45) for accessing functions specific to the order or workflow.
- Exception recording panel (page 49) for adding exceptions and comments.
- Status bar for displaying general information such as the logged-in user with his full name, the database name, and the local time and time zone information.

Figure 1: Overview panel

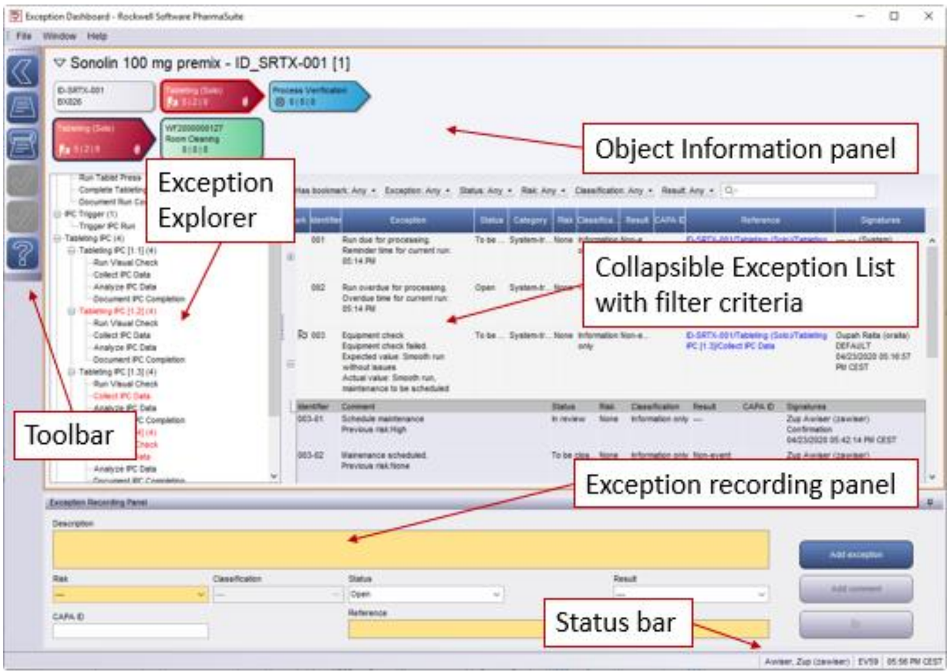


Figure 2: Details panel

Panel Management

When you start PharmaSuite for Production Responses for the first time it opens with the default screen layout, with the dockable main menu bar at the top and, depending on the application, application-specific menus, toolbars, and panels.

You can rearrange the position of all dockable bars and panels if you prefer another layout. You can also always revert back to the default layout (page 5).

To change the position and size of the panels, click a panel header bar and drag the panel to the desired position on the screen. The system will display the new panel size and position with a gray preview frame. Panels can be

- free floating
- docked horizontally or vertically
- nested into another panel, accessible for switching by tab.

> **TIP**
>
> To move a menu bar or a toolbar you have to use their drag handles, which are located at the left margins of horizontal bars and at the top margins of vertical bars.

Each panel header provides a toolbar for further panel resizing and movements:

Toggle floating
Floats or unfloats a panel. An unfloated panel reverts to its original position and size.

Toggle auto-hide
Auto-hides a docked panel. It can be accessed by tab. If you revoke the auto-hide, the panel reverts to its original position and size.

Hide active auto-hide window
Re-hides an active and thus unhidden panel that has its auto-hide option enabled.

To manage your screen layout changes, the system provides the **Window** menu with the following functions:

- **Reset layout**
  Resets the window layout to the system-defined default layout. This function does not affect the saved user layout, which can be restored with the **Load user layout** function.

- **Save user layout**
  Saves the current window layout and overwrites the layout that was last saved by you on this computer.

- **Load user layout**
  Loads the last layout you have saved on this computer with the **Save user layout** function.

Dialogs

PharmaSuite for Production Responses uses dialogs or pop-up windows on top of its basic screen areas to cover a variety of functions:

- Dialogs for editing (page 6) the filter criteria available from the Filter Definition panel
- Context-sensitive Help system (page 13)
- About dialog (page 15) for further information on PharmaSuite and its system environment.

Editors

PharmaSuite for Production Responses provides specific editors to facilitate easy editing of the different types of filter criteria available in the Filter Definition panel.

- For defining text strings as criteria
  - String editor (page 7)
- For selecting one of several options
  - Boolean options editor (page 7)
  - Finite options editor (page 8)
  - Infinite options editor (page 8)
- For defining date and time-related criteria
  - Complex date, time, and duration editor (page 10)
  - Date and time picker (page 11)
  - Duration editor (page 13)

STRING EDITOR

The **String** editor supports you with filtering for any sequence of characters, as contained in identifiers or descriptions, for example.

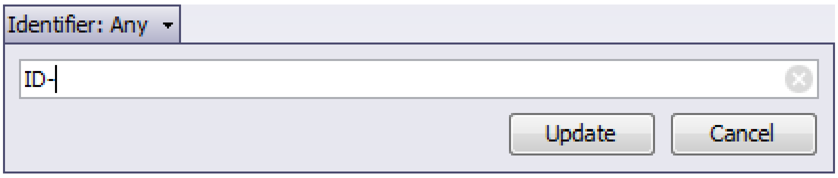


Figure 3: String editor

To define a filter with the **String** editor, proceed as follows:

- In the input box, type the string of characters you wish to filter for.
  - To apply your filter to the objects shown in the Overview panel and close the editor, click anywhere outside of the editor dialog or press the ENTER key.
  - To apply your filter to the objects shown in the Overview panel and keep the editor dialog open, click the **Update** button.
  - To clear the input box, click the **Cancel** icon that appears when you have typed the first character in the box.
  - To close the **String** editor without applying your changes, click the **Cancel** button or press the ESC key.

BOOLEAN OPTIONS EDITOR

The **Boolean Options** editor supports you with filter criteria that represent yes/no questions but includes an option to select all.

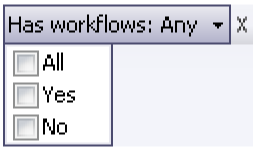


Figure 4: Boolean Options editor

To define a filter with the **Boolean Options** editor, proceed as follows:

- Select the option you wish to filter for. Selecting the **All** option automatically selects both, **Yes** and **No**.
  The system immediately applies the filter to the objects shown in the Overview panel.
  - To close the editor, click anywhere outside of the editor dialog or press the ESC key.
  - To clear the filter, unselect the selected options.

FINITE OPTIONS EDITOR

The **Finite Options** editor supports you with filter criteria that represent a finite number of options, such as a list of statuses.

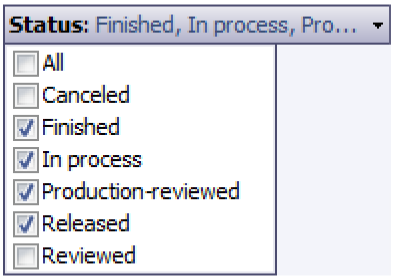


Figure 5: Finite Options editor

To define a filter with the **Finite Options** editor, proceed as follows:

- Select the option or options you wish to filter for. Selecting the **All** option automatically selects all options.
  The system immediately applies the filter to the objects shown in the Overview panel.
  - To close the editor, click anywhere outside of the editor dialog or press the ESC key.
  - To clear the filter, unselect the selected options.

  > **TIP**
  > Please note that to quickly clear the filter when you have several options selected, you can select/unselect the **All** option.

  - To resize the dialog, use the bottom right corner as drag handle.

INFINITE OPTIONS EDITOR

The **Infinite Options** editor supports you with filter criteria that represent a potentially large number of options that can change, such as a list of work centers.

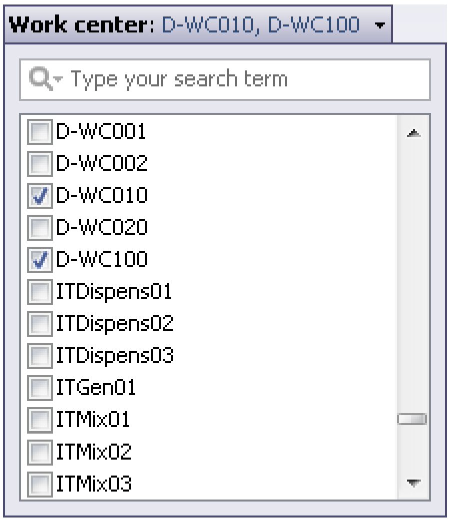


Figure 6: Infinite Options editor

To define a filter with the **Infinite Options** editor, proceed as follows:

- Select the option or options you wish to filter for. Selecting the **All** option automatically selects all options.
  The system immediately applies the filter to the objects shown in the Overview panel.
  - To reduce the number of options listed, use the search tool:
    - In the input box, type the string of characters you wish to filter for.
    - To clear the input box, click the **Cancel** icon that appears when you have typed the first character in the box.
  - To close the editor, click anywhere outside of the editor dialog or press the ESC key.
  - To clear the filter, unselect the selected options.

  > **TIP**
  > Please note that to quickly clear the filter when you have several options selected, you can select/unselect the **All** option.

  - To resize the dialog, use the bottom right corner as drag handle.

Complex Date/Time and Duration Editor

The **Complex Date/Time and Duration** editor supports you with filtering for various types of date and time-related scenarios, such as all orders started during a defined period of time. It covers the following scenarios:

- Between ... and ...
  A time between two definable dates, which also allows an open start or an open end date.
- Within the last ...
  A definable period up to the current date and time. The filter is not updated continuously as the current time progresses but uses the time when the filter was set or last updated as reference date and time.
- More than ... ago
  A period that ended at a definable period before the current date and time. The filter is not updated continuously as the current time progresses but uses the time when the filter was set or last updated as reference date and time.

