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## REVIEW AND APPROVAL

RELEASE 8.4

## FUNCTIONAL REQUIREMENT SPECIFICATION

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## Introduction

This document details the requirements of functions implemented related to review and approval that are available through the functionality of Batch Production Records and Reports as well as through the Production Response Client.

Each requirement is composed of a name and a unique identifier (e.g. Batch Production Record API (SR3200.1.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g. Batch Production Record (SR3200.1+)).

In some cases, additional context information is available, indicated in the document by a frame and a gray background color. This context information is related to the respective requirement, but not part of the formal requirement description.

The revision history (page [35](#)) lists the changes made to the document with PharmaSuite 8.3 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

## Typographical Conventions

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

<b>Bold typeface</b>	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).

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## Review and Approval (SR3200+)

In PharmaSuite, the **batch production record** supports the review and approval of data that has been collected during execution of recipes and workflows on the shop floor.

- The PharmaSuite API (Application Programming Interface) provides basic batch production record-relevant data in an S88-compliant structure (header data, list or recorded exceptions, executed control recipe).  
See **Batch Production Record (SR3200.1+)** requirements (page 5).
- The batch production report and the device history report support an online review by exception and are also available in a printable paper format (PDF).  
See **Exception Dashboard - Details panel (SR3200.3.3)** requirements (page 24).
- The workflow report supports an online review by exception and is also available in a printable paper format (PDF).  
See **Exception Dashboard - Details panel (SR3200.3.3)** requirements (page 24).
- The exception dashboard of the **Production Response Client (SR3071.5+)** application (page 31) allows to track the exception status per running or completed order or workflow, handle performance-related exceptions in their way, process exceptions (review, comment, close), and review the corresponding report (batch, device, workflow).  
See **Exception Dashboard (SR3200.3+)** requirements (page 21).

This description is structured in the following sections:

- **Batch Production Record (SR3200.1+)** requirements (page 5)
- **Batch Production Report (SR3200.2+)** requirements (page 7)
- **Device History Report (SR3200.5+)** requirements (page 11)
- **Workflow Report (SR3200.4+)** requirements (page 15)
- **Dispensing Report (SR1090.4.7)** requirements (page 19)
- **Exception Dashboard (SR3200.3+)** requirements (page 21)
- **Production Response Client (SR3071.5+)** requirements (page 31)

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## Batch Production Record (SR3200.1+)

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### Batch production record API (SR3200.1.1)

The batch production record API (Application Programming Interface) allows to access production data based on an S88 part4-compliant data structure.

---

### Content (SR3200.1.1.1)

The batch production record API-relevant data includes:

- Batch record header data (from the **ProcessOrder** object of Process Designer of FactoryTalk ProductionCentre)
- List of recorded exceptions
- Representation of the executed control recipe

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## Batch Production Report (SR3200.2+)

### Batch Production Report GUI (SR3200.2.1)

The electronic representation of the batch production report provides context data during online batch reviews.

---

#### Content (SR3200.2.1.1)

The batch production report-relevant data includes:

- Batch record basic data, incl. master recipe and order data.
- Order-related barcode
- Order-related comment
- List of recorded exceptions
- Order-related BOM
- List of appended workflows (without exceptions)
- Representation of the executed control recipe

---

#### Cover page (SR3200.2.1.7)

The cover page of the batch production record report includes the following data:

- Report title
- Batch and order-related barcode
- Order status
- Planned quantity
- Actual start date and Actual finish date
- Reviewed by (login and user name, timestamp)
- Review comment

---

#### Table of contents (SR3200.2.1.5)

The table of contents section presents the structure of the batch production record report and reflects the hierarchy of the procedure and its unit procedures.