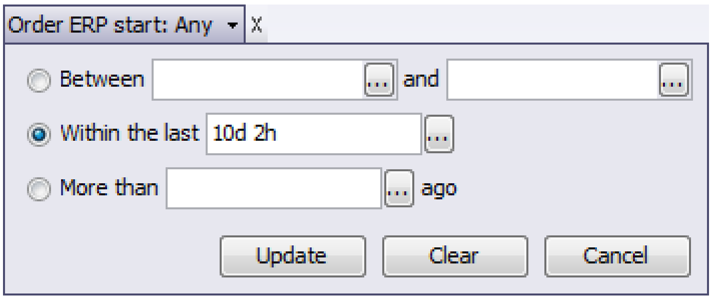


Figure 7: Complex Date/Time and Duration editor

To define a filter with the **Complex Date/Time and Duration** editor, proceed as follows:

1. Select the scenario you wish to filter for.
2. Depending on the selected scenario, you need to enter either a date/time or a duration.
   - Type the date/time or click the **...** button to open the Date/Time Picker editor (page 11).
     When you type only a date without time, the system automatically extends your entry to the start of the given day at 12:00 AM.
   - Type the duration or click the **...** button to open the Duration (page 13) editor.
     When you type a duration, please note the formatting requirements:
     - Make sure to write the duration as consecutive string of characters without blanks, since otherwise, the system will not be able to interpret it correctly.
     - You can leave out any units you do not need for specifying your duration, so instead of **0d6h0min30s0ms** you can write **6h30s**.

- You have to observe the order of the units, which means, for instance, that the system cannot interpret a duration that starts with seconds, followed by minutes and hours.
- The values you specify for the various time units must not exceed the maximum number of each time unit that would move it to the next higher unit. Thus, for hours (**h**) the maximum is 23, for minutes (**min**) and seconds (**s**) it is 59, and for milliseconds (**ms**) it is 999.
This restriction, however, does not apply to the highest unit you specify, which means that the system allows a duration such as **49h30min15s**, whereas typing **48h89min75s** in this context would not be valid.

3. When you have filled in all required date/time or duration criteria, you can proceed as follows:
   - To apply your filter to the objects shown in the Overview panel and close the editor, click anywhere outside of the editor dialog or press the ENTER key.
   - To apply your filter to the objects shown in the Overview panel and keep the editor dialog open, click the **Update** button.
   - To clear the filter, click the **Clear** button.
   The system applies the change to the objects shown in the Overview panel.
   - To close the **Complex Date/Time and Duration** editor without applying your changes, click the **Cancel** button or press the ESC key.

Date/Time Picker Editor

The Date/Time Picker editor supports you with entering a date with or without a time. You can either type the date or time directly in the input box or open the calendar control to pick it. Depending on the data expected by the input box you are about to fill, the calendar either only provides date picking or it holds an additional spin control to pick a time as well. The calendar opens with the date (and time) that is currently displayed in the input box. It highlights the selected date in orange and displays the current date with a red border.
For occurrences that only require a date, the calendar control closes automatically when you have entered the date.
For occurrences that require both a date and a time, the calendar control remains open after you have made an entry to allow you to set all data at once. The editor provides an **OK** button to close it when you have entered both date and time.

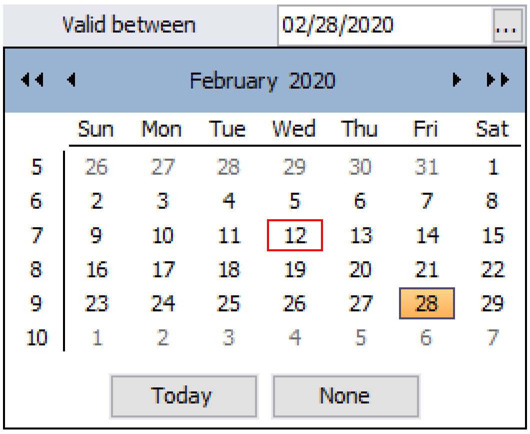


Figure 8: Date/Time Picker editor

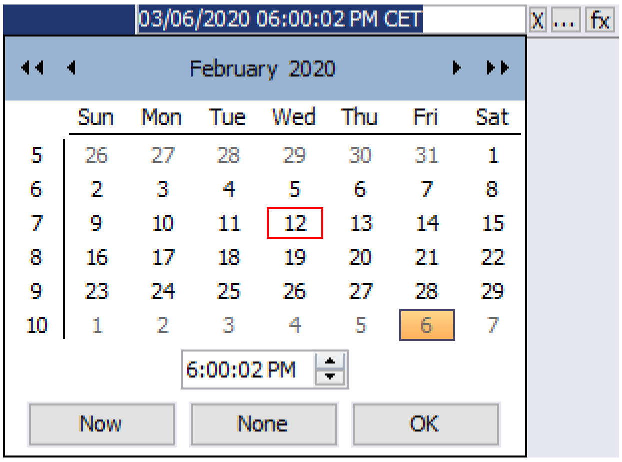


Figure 9: Date/Time Picker editor

- To navigate the calendar to other months or years, use the controls in the calendar header.
  - Months: SINGLE ARROW keys or option list that appears when you click the current month name.
  - Years: DOUBLE ARROW keys or spin control that appears when you click the current year.
- To edit a time, click the position (hours, minutes, seconds) in the time text box you wish to change. Then use the spin control or the UP and DOWN ARROW keys to increase or decrease the number.
- In the Date Picker, to select the current date, click the **Today** button.
- In the Date and Time Picker, to select the current date and time, click the **Now** button.
- To clear the date and or time from the input box, click the **None** button.

- To close the calendar control without changing the date or time, click anywhere in the dialog outside the calendar control, press the ESC key, or click the **OK** button (if present).

Duration Editor

The Duration editor supports you with entering a duration with days as largest and milliseconds as smallest unit.

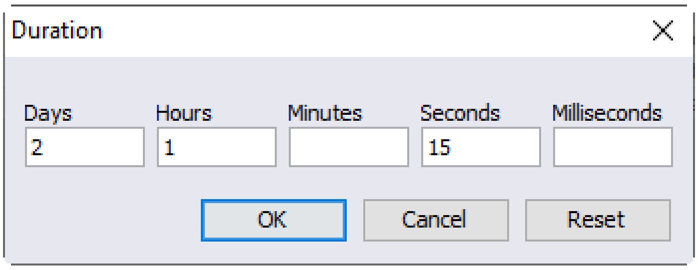


Figure 10: Duration editor

- Fill the text boxes as required. You can leave non-required boxes blank. To save your value and close the Duration editor, click the **OK** button or press the ENTER key.

> **TIP**
> Please note that the system does not allow you to type values for the various time units that exceed the maximum number of each time unit and would move it to the next higher unit. Thus, for hours the maximum is 23, for minutes and seconds it is 59, and for milliseconds it is 999.

- To close the Duration editor without saving your changes, click the **Cancel** button or press the ESC key.
- To reset your duration values to their last saved form, click the **Reset** button.

Help Access

The help system of PharmaSuite for Production Responses is context-sensitive on panel and window level. This means that clicking the help button or pressing the F1 key will open a web browser to display a help window with information relevant to the panel you have currently focused. The help window is non-modal and resizable.

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

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

- To access an overview of all available topics, open the **Contents** tab in the **Contents and Index** frame. The system additionally provides **Expand all** and **Collapse all** buttons to facilitate easier navigation in the contents tree.

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

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

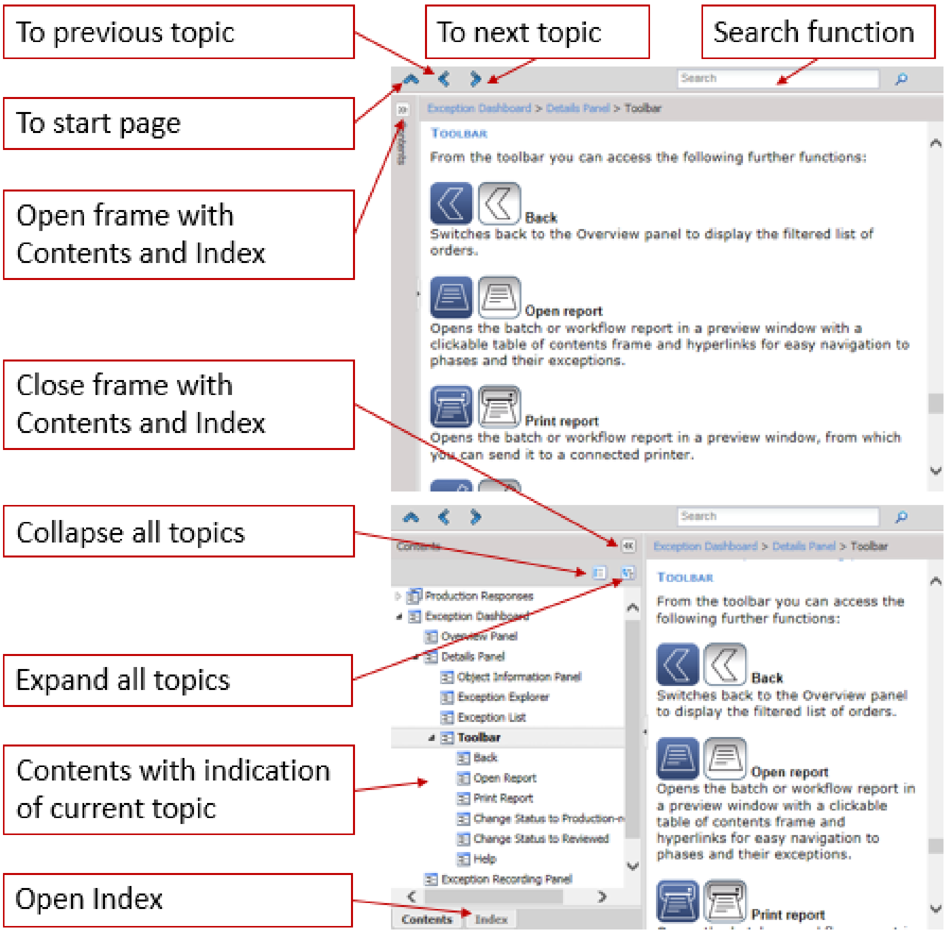


Figure 11: Help window navigation

About PharmaSuite

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

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

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

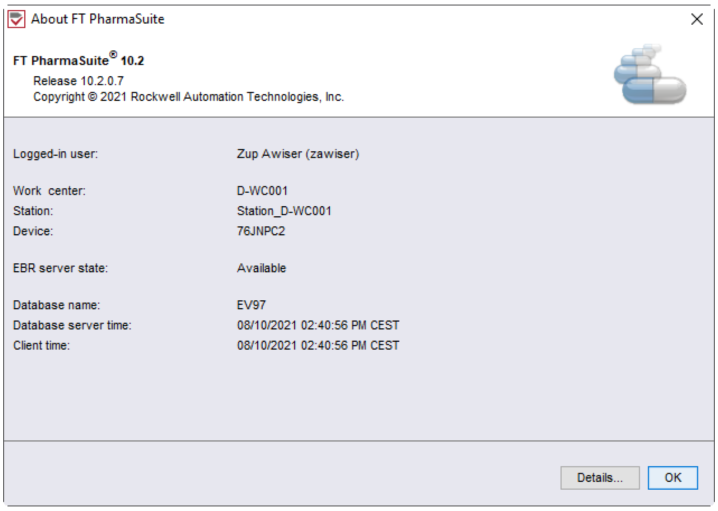


Figure 12: About PharmaSuite

DETAILS

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

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

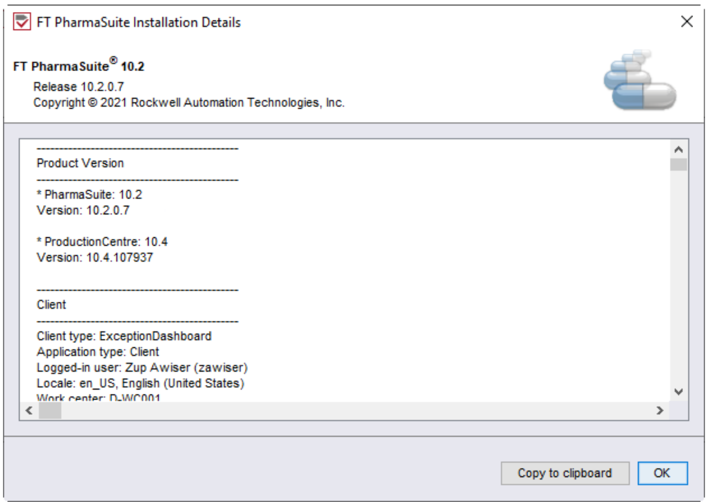


Figure 13: PharmaSuite Installation Details

Menus and Toolbars

You can access all relevant functions either from the main menu bar, from the shortcut menu in the Filter Selection panel, or from the toolbar provided on the Details panel.

Menu Bar

The main menu bar holds framework-relevant functions and provides access to the help system.
The following menus and functions are available:

- File
  - New filter (CTRL+N)
    Creates a new filter, thus first opening the **New Filter** dialog.
  - Exit (ALT+F4)
    Closes the application window.
- Window
  - Reset layout (page 5)
  - Save user layout (page 5)
  - Load user layout (page 6)
- Help
  - PharmaSuite for Production Responses Help (ALT+F1)
    Opens a web browser to display the start page of the help system (page 13).
  - About PharmaSuite
    Opens the **About PharmaSuite** dialog (page 15).

Filter Shortcut Menus

The Filter Selection panel provides two shortcut menus for accessing filter-relevant functions.
The following menus and functions are available:

- Filter creation menu
  accessible by right-clicking the background of the Filter Selection panel.
  - New filter
    Creates a new filter, thus first opening the **New Filter** dialog.
- Filter management menu
  accessible by right-clicking one of the filters listed in the Filter Selection panel.
  - Save <filter identifier>
    Saves all changes made to the filter.
  - Save <filter identifier> as
    Opens the **Save Filter as** dialog to save the filter under a new identifier. If you made changes to the filter, they are saved under the new identifier, while the old filter remains unchanged.
  - Rename <filter identifier>
    Opens the **Rename Filter** dialog where you can type a new identifier.
  - Delete <filter identifier>
    Deletes the filter.
  - Reset <filter identifier>
    Undoes all changes and resets the filter to its last saved form.

Toolbar

The toolbar on the Details panel provides the following functions:

- **Back**
  to the Overview panel
- **Open report**
  batch or workflow report of the currently selected object
- **Print report**
  batch or workflow report of the currently selected object
- **Change status to Production-reviewed**
  of orders or workflows. It is only available for **Finished** orders or workflows.
- **Change status to Reviewed**
  of orders or workflows. It is only available for **Finished** or **Production-reviewed** orders or workflows.

- **Help**
  to open a web browser that displays the help for the Details panel.

Keyboard Operation

Control by keyboard is primarily necessary for navigation purposes.

Framework Navigation Shortcuts

Use the following keys and keyboard shortcuts to navigate the general framework of PharmaSuite for Production Responses:

- ALT+F1
  Opens a web browser to display the start page of the help system (page 13) of PharmaSuite for Production Responses.
- ALT+F4
  Closes the application window.
- CTRL+N
  Creates a new filter, thus first opening the **New Filter** dialog.
- CTRL+S
  Saves all changes made to the filter that is displayed in the Filter Definition panel.
- F1
  Opens a web browser to display the context-sensitive help (page 13) of PharmaSuite for Production Responses.

Screen Area Shortcuts

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

- CTRL+DOWN ARROW
  Expands the whole tree.
- CTRL+UP ARROW
  Collapses the whole tree.
- CTRL+LEFT ARROW
  Collapses the selected tree node or, if the node is collapsed, moves the focus to its next parent object.

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

Basic Operations

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

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 22).

START PHARMASUITE

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

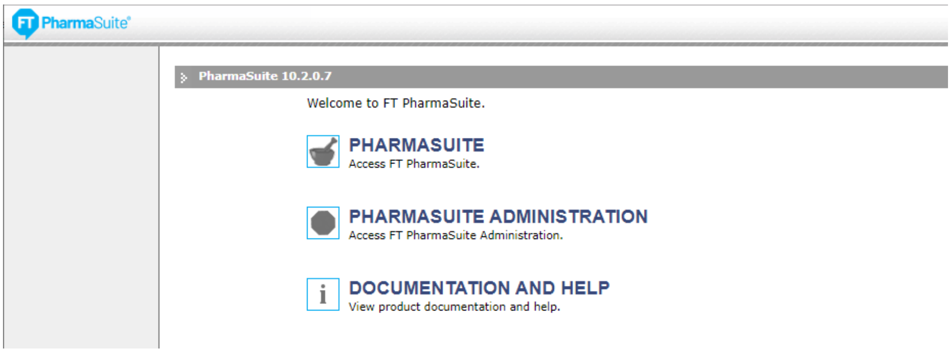


Figure 14: PharmaSuite webstart page

LOGIN

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

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

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

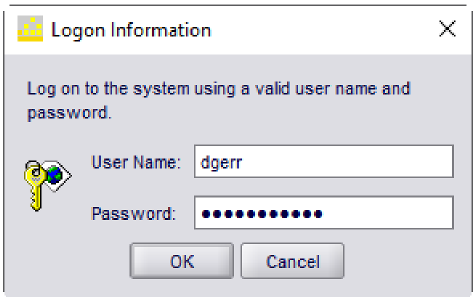


Figure 15: Login form

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

Figure 16: PharmaSuite welcome page

TIP

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

Logout

In PharmaSuite for Production Responses, from the **File** menu, select the **Exit** function or use the ALT+F4 keyboard shortcut to quit PharmaSuite and return to the webstart page.

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

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

Password Change

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

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

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

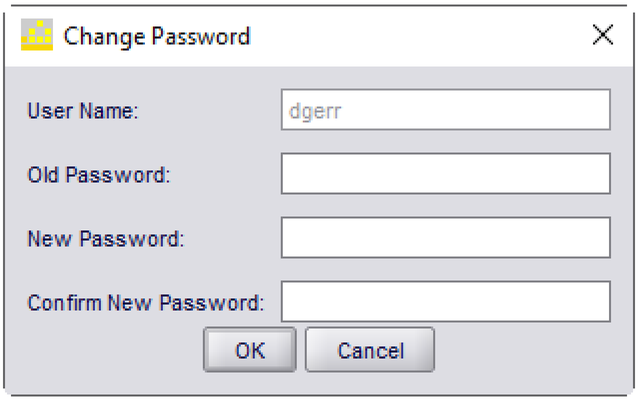


Figure 17: Change password

Required Servers

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

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

Working with Filters

For handling the large quantities of data that result from order and workflow processing, you can define and save filter criteria (page 25) and thus build yourself a set of filters (page 24) that are available to you whenever you work with PharmaSuite for Production Responses.

Filter Selection

The Filter Selection panel lists all filters you have created and saved in your current session or during your previous sessions of PharmaSuite for Production Responses. Filters are sorted alphabetically.
The currently active filter is indicated by a colored background.

TIPS

When you start PharmaSuite for Production Responses for the first time, both the Filter Selection and the Overview panels are empty. Thus, you first need to create and define a filter before you can work with the system.

Please note that filters are user-specific and cannot be shared or made available to other users.

The number of orders and workflows listed as filter result can be further restricted by the access rights of the logged-in user. If a user does not have the necessary rights to access specific master recipes or master workflows, the system does not display the orders or workflows based on the confidential master recipes or master workflows.

To create a new filter, proceed as follows:

1. Right-click the background of the Filter Selection panel or open the **File** menu and select the **New filter** function or use the CTRL+N keyboard shortcut.
   The system opens the **New Filter** dialog.
2. Type an identifier for your new filter and click the **OK** button.
   The system adds the new filter to the list of filters in the Filter Selection panel, selects it, displays its criteria in the Filter Definition panel, and updates the Overview panel accordingly.
   The new filter is now available for further refining.

   TIP
   Please note that the number of displayable objects in the Overview panel is restricted. If the default filter settings return too many objects initially, the Overview panel remains empty, and the system requests you to refine your order-related search criteria first.