It contains the following elements:

- Basic batch record
- Comment
- Exceptions
- Order-related BOM items
- Appended workflows
- Procedure
  - Unit procedure(s)
    - Operation(s)

---

#### **List of recorded exceptions (SR3200.2.1.4)**

The exception section presents the following information of exceptions and related comments, ordered by exception/comment number:

- Number
- Description
- Status, Result
- Risk
- Category
- Control recipe element
- Signature (first and last name, reason, timestamp)

---

#### **Order-related BOM (SR3200.2.1.3)**

The order-related BOM section presents the following information, ordered by position:

- Position
- Material
- Identified batch ID (if applicable, may be multiple)
- Planned quantity (execution)
- Planned quantity (original)
- Actual quantity

The following rules apply:

- Each position is presented in its own row.
- Additional rows are shown for alternative BOM items.

- Canceled positions are marked with strikethrough formatting.
- Actual quantities reflect the consumed quantities and do not include replaced sublots.

---

#### List of appended workflows (SR3200.2.1.6)

The section for the workflows appended to order steps presents the following information of the workflows:

- Workflow ID
- Processing name
- Master workflow ID and Version
- Master workflow short description
- Workflow start date
- Workflow end date
- Workflow status
- Unit procedure (order step) to which the workflow has been appended

---

#### Navigation (SR3200.2.1.2)

The batch production report allows navigation by using the clickable table of content and by hyperlinks to procedural elements (phases, operations, unit procedures) and their exceptions.

### Layout per Usage Type (SR3200.2.2+)

For each usage type of a master recipe/order, a separate report layout can be used.

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#### Cost center per usage type (SR3200.2.2.1)

For orders of the **Cost center** usage type, an alternative Batch Production Report layout is available, which includes the cost center as one of the header attributes.

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## Device History Report (SR3200.5+)

### Device History Report GUI (SR3200.5.1)

The electronic representation of the device history report provides context data during online device history reviews.

---

#### Content (SR3200.5.1.1)

The device history report-relevant data includes:

- Device record basic data, incl. master recipe and order data.
- Serial number-related barcode
- Order-related comment
- List of recorded exceptions
- Order-related BOM
- List of appended workflows (without exceptions)
- Representation of the executed control recipe

---

#### Cover page (SR3200.5.1.7)

The cover page of the batch production record report includes the following data:

- Report title
- Serial number and Barcode
- Batch
- Order status
- Planned quantity
- Actual start date and Actual finish date
- Reviewed by (login and user name, timestamp)
- Review comment

---

#### Table of contents (SR3200.5.1.2)

The table of contents section presents the structure of the device history report and reflects the hierarchy of the procedure and its unit procedures.

It contains the following elements:

- Basic device history record
- Comment
- Exceptions
- Order-related BOM items
- Appended workflows
- Procedure
  - Unit procedure(s)
  - Operation(s)

---

#### **List of recorded exceptions (SR3200.5.1.3)**

The exception section presents the following information of exceptions and related comments, ordered by exception/comment number:

- Number
- Description
- Status, Result
- Risk
- Category
- Control recipe element
- Signature (first and last name, reason, timestamp)

---

#### **Order-related BOM (SR3200.5.1.4)**

The order-related BOM section presents the following information, ordered by position:

- Position
- Material
- Identified batch ID (if applicable, may be multiple)
- Planned quantity
- Actual quantity

The following rules apply:

- Each position is presented in its own row.
- Additional rows are shown for alternative BOM items.
- Canceled positions are marked with strikethrough formatting.

---

**List of appended workflows (SR3200.5.1.5)**

The section for the workflows appended to order steps presents the following information of the workflows:

- Workflow ID
- Processing name
- Master workflow ID and Version
- Master workflow short description
- Workflow start date
- Workflow end date
- Workflow status
- Unit procedure (order step) to which the workflow has been appended

---

**Navigation (SR3200.5.1.6)**

The device history report allows navigation by using the clickable table of content and by hyperlinks to procedural elements (phases, operations, unit procedures) and their exceptions.

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## Workflow Report (SR3200.4+)

### Workflow Report GUI (SR3200.4.1)

The electronic representation of the workflow report provides context data during online workflow reviews.