Right-click any of the listed filters to open a shortcut menu with the following functions:

- Save <filter identifier>
  Saves all changes made to the filter.
  Only available if the filter has unsaved changes, which is indicated by an asterisk marker (*) to the right of its identifier.
- Save <filter identifier> as
  Opens the **Save Filter as** dialog to save the filter under a new identifier. If you made changes to the filter, they are saved under the new identifier, while the old filter remains unchanged.
- Rename <filter identifier>
  Opens the **Rename Filter** dialog where you can type a new identifier.
- Delete <filter identifier>
  Deletes the filter.
  After deleting a filter there is no filter selected in the Filter Selection panel and the Filter Definition and Overview panels are blank.
- Reset <filter identifier>
  Undoes all changes and resets the filter to its last saved form.
  Only available if the filter has unsaved changes, which is indicated by an asterisk marker (*) to the right of its identifier.

Filter Definition

The Filter Definition panel displays the filter identifier of the active filter as header. If the filter has unsaved changes, it displays an asterisk marker (*) to the right of its identifier.

Each filter holds a basic set of criteria that are always available. In addition to the basic criteria, you can select further optional criteria. For this purpose, the system provides a **More filter criteria** button (+) to the right of the basic criteria.
To put the basic and optional criteria into effect, you need to define their values, for example by typing a search string or by selecting one or several options from an options list. For defining criteria values, the system supports you with specific editors (page 6).
Criteria with defined values display in bold font and show their values in dark blue.

> **TIP**
>
> If the filter criteria number of objects that match the filter criteria exceeds the limit for the number of displayable objects in the overview panel, the system requests you to refine the order-related filters. Unit procedure, work center, or exception-related filter criteria, however, will not reduce the number of found objects in this situation.

Once a criterion is defined it is immediately effective and thus changes the number of filtered objects that appear on the Overview panel. The system displays the number of batch orders, workflows, and unit procedures found by your search criteria in a semi-transparent overlay banner at the bottom of the Overview panel.

When you are done with defining a filter and do not need to see its criteria anymore, you can click its header. The system collapses the section and only displays the header. Re-click the header to expand the section again. A **Collapse/Expand** marker to the left of the header indicates whether or not a section is collapsed.

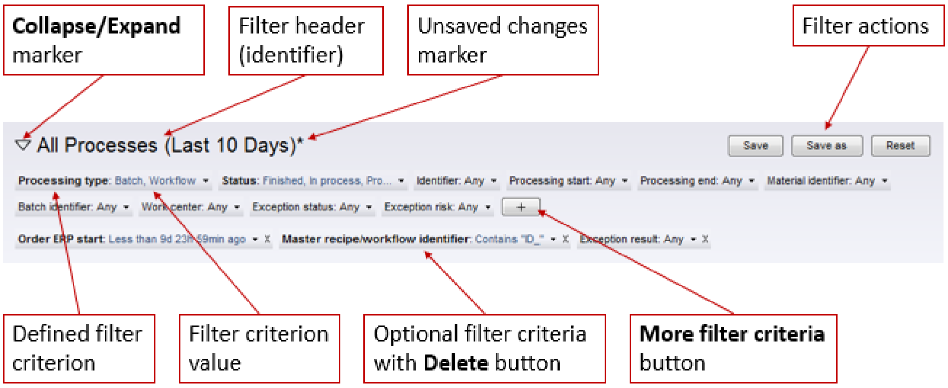


Figure 18: Filter Definition panel

The following basic criteria are available:

- Processing type
  definable with a Finite Options editor (page 8).
- Status
  definable with a Finite Options editor (page 8).
- Identifier
  definable with a String editor (page 7).
- Processing start
  definable with a Complex Date/Time and Durations editor (page 10).
- Processing end
  definable with a Complex Date/Time and Durations editor (page 10).
- Material identifier
  definable with a String editor (page 7).
- Batch identifier
  definable with a String editor (page 7).

- Work center
  definable with an Infinite Options editor (page 8).

> **TIP**
> Please note that the **Work center** criterion filters for unit procedures that are currently active at the selected work center. Unit procedures that are only planned for processing at the work center do not show.

- Exception status
  definable with a Finite Options editor (page 8).
- Exception risk
  definable with a Finite Options editor (page 8).

To add further filter criteria, proceed as follows:

1. Click the **More filter criteria** button to open an options list with all available additional criteria.
2. Select the criteria you wish to add.
   The system displays the optional criteria in a new row below the basic criteria.
3. To close the options list, click anywhere outside of the list.

To remove an optional filter criterion, either open the options list and unselect it or click its **Delete** button, which is located directly to the right of each optional criterion.

The following optional criteria are available:

- Order ERP start
  definable with a Complex Date/Time and Durations editor (page 10).
- Order ERP end
  definable with a Complex Date/Time and Durations editor (page 10).
- Treatment ID (only available if the system is configured to use treatment IDs)
  definable with a String editor (page 7).
- Material description
  definable with a String editor (page 7).
- Master recipe/workflow identifier
  definable with a String editor (page 7).
- Unit procedure identifier
  definable with a String editor (page 7).
- Unit procedure start
  definable with a Complex Date/Time and Durations editor (page 10).
- Unit procedure completion
  definable with a Complex Date/Time and Durations editor (page 10).

- Has workflows
  definable with a Boolean Options editor (page 7)
- Exception classification (only available if the system is configured accordingly)
  definable with a Finite Options editor (page 8).
- Exception result
  definable with a Finite Options editor (page 8).
- Exception CAPA ID (only available if the system is configured accordingly)
  definable with a String editor (page 7).
- Exception has bookmark
  definable with a Boolean Options editor (page 7).
- Workflow type
  definable with a Finite Options editor (page 8).
- Workflow processing name
  definable with a String editor (page 7).
- Workflow is production-relevant
  definable with a Boolean Options editor (page 7).
- Is appended
  definable with a Boolean Options editor (page 7).

The following filter actions are available as buttons from the Filter Definition panel:

- Save <filter identifier>
  Saves all changes made to the filter.
  Only available if the filter has unsaved changes, which is indicated by an asterisk marker (*) to the right of its identifier.
- Save <filter identifier> as
  Opens the **Save Filter as** dialog to save the filter under a new identifier. If you made changes to the filter, they are saved under the new identifier, while the old filter remains unchanged.
- Reset <filter identifier>
  Undoes all changes and resets the filter to its last saved form.
  Only available if the filter has unsaved changes, which is indicated by an asterisk marker (*) to the right of its identifier.

TIP

Please note that the functions to rename or delete a filter are only available from the respective filter's shortcut menu (page 17) on the Filter Selection (page 24) panel.

Signature Requests

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

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

TIP

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

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

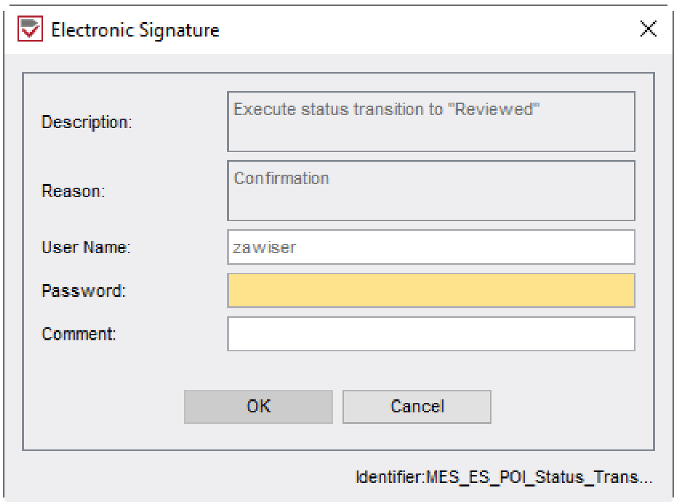


Figure 19: Single electronic signature

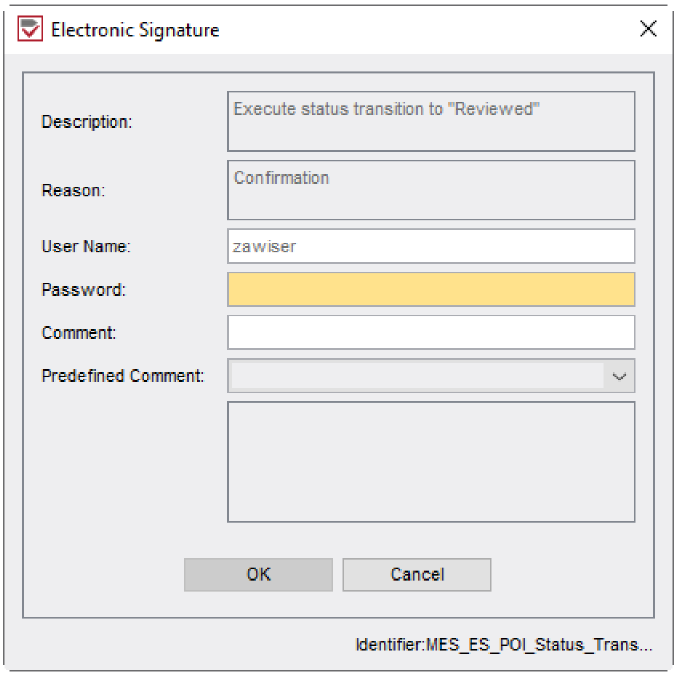


Figure 20: Single electronic signature with pre-defined comment

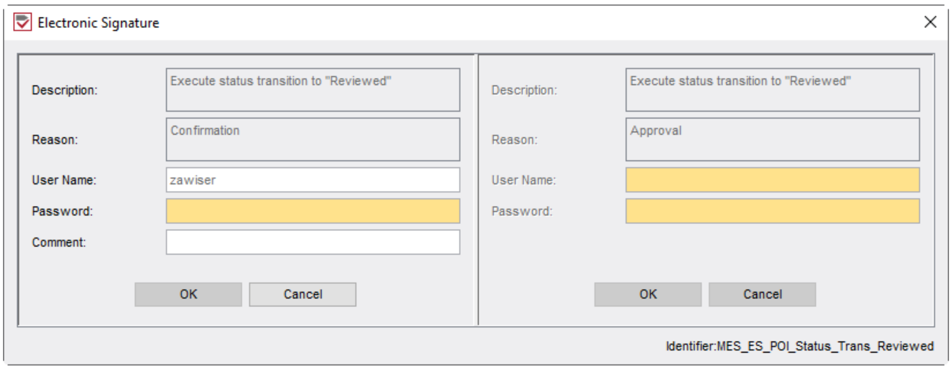


Figure 21: Double electronic signature to support witness role

Exception Dashboard

The Exception Dashboard represents a set of functions within the framework of Production Responses. It enables QC personnel to review and process exceptions of running and completed orders including the workflows appended to them.

TIP

Exceptions are distinguished between **quality exceptions** that have a risk level of **High**, **Medium**, or **Low** and **performance exceptions** whose risk is **None**.

Overview Panel

The Overview panel displays the list of orders and workflows that match the filter you have selected in the Filter Selection panel (page 24).

TIP

Please note that if the logged-in user does not have the necessary rights to access specific master recipes or master workflows, the system does not display the orders or workflows based on the confidential master recipes or master workflows.

It first displays a list of orders, structured in groups of orders that produce the same material on the basis of the same master recipe. The header of an order group thus consists of the short description of its produced material and the identifier of its master recipe. Below the list of orders, the panel displays a list of workflows, grouped by processing name. The header of a workflow group consists of its processing name and the identifier of its master workflow.

The lists of orders and workflows under their respective group headers are sorted by identifier. Each list row represents an order/workflow and consists of the clickable order/workflow button and its individual unit procedures, also shown as clickable buttons. The sequence of the unit procedures of the order or workflow initially corresponds to their sequence defined in the master recipe/workflow.

A unit procedure appears in the Overview panel if it is ready to be started after the currently running unit procedure has been finished. Once an order or workflow has been started, the sequence is controlled by the actual start time of each unit procedure. Thus, the initial sequence of unit procedures may change when

- parallel unit procedures are started in another sequence than initially shown or
- a unit procedure is reactivated and inserted as new button in the chain of unit procedures.

To collapse a list of orders/workflows under its header, click the header. The system collapses the section and only displays the header. Re-click the header to expand the section again. A **Collapse/Expand** marker to the left of the header indicates whether or not a section is collapsed.

TIP

Please note that the lists of orders and workflows update automatically as

- order or workflow execution progresses,
- new orders or workflows are started,
- workflows are appended to the unit procedures of orders,
- workflows are unappended from the unit procedures of orders, and
- exceptions are recorded and processed.

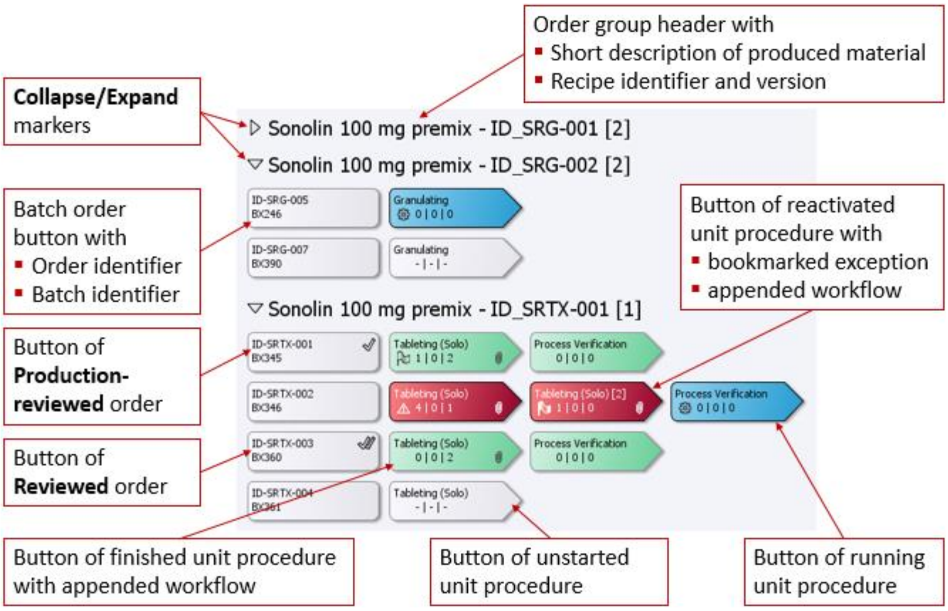
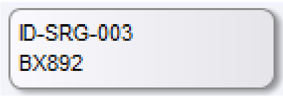
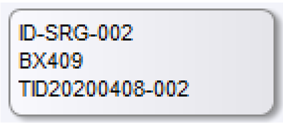


Figure 22: Overview panel - grouped list of orders

Order buttons have a light gray background, display several rows of text, and in the top-right corner of the button a status marker that indicates whether an order is **Production-reviewed** or **Reviewed**. Other order statuses are not specifically indicated by a marker.

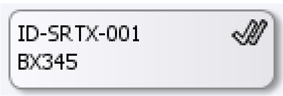


Order buttons shows two rows of text, with the order's identifier in the first row and, in the second row, the identifier of the batch that is being produced with the order.



If an order has a treatment ID, its button shows three rows of text, with the order's identifier in the first row, in the second row the identifier of the batch that is being produced with the order, and in the third row the treatment ID.

A **Production-reviewed** order displays a checkmark in its top-right corner.



A **Reviewed** order displays a double checkmark in its top-right corner.

Batch order buttons show the order's identifier in the first row and, in the second row, the identifier of the batch that is being produced with the order.

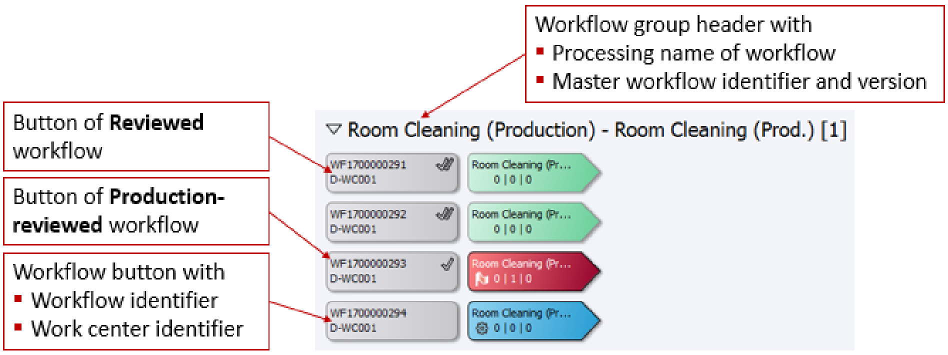
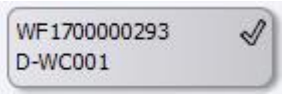


Figure 23: Overview panel - grouped list of workflows

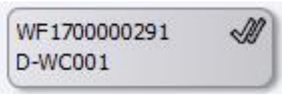
Workflow buttons have a background that is darker gray than that of orders. They display several rows of text and in the top-right corner of the button a status marker that indicates whether a workflow is **Production-reviewed** or **Reviewed**. Other workflow statuses are not specifically indicated by a marker.

Workflow buttons show two rows of text, with the workflow's identifier in the first row and, in the second row, the identifier of the work center where the workflow is being processed.

If a workflow has a treatment ID, its button shows three rows of text, with the workflow's identifier in the first row, in the second row the identifier of the work center where the workflow is being processed, and in the third row the treatment ID.



A **Production-reviewed** workflow displays a checkmark in its top-right corner.



A **Reviewed** workflow displays a double checkmark in its top-right corner.

For **unit procedure** buttons, the system also provides two rows of information. The first row contains the identifier of the unit procedure and its count if it has been reactivated. The second row shows status markers that apply to the unit procedure and a numeric representation of the exceptions recorded for the unit procedure, the exception triplet. The background color in which a unit procedure appears, is determined by three factors:

- the processing status of the unit procedure (**Not started**, **In progress**, **Reactivated**, **Finished**),
- the status of the exceptions recorded for the unit procedure (**Open**, **In review**, **To be closed**, **Closed**),
- the risk types of the exceptions recorded for the unit procedure (quality exceptions with a **High**, **Medium**, or **Low** risk and performance exceptions whose risk level is **None**).

The three figures of the exception triplet refer to the number and status of the exceptions recorded for a unit procedure and its appended workflows. The left figure indicates the number of **Open** exceptions and the center figure the number of exceptions that are **In review** and **To be closed**. The right figure shows the number of **Closed** exceptions.

TIP

Please note that the exception triplets and background colors of the unit procedure buttons show the aggregated values for the unit procedure including its appended workflows.

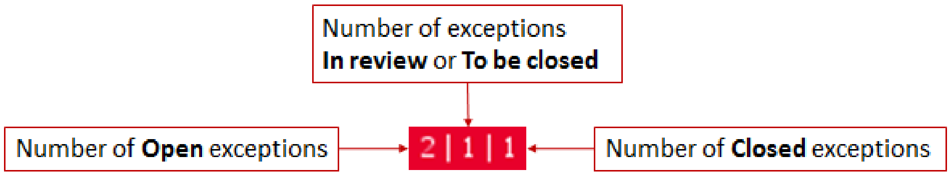
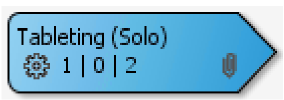


Figure 24: Exception triplet

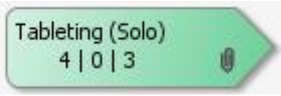
A unit procedure is displayed in red and carries an **Attention** marker to the left of its exception triplet if one or more of the exceptions recorded for it are quality exceptions and either **Open**, **In review**, or **To be closed**, thus appearing in the left and center positions of the triplet.
If the unit procedure has been reactivated, it shows the reactivation count to the right of its identifier.

TIP

Please note that an exception-triggered color change to red overrides the color the unit procedure would otherwise have.
Closed exceptions do not cause a unit procedure's background to be red, so closing the last quality exception of a unit procedure resets its color to blue or green, depending on its processing status.



A unit procedure is displayed in blue and carries a **Progress** marker to the left of its exception triplet if it is currently **In progress**. Any figures in the left and center position of its triplet indicate performance exceptions that are **Open**, **In review**, or **To be closed** and pose no risk to product quality.
If there are one or more workflows appended to the unit procedure, it shows the **Appended** marker to the right of its exception triplet.