---

#### Content (SR3200.4.1.1)

The workflow report-relevant data includes:

- Workflow header data with basic workflow data
- Workflow-related comment
- List of recorded exceptions
- List of linked unit procedures (order steps)
- Representation of the workflow

---

#### Cover page (SR3200.4.1.7)

The cover page of the workflow report includes the following data:

- Report title
- Master workflow
  - Identifier
  - Version
  - Short description
  - Type
- Workflow
  - Status
  - Actual start date and Actual finish date
  - Reviewed by (login and user name, timestamp)
  - Review comment

---

#### **Table of contents (SR3200.4.1.4)**

The table of contents section presents the structure of the workflow report and reflects the hierarchy of the procedure and its unit procedures.

It contains the following elements:

- Basic workflow data
- Comment
- Exceptions
- Procedure
  - Unit procedure(s)
    - Operation(s)

---

#### **Basic workflow data (SR3200.4.1.5)**

The basic data section presents the following information:

- Master workflow
  - Identifier
  - Version
  - Processing name
  - Short description
  - Type
- Workflow
  - Status
  - Actual start date and Actual finish date
  - Reviewed by (login and user name, timestamp)
  - Review comment

---

#### **List of recorded exceptions (SR3200.4.1.2)**

The exception section presents the following information of exceptions and related comments, ordered by exception/comment number:

- Number
- Description
- Status, Result
- Risk

- Category
- Workflow element
- Signature (first and last name, reason, timestamp)

---

#### **List of linked unit procedures (order steps) (SR3200.4.1.6)**

The section for the unit procedures (order steps) to which the workflow has been appended presents the following information:

- Order ID
- Unit procedure
- Order status
- Batch
- Material ID, short description

---

#### **Navigation (SR3200.4.1.3)**

The workflow report allows navigation by using the clickable table of content and by hyperlinks to phases and their exceptions.

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## Dispensing Report (SR1090.4.7)

The Dispensing report shall contain information about the Dispensing process. This includes:

- Header data including report title
- Order-related data
- List of recorded exceptions
- Order-related BOM
- Executed control recipe for the given unit procedure (order step), sorted by material positions, with details of the Dispensing process (including resources, produced resources, target quantities, recorded quantities, UoMs, weighing methods, electronic signatures).
- Footer data (including page x of y)

### Order-related Data (SR1090.4.7.1)

The Dispensing report shall include the following order-related data:

- Batch identifier of the product
- Order identifier
- Material identifier and short description of the product

### Dispensing Data (SR1090.4.7.3)

The dispensing data is covered by the phase-specific sub-reports. For details see:

- D Identify Material Phase (SR0200+), Representation in Sub-report (SR0200.5+)
- D Select Scale Phase (SR0210+), Representation in Sub-report (SR0210.5+)
- O Identifier Container (SR0750+), Representation in Sub-report (SR0750.5+)
- D Tare Phase (SR0220+), Representation in Sub-report (SR0220.5+)
- D Weigh Phase (SR0230+), Representation in Sub-report (SR0230.5+)
- D Release Scale Phase (SR0240+), Representation in Sub-report (SR0240.5+)

in "Functional Requirement Specification Dispense and Inline Weighing" [A5] (page 33) and "Functional Requirement Specification Output Weighing" [A6] (page 33).

### Signature Data (SR1090.4.7.5)

The Dispensing report shall include the following information about phase-completion signatures:

- Signature meaning
- Logged-in user (first and last name, login name (in parentheses))
- Timestamp

### Exceptions (SR1090.4.7.6)

The Dispensing report shall include a list of recorded exceptions including the following information of exceptions and related comments, ordered by exception/comment number:

- Number
- Description
- Status, Result
- Risk
- Category
- Control recipe element
- Signature (first and last name, reason, timestamp)

### Non-Dispense Phases (SR1090.4.7.7)

In case non-Dispense phases are part of the Dispense operation, the executed control recipe that represents the Dispense phases shall also include the non-Dispense phases, sorted per related BOM position and timestamp of the execution.

Non-Dispense phases must not be modeled as part of the dispensing loop if they do not support the Dispense-specific features **Return to material identification** and **Unforeseen resume**.

## Exception Dashboard (SR3200.3+)

The exception dashboard enables QC personnel to review and process exceptions of running and completed orders or workflows. Exceptions are either quality- or performance-related. The latter are indicated by the **None** risk level and need not be closed to set an order or workflow to **Reviewed**.

### Filter (SR3200.3.1)

- For recent changes, see revision history (page [35](#)).

The system allows to define an access privilege for the protection of master recipes and master workflows from unauthorized access. Subsequently, it shall only include orders and workflows in the Overview panel whose master recipe's and master workflow's access privilege matches the access privilege of the logged-in user.

The QC personnel can apply a filter to select the groups of orders and workflows to be displayed in the **Overview panel (SR3200.3.2)** view (page [23](#)).

The Filter Selection panel provides the available filters.  
The Filter Definition panel provides the attributes of the applied filter.  
They are positioned to the left and above the **Overview panel (SR3200.3.2)** view (page [23](#)).

---

#### Filter configuration (SR3200.3.1.1)

A user can manage and configure user-specific filters for the groups of orders and workflows to be displayed in the **Overview panel (SR3200.3.2)** view (page [23](#)).

---

#### Fixed filter attributes (SR3200.3.1.2)

The following filter attributes are always available for the filter configuration:

- Processing type (default selection: Batch)
- [Order/workflow] Status (default selection: Released, Production-reviewed, In process, Finished)
- [Order/workflow] Identifier
- Processing start and end [dates]
- Material identifier

- Batch identifier
- Work center
- Exception status
- Exception risk

---

#### **Flexible filter attributes (SR3200.3.1.3)**

The following filter attributes can be added by a user to be available for the filter configuration:

- Order ERP start and end [dates]
- Material description
- Master recipe/workflow identifier
- Unit procedure identifier
- Unit procedure start and completion [dates]
- Has workflows [assigned]
- Exception result
- Exception CAPA ID
- Exception has bookmark
- Device serial number
- Workflow type
- Workflow processing name
- Workflow is production-relevant
- Is appended

---

#### **Filter operations (SR3200.3.1.4)**

The following filter operations are supported:

- Create new
- Save
- Edit
- Save as
- Rename
- Delete
- Reset

## Overview Panel (SR3200.3.2)

The exception dashboard provides an Overview panel that displays a representation of orders (batch- and device-related) followed by workflows. The panel provides an overview of all of their unit procedures.

The Overview panel is described in the following requirements:

- **Overview panel - Product-related (SR3200.3.5)** feature (page 28)
- **Overview panel - Workflow-related (SR3200.3.10)** feature (page 29)

---

### Status information (SR3200.3.2.2)

For each unit procedure, status information is displayed.

A unit procedure has one of the following statuses: **Not started**, **In process**, and **Finished**.

The background color used to display a unit procedure is determined by the status of the unit procedure, the status of its exceptions along with the associated risk level, see **Color of status indicator (SR3200.3.2.2.1)** feature (page 23).

---

### Color of status indicator (SR3200.3.2.2.1)

As soon as at least one exception with an associated risk exists in the **Open** or **In review** status, the color of the status indicator of the unit procedure turns red.

This does not apply to performance exceptions whose risk level is **None**.

An exception has one of the following statuses: **Open**, **In review/To be closed**, and **Closed**.

The background color used to display a unit procedure is determined by the status of the unit procedure, the status of its exceptions along with the risk level, see **Status information (SR3200.3.2.2)** feature (page 23).

---

### Workflow appended (SR3200.3.2.6)

For each batch- or device-specific unit procedure, an indicator is displayed if a workflow is appended to that unit procedure.