A unit procedure is displayed in green without marker if it is **Finished**. Only performance exceptions can be **Open**, **In review**, or **To be closed**, and would be indicated by the left and center counters in its triplet.

A unit procedure that has not been started yet is displayed in gray and only shows its identifier and an empty exception triplet.

All buttons have tooltips that show the full identifier of the order, workflow, or unit procedure as the system truncates identifiers that are too long for being displayed on the available button space. Additionally, the tooltips provide further information

- for order buttons
  - Order identifier
  - Batch
  - Status
  - Master recipe identifier
- for orders with treatment ID
  - Order identifier
  - Batch
  - Treatment ID
  - Status
  - Master recipe identifier
- for workflow buttons
  - Workflow identifier
  - Work center identifier
  - Status
  - Master workflow identifier

- for workflows with treatment ID
  - Workflow identifier
  - Work center identifier
  - Treatment ID
  - Status
  - Master workflow identifier
- for unit procedures
  - Unit procedure identifier
  - Work center
  - Status
  - Number of appended workflows (if applicable)

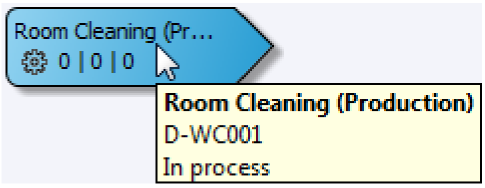


Figure 25: Button with tooltip

When a unit procedure has bookmarked exceptions, the bookmark icons replace the respective status markers:

To switch to the Details panel of a unit procedure for reviewing its exceptions,

- click a unit procedure button to access only the exceptions recorded for it or
- click an order/workflow button to access the exceptions of all unit procedures of the order or workflow.

Details Panel

The Details panel displays a graphical Object Information panel with clickable buttons for the order or workflow with its unit procedures and appended workflows (if applicable), the Exception Explorer with a structural overview of the selected order or workflow in the form of a tree view, and the Exception List with all exceptions and comments recorded for the selected order, workflow, or unit procedure. If an order with appended workflows is selected, their exceptions are included as well.
A toolbar provides access to all further actions available for the selected order or workflow.

Object Information Panel

At the top of the Details panel the system shows the Object Information panel, which consists of two rows of buttons for orders and one row for workflows.
When accessed by clicking an order or one of its unit procedures in the Overview panel, the first row displays the order like in the Overview panel with the order button as first button followed by the buttons of the individual unit procedures. The button you have clicked in the Overview to access its Details is indicated by a red selection frame. The second row is dedicated to displaying the workflows appended to the unit procedures of the order. Thus, it remains blank when you have selected an order in the first row and is only visible when you have selected a unit procedure. It shows the selected unit procedure as first button followed by the buttons of the workflows appended to it.

TIP

Please note that in order to display the full context of an order, the system shows all appended workflows including those that are confidential, even if the currently logged-in user does not have the required user rights to access them individually.

When accessed by clicking a workflow or its unit procedure in the Overview panel, the Object Information panel shows only one row with the workflow button first followed by its unit procedure button.

While order and workflow buttons display the same two rows of text as in the Overview panel, the buttons of appended workflows show three rows and in the top-right corner of the button a review status marker that indicates whether the workflow is **Production-reviewed** or **Reviewed**. The first row shows the workflow's identifier, the second row shows the identifier of the workflow's unit procedure, which is displayed in the Cockpit of PharmaSuite for Production Execution, and the third row shows the processing status markers and the exception triplet.

TIP

Please note that the exception triplets and background colors of the unit procedure buttons of the first row show the aggregated values for the unit procedure with its appended workflows, whereas the exception triplets of the second row only display the exception counts, the corresponding background colors, and status markers of the individual unit procedure or workflow.

In addition to the red (primary) selection frame, the button rows also show a secondary, blue selection frame, which indicates a hierarchical relationship between the objects represented by the buttons:

- Red frame on first-row order button:
  Blue frame on first-row unit procedure buttons, since they are component parts of the order.

Figure 26: Primary selection on order

- Red frame on workflow accessed by clicking the workflow in the Overview panel:
  Blue frame on its unit procedure button.

Figure 27: Workflow display in Details panel

- Red frame on first-row unit procedure button:
  Blue frame on second-row unit procedure button, since it is the same object.
  Blue frame on second-row workflows, since they are appended to the unit procedure.

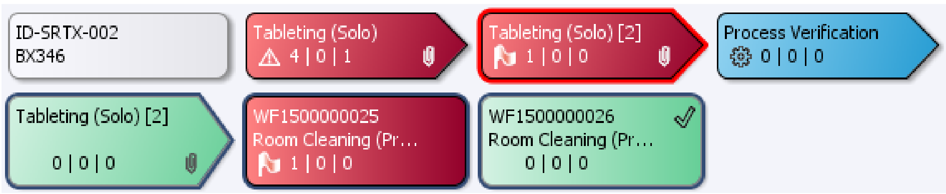


Figure 28: Primary selection on first-row unit procedure

- Red frame on second-row unit procedure button:
  Blue frame on first-row unit procedure button, since it is the same object.

Figure 29: Primary selection on second-row unit procedure

- Red frame on second-row appended workflow button:
  Blue frame on first-row unit procedure button, since the workflow is appended to it.

Figure 30: Primary selection on appended workflow

To collapse the Object Information panel, click its header. The system collapses the section and only displays the header. Re-click the header to expand the section again. A **Collapse/Expand** marker to the left of the header indicates whether or not a section is collapsed.

Exception Explorer

In the left panel below the two button rows of the Object Information panel, the Exception Explorer panel shows the structure of the selected order, unit procedure, or workflow in the form of a tree view.

> **TIP**
>
> Please note that the tree view does not refresh automatically when new unit procedure or workflow buttons are added to an order during processing on the shop floor. To update the tree view, go back to the Overview panel and then return again to the Details panels.

In addition to the structure view, the system provides further information on the individual tree nodes:

- Red tree nodes indicate that one or more exceptions have been recorded for the respective unit procedure, operation, phase, or workflow.
- Selected tree nodes are shown with gray highlighting and in italics.

  > **TIP**
  > Please note that selecting an exception or a comment in the Exception List (page 43) also selects the corresponding tree node.

- An order or workflow node shows with its identifier.
- A procedure node shows with its identifier and
  - in parentheses, the number of its active or completed unit procedures.
- A unit procedure node shows with its identifier and

  - in square brackets, its count if it has been reactivated,
  - the identifier of the work center where it was or is being processed,
  - in parentheses, the number of its active or completed operations.
- An operation node shows with its identifier and
  - in square brackets, its count if it has been run more than once,

> **TIP**
> 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.

  - in parentheses, the number of its active or completed phases.
- A phase node shows with its identifier and
  - in square brackets, its count if it has been run more than once,
  - in parentheses, a **Hidden** marker if the phase is set to be excluded from the batch or workflow report.

> **TIP**
> Whether or not a phase is to be excluded from the batch or workflow report is defined in the phase properties in its master recipe or master workflow.

- Hovering over a node, displays its start and completion times in a tooltip.

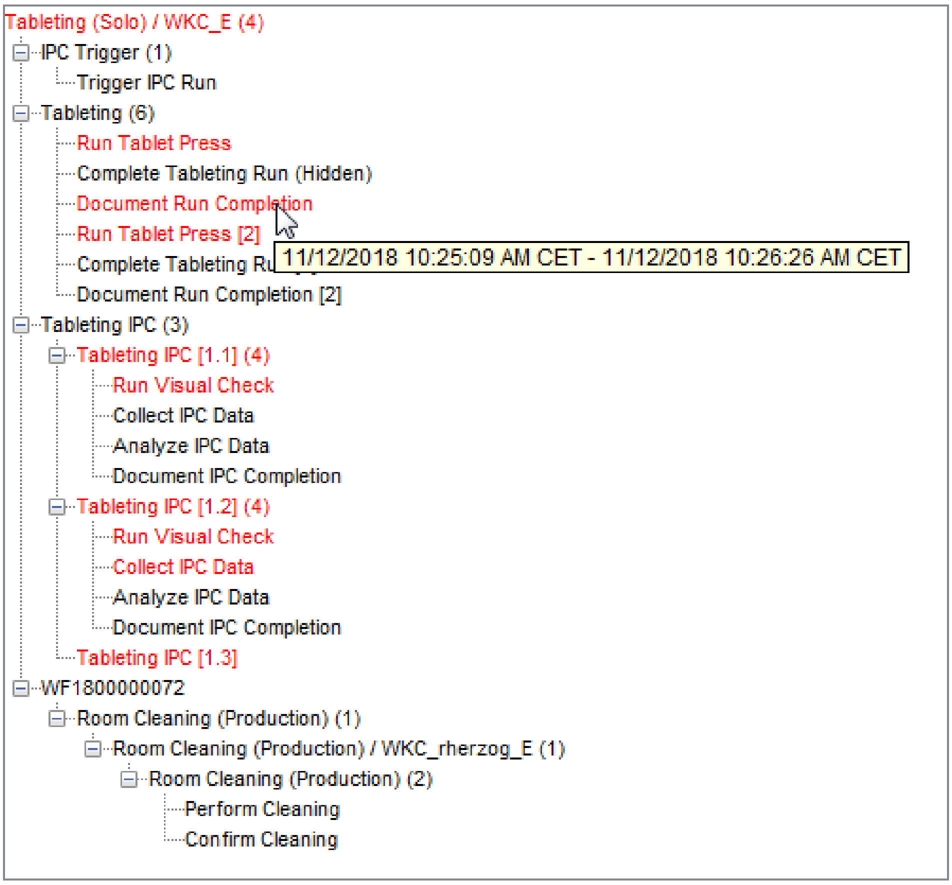


Figure 31: Exception explorer with tooltip

From the tree view, you can access the following further functions:

- To view the section of the batch or workflow report that refers to a node, double-click the node.
  The system opens the sub-report in a preview window with a clickable table of contents frame and hyperlinks for easy navigation to sub-nodes of the selected node. As phase nodes cannot have any sub-nodes, their sub-report preview provides no contents frame.

TIP
The sub-report of a phase that is defined to be hidden in the batch or workflow report is still available by directly double-clicking the phase node. Any nodes located further up in the order or workflow hierarchy, however, do not show the phase in their sub-reports.

- To print the sub-report of a node CTRL+double-click the node.
  The system opens the preview window with a paginated version of the sub-report and provides a button to send it to a connected printer.

> **TIP**
> Please note that there is no sub-report on procedure, order, or workflow level available, since it would be the same as the batch report that can be accessed from the **Open report** button (page 45) and the **Print report** button (page 46) of the toolbar.

- To fill the **Reference** box that is a mandatory entry when adding a new exception with the exception recording panel (page 49), single-click the tree node for which you need to create the exception record.

EXCEPTION LIST

Under the two button rows of the Object Information panel, the Details panel lists all exceptions and comments that have so far been recorded for the selected object. Thus, the list of displayed exceptions changes when you select another button. The list is represented as collapsible tree table, with exceptions as main nodes and the comments to each exception as its sub-nodes.
Above the Exception List the system provides filter criteria to support processing exceptions. The following filter criteria are available:

- (Exception) Has bookmark
  definable with a Boolean Options editor (page 7).
- Exception (text)
  definable with a String editor (page 7).
- (Exception) Status
  definable with a Finite Options editor (page 8).
- (Exception) Risk
  definable with a Finite Options editor (page 8).
- (Exception) Classification
  definable with a Finite Options editor (page 8).
- (Exception) Result
  definable with a Finite Options editor (page 8).
- A search tool to further refine the filtered list:
  - In the input box, type the string of characters that will be applied to the exception list. The search becomes effective with the second character.
  - To clear the input box, click the **Cancel** icon that appears when you have typed the first character in the box.

The Exception List table has the following columns:

- Mark
  Displays the bookmark icon if it is assigned to the exception.
- Identifier
  System-generated identifier of an exception. As the identifiers are generated per unit procedure, the same number can appear twice, once for an order's unit procedure and once for an assigned workflow.
- Exception/comment
  Description text recorded with the exception/comment.
- Status
  Review status of the exception (**Open**, **In review**, **To be closed**, **Closed**, **N/A** (read-only), and **---** for comments).

  > **TIP**
  > Please note that the read-only **N/A** status is only set when **None** is selected as risk level.

- Category
  Creation type of the exception (**System-triggered**, **User-triggered**, **Post-completion**, **User-defined**, and **---** for comments).
- Risk
  Result of the risk assessment performed for the exception (**High**, **Medium**, **Low**, **None**).

  > **TIP**
  > Please note that setting the risk level of an exception to **None** automatically sets its status to **N/A** only. The **N/A** status will not be available when the risk level is other than **None**.

- Classification
  Classification for the exception, such as **Information only** or **Machine error**. Classifications can only be selected when recording a comment to an exception and not during recording of the exception itself.
- Result
  Review result established for the exception (**Non-event**, **Note to record**, **Deviation**, and **---**).
- Communication status
  Indicates the status of the exception with regard to messages to and from an external QMS (**Not sent**, **Sent**, **Received**, **Error**).

  > **TIP**
  > Please note that the column is only displayed if the system is configured for integration with an external QMS.

- External ID
  Displays the identifier the exception holds in an external QMS.

  > **TIP**
  > Please note that the column is only displayed if the system is configured for integration with an external QMS.

- CAPA ID
  Refers to corrective and preventive actions related to the exception.

  > **TIP**
  > Please note that it depends on your system configuration whether the **CAPA ID** column is shown.

- Reference
  Path to the specific recipe or workflow component for which the exception was recorded. To access context information of an exception recorded in the corresponding batch or workflow report, double-click the blue link.
  For comments, the column always shows **---**.

- Signatures
  The signature (first name, last name (login name)) is displayed with its meaning and the timestamp taken when an exception is recorded. For double signatures, both signatures are displayed.

> **TIP**
>
> Please note that the list of exceptions and comments updates automatically if another user at another work center adds a new exception or comment to the unit procedure.

To add new exceptions or comments, use the exception recording panel (page 49).

TOOLBAR

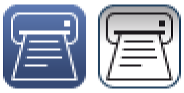
From the toolbar you can access the following further functions:

 **Back**

Switches back to the Overview panel to display the filtered list of orders.

 **Open report**

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



Print report

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

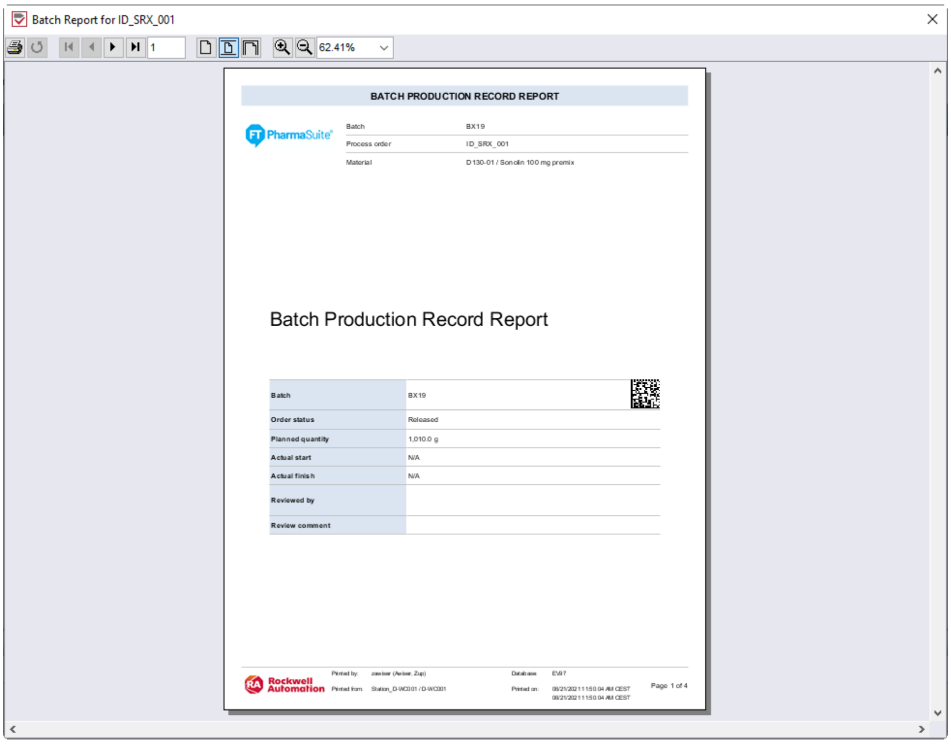


Figure 32: Batch production record report

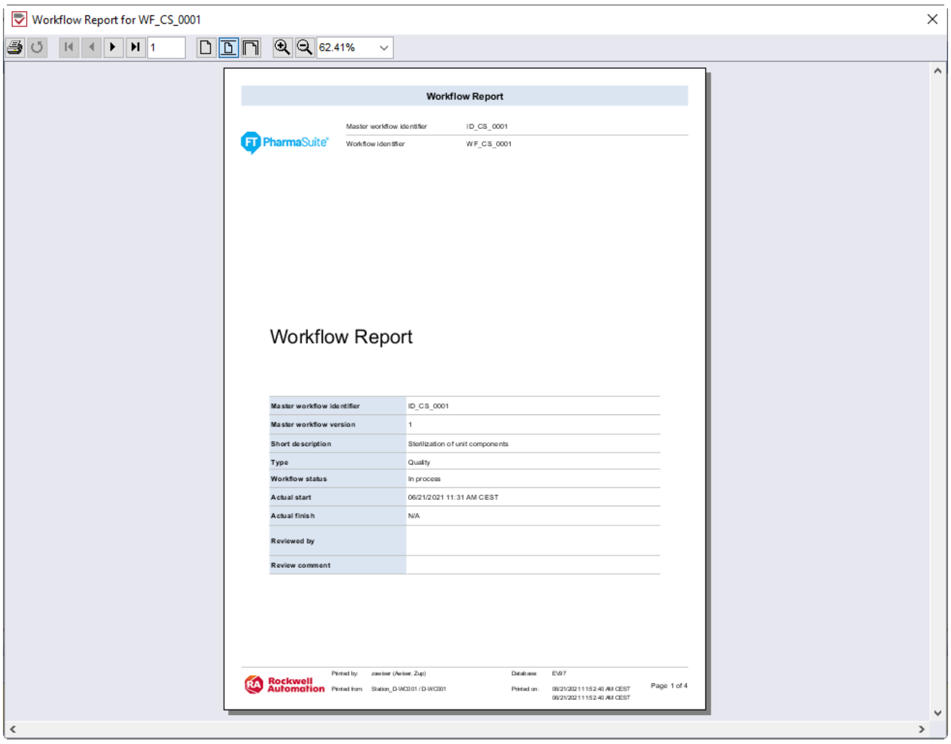
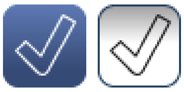


Figure 33: Workflow report



Change status to Production-reviewed

Available for **Finished** orders and workflows.

> **TIP**
>
> A workflow that has been set to **Production-reviewed** displays a checkmark in its top-right corner.

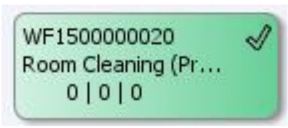


Figure 34: Button of Production-reviewed workflow

Change status to Reviewed

Available for **Finished** or **Production-reviewed** orders and workflows, whose quality exceptions have all been set to **Closed**.

An order can only move to the **Reviewed** status if all of its appended workflows are either **Finished**, **Production-reviewed**, or **Reviewed**.

Moving an order to **Reviewed** also moves those of its appended workflows to **Reviewed** that are still in the **Finished** or **Production-reviewed** statuses. You can no longer add exceptions or comments to the workflows even though they may be appended to other orders that are not yet **Reviewed** themselves.

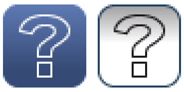
TIP

A workflow that has been set to **Reviewed** displays a double checkmark in its top-right corner.

Figure 35: Button of Reviewed appended workflow

TIP

Performance exceptions that pose no risk to product quality do not have to be **Closed** before an order or workflow can be set to **Reviewed**.