---

### Exception triplet (SR3200.3.2.3)

For each unit procedure, an exception triplet is displayed. A triplet represents the number of exceptions per status (**Open**, **In review/To be closed**, and **Closed**).

---

### Exception triplet aggregation (SR3200.3.2.3.1)

For batch- or device-specific unit procedures, the system aggregates the number of exceptions in the **Open**, **In review**, and **Closed** statuses including their appended workflows.

---

### Bookmark (SR3200.3.2.4)

For each unit procedure, a bookmark icon is displayed if at least one of the exceptions has been bookmarked, including exceptions that have been recorded for appended workflows (if applicable).

The bookmark indicator overwrites the **status information (SR3200.3.2.2)** indicator (page 23) of the unit procedure and the indicator of not yet closed exceptions (see **color of status indication (SR3200.3.2.2.1)** feature (page 23)).

---

### Switch to Details panel (SR3200.3.2.5)

Clicking an order-related, workflow-related, or unit procedure-related representation in the Overview panel switches to the corresponding **Details panel (SR3200.3.3)**, which lists the exceptions that have been recorded for the order, workflow, or unit procedure, including their appended workflows, if available.

The different Details panels are described in the following requirements:

- **Details panel - Product-related (SR3200.3.6)** feature (page 28)
- **Details panel - Workflow-related (SR3200.3.11)** feature (page 29)

## Details Panel (SR3200.3.3)

- For recent changes, see revision history (page 35).

The exception dashboard provides a Details panel that displays the exceptions of an order, workflow, or unit procedure for review. The Details panel provides the following features:

- Display a list of recorded exceptions and their comments (per unit procedure, order, or workflow). The exceptions can relate to phases, operations, or unit procedures.
- Display and print the batch report, the workflow report, or the device history report in a preview window.
- Exceptions can be added to a phase, operation, or unit procedure.  
See **User-defined Exceptions in Production Response Client (SR1079.1.1.1)**, **Signatures for User-defined Exceptions (SR1079.2.1.1)**, and **Signatures for Exception-related Comments (SR1079.2.1.2)** in "Functional Requirement

Specification Execution Framework" [A1] (page 33).

Exceptions can no longer be added to orders or workflows that are already in the **Reviewed** status.

- Comments can be added to an exception.  
See **Comments related to an Exception (SR1079.2.3)** in "Functional Requirement Specification Execution Framework" [A1] (page 33).  
Comments to exceptions can no longer be added if the order or workflow is already in the **Reviewed** status.
- Exceptions can be bookmarked to simplify the review process.  
Bookmarks can be removed.
- Status of an order can be changed to **Production-reviewed** and to **Reviewed**, see **Review an order (SR3200.3.3.2)** feature (page 26).
- Status of a workflow can be changed to **Production-reviewed** and to **Reviewed**, see **Review a workflow (SR3200.3.3.3)** feature (page 27).
- Multi-selection of exceptions is supported to inform an external QMS.
- The access to the following features depends on the system configuration:
  - Changing risk or status of exception
  - Performing status change to **Production-reviewed**
  - Performing status change to **Reviewed**
  - Adding a **CAPA ID** to a user-defined exception or its comment and display it in the list of recorded exceptions.  
See **User-defined Exceptions in Production Response Client (SR1079.1.1.1)** in "Functional Requirement Specification Execution Framework" [A1] (page 33).
    - Enabled in the default configuration.
  - Display the **Communication status** and **External ID** of an external QMS in the list of recorded exceptions.
    - Disabled in the default configuration.
  - Sending exceptions to an external QMS, see **Manually inform an external QMS about an exception (SR3200.3.3.4)** feature (page 27).
    - Disabled in the default configuration.

In the report preview window, the report (batch, device, workflow) is positioned at the start of the report or at the selected unit procedure when called using the standard button and at the referenced procedural element when called with the link in the reference column from the list of exceptions.