Help

Opens the context-sensitive help.

TIP

Please note that your user rights determine whether you can execute the functions provided in the toolbar.

Exception Recording Panel

The exception recording panel provides all functions to add, review, comment, and bookmark exceptions. It is linked to the list of exceptions and comments displayed in the Details panel (page 37). Your user rights determine which data you can record or change for exceptions.

TIP

Please note that you can only add exceptions to orders and workflows that have been started. Orders or workflows that are **Released** but not **Started** yet as well as orders or workflows that are already **Reviewed** have disabled controls in the exception recording panel. To **Production-reviewed** workflows, however, you can still add exceptions. When you add an exception or comment, the system indicates mandatory text boxes with a yellow background color.

Once an exception has been added it cannot be deleted or edited directly any longer. All changes that result from reviewing are added as comments to the respective exception. Status changes made in an exception comment apply to the exception itself and are propagated to the exception when the comment is added.

TIP

It depends on your selection in the list of exceptions and comments on the Details panel whether you can add an exception or add comment or bookmark, since the buttons on the exception recording panel are enabled accordingly:

- To add an exception, make sure you have no exception selected.
- To add a comment, make sure you have no comment selected.

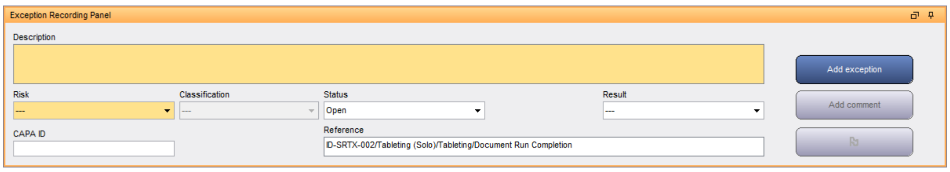


Figure 36: Exception recording panel with free-text entry

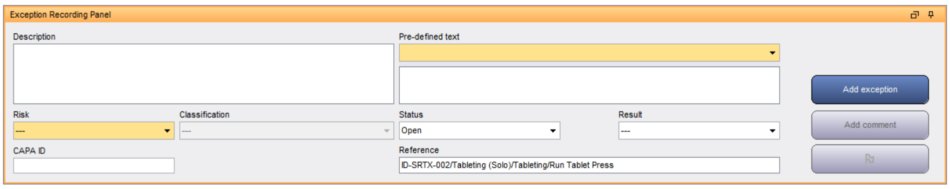


Figure 37: Exception recording panel with pre-defined text options

When an exception is selected for review, either in another session of the Exception Dashboard of PharmaSuite for Production Responses or in PharmaSuite for Production Execution, it is locked and cannot be accessed for processing by another user. The system displays a locked exception with a textual marker (**Under review**) above the **Add exception** button. The text also includes the login name of the reviewing user.

TIP

Please note that locked exceptions can be unlocked with the **Unlock Objects** task of PharmaSuite for Production Management.

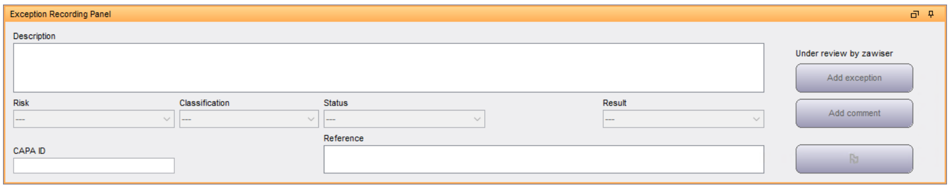


Figure 38: Exception recording panel with locked exception

The following controls are available on the exception recording panel:

- **Description** input box
  Holds the explanation why a user adds an exception or comment.
- **Pre-defined text** option list and text box
  If a list of pre-defined exception texts is configured, the system displays the **Pre-defined** option list, which shows the headers of the available text options. The system displays the full text of the selected option in the read-only text box.
- **Risk** option list
  Specifies the risk an exception represents to patient safety, product quality, or data integrity: **High**, **Medium**, **Low**, **None**. Performance exceptions should be set to **None** so that they do not interfere with the quality-related review of the order and its exceptions.
  If changed with a comment, the new risk is propagated to the commented exception.

  TIP
  Please note that setting the risk level of an exception to **None** automatically sets its status to **N/A** only. The **N/A** status will not be available when the risk level is other than **None**.

- **Classification** option list
  Specifies the class of an exception, such as **Information only** or **Machine error**. Classifications can only be selected when recording a comment to an exception and not during recording of the exception itself.

- **Status** option list
  Specifies the review status of an exception: **Open**, **In review**, **To be closed**, **Closed**, and **N/A** (read-only).
  If changed with a comment, the new status is propagated to the commented exception.

> **TIP**
> Please note that the read-only **N/A** status is only set when **None** is selected as risk level.

- **Result** option list
  Specifies the review result of an exception: **Non-event**, **Note to record**, **Deviation**.
  The result must be set before an exception can be **Closed**.
  If changed with a comment, the result is propagated to the commented exception.

- **CAPA ID** input box
  Refers to corrective and preventive actions related to the exception.
  If changed with a comment, the new CAPA ID is propagated to the commented exception.

> **TIP**
> Please note that it depends on your system configuration whether the **CAPA ID** input box is available.

- **Reference** box
  Specifies the path to the recipe element (unit procedures, operations, templates of event-triggered operations, phases of both orders and workflows) for which an exception is recorded.
  Only enabled for exceptions. The path cannot be entered by typing but must be filled in by selecting the respective tree node in the Exception Explorer (page 40) or by selecting a comment in the Exception List (page 43).

- **Add exception** button
  Adds a new exception to the list of exceptions on the Details panel.

- **Add comment** button
  Adds a new comment to the exception selected in the list of exceptions on the Details panel and updates its **Risk**, **Status**, or **Result** if set to a new value in the comment.

> **TIP**
> Please note that you can also add the comment to more than one exception by multi-selecting all exceptions to which the comment and, if applicable, the changed **Risk**, **Status**, or **Result** will be added.

- **Bookmark** button
  Bookmarks the exception selected in the list of exception on the Details panel to support reviews.

- **Send exception** button
  Sends all exceptions selected in the list of exceptions on the Details panel to an external QMS for an external review process.

  > **TIP**
  > Please note that the button is only displayed, if the system is configured for integration with an external QMS.

Integration with an External Quality Management System

Your system can be configured to integrate with an external QMS for reviewing exceptions.
When exceptions are created during execution, their risk assessment determines if they are transferred automatically to the external QMS. This also means that an exception that was below the risk threshold when it was created is transferred automatically as soon as a reviewer has added a comment that raises the risk above the risk threshold.
Additionally, it is possible to transfer exceptions manually.
In this scenario, you can select exceptions listed in the exception table (page 43) and send them to the external QMS for further processing.
Once the exceptions have been received by the external system, they can be reviewed there. At some point during the external review process, the external QMS sends a reply message, which contains the identifier the exception assigned by the external system. In addition, the external system can send review comments, which are attached to the exception and can update the status of the exception until the order or workflow has been moved to the **Reviewed** status (page 48).

To handle the review process in an external QMS, proceed as follows:

1. From the list of exceptions in the Details panel, select or multi-select all exceptions you wish to send to the external QMS.

   > **TIP**
   > Please note that you can only send exceptions that have not been sent successfully before, which means that they need to have either the **Not sent** or the **Error** communication status.

2. Click the **Send exception** button.
   You need to confirm the action with an electronic signature (page 29).
   The system sends the exceptions to the external QMS for an external review process. It sets the communication status of the exception to **Sent** and its review status to **In review**. Additionally, it adds a comment to the exception, stating that it has been sent.

3. Once the external QMS receives the exceptions, it should return a message to set the communication status to **Received** and supply the external identifier of the exception. With this message or with later messages, the external system can update the review status of the exception up to **Closed**.

> **TIP**
> Please note that the external system cannot update orders or workflows that are **Reviewed**, **Annulled**, or **Canceled**.

Working with the Exception Dashboard

The Exception Dashboard is designed to support users who control the quality of products using the review-by-exception method.

To perform a review in this manner, proceed as follows:

1. From the Filter Selection panel (page 24), click a suitable filter to apply it to the pool of available orders.
   The system fills the Overview panel with the filtered list of orders.
2. In the Overview panel (page 31), identify the orders with exceptions by the color coding of their unit procedures.
   Click to select the unit procedure whose exceptions you wish to review in detail.

   > **TIP**
   > Please note that only quality exceptions, i.e. exceptions with a risk level of **High**, **Medium**, or **Low**, cause a unit procedure to display with a red background. Performance exceptions that do not pose a risk to product quality are only indicated in the exception triplet.

3. The system opens the Details panel (page 37) that lists all exceptions and comments recorded for the unit procedure including its appended workflows.
4. If required, open the order's or workflow's report as preview (page 45) or for printing (page 46) to access additional information on the phases and the circumstances under which the exceptions were recorded.
5. Use the exception recording panel (page 49) to process the exceptions until you can set their status to **Closed**.
   Workflows display a status marker in their top-right corner that indicates if they have already been moved to **Production-reviewed** or **Reviewed**.
6. If suitable for your process, you can run a preliminary review and set your **Finished** order to **Production-reviewed**. This means that all of its appended workflows need to be either **Finished**, **Production-reviewed**, or **Reviewed**.
   Click the **Change status to Production-reviewed** button (page 47) to change your order's status. On the order button, the new status is indicated by a checkmark in its top-right corner.
7. To be able to complete the review of your order and move it to the **Reviewed** status, you need to
   - close all quality exceptions of all of its unit procedures,
   - close all quality exceptions of all of its appended workflows, and

- make sure, all of its appended workflows are **Finished**.

8. On the toolbar, click the **Change status to Reviewed** button (page 48) to complete your order review. On the order button, the new status is indicated by a double checkmark in its top-right corner.

TIP
Please note that setting an order to **Reviewed** also changes the status of its appended **Finished** or **Production-reviewed** workflows to **Reviewed**, even if an appended workflow is confidential and the currently logged-in user does not have the required user rights to access it individually.

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