The following restrictions apply to exported workflows according to the **Export Workflow for Archive (SR1085.2.10)** operation, see "Functional Requirement Specification Runtime Data Management" [A2] (page 33):

- Neither exceptions nor comments to existing exceptions can be created for the workflow.
- The status cannot be changed. **Finished** workflows remain in their status. They never reach the **Production-reviewed** or **Reviewed** status.

---

### Exception management (SR3200.3.3.1)

The exception dashboard supports requirements of **Exception Management (SR1079+)** as:

- Display a list of recorded exceptions and their comments related to a phase, operation, or unit procedure.
- User-defined exceptions can be added to a phase, operation, or unit procedure.

Adding an exception is only allowed after processing of a unit procedure has been started.

- Comments can be added to an exception.
- Exceptions can be bookmarked to simplify the review process. Bookmarks can be removed.

See "Functional Requirement Specification Execution Framework" [A1] (page 33).

---

### Review an order (SR3200.3.3.2)

- For recent changes, see revision history (page 35).

The exception dashboard allows to change the status of an order to **Production-reviewed** and to **Reviewed**.

- To change the status to **Production-reviewed**, the order must be in the **Finished** status. However, exceptions do not need to be set to **Closed**. A decorator indicates the **Production-reviewed** status.
- To change the status to **Reviewed**, the order must be in the **Finished** or **Production-reviewed** status and all exceptions with a risk other than **None** must have been set to **Closed**, including exceptions that have been recorded for appended workflows (if applicable). This does not apply to performance



exceptions whose risk level is **None**. They can still be in the **Open** or **In review** statuses.

In addition, all appended workflows must be in the **Finished**, **Production-reviewed**, or **Reviewed** status. Changing the status of an order to **Reviewed** also changes the status of those of its appended workflows to **Reviewed** that are still in the **Finished** or **Production-reviewed** statuses. In this case it is not required that the access privilege of the master workflow matches the access privilege of the logged-in user.

A decorator indicates the **Reviewed** status.

The status change must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A7] (page 33)).

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### Review a workflow (SR3200.3.3.3)

The exception dashboard allows to change the status of a workflow to **Production-reviewed** and to **Reviewed**.

- To change the status to **Production-reviewed**, the workflow must be in the **Finished** status. However, exceptions do not need to be set to **Closed**.  
A decorator indicates the **Production-reviewed** status.
- To change the status to **Reviewed**, the workflow must be in the **Finished** or **Production-reviewed** status and all exceptions with a risk other than **None** must have been set to **Closed**. This does not apply to performance exceptions whose risk level is **None**. They can still be in the **Open** or **In review** statuses.  
A decorator indicates the **Reviewed** status.

The status change must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A7] (page 33)).

The status of an exported workflow cannot be changed according to the **Export Workflow for Archive (SR1085.2.10)** operation, see "Functional Requirement Specification Runtime Data Management" [A2] (page 33). **Finished** workflows remain in their status. They never reach the **Production-reviewed** or **Reviewed** status.

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### Manually inform an external QMS about an exception (SR3200.3.3.4)

- For recent changes, see revision history (page 35).

In the default configuration, the feature to send exceptions to an external QMS is disabled.

In case the feature is enabled, the system allows to configure the **Communication status** values for which the **Send exception** button is enabled and thus allows to inform the

external system. The following statuses are available: **Not sent**, **Sent**, **Received**, and **Error**. The list can be extended.

Sending an exception must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A7] (page 33)).

The system documents the send event by adding a comment to the exception. Additionally, it sets the communication status to **Sent** and the status of the exception to **In review**.

In case several exceptions are selected and at least one of the exceptions has a **Communication status** that does not allow to send exceptions, the system displays an error message and no exception is sent. If the exceptions can be sent, for each exception one event is sent.

For the content of the send event, see **Inform an External QMS about New Exceptions (SR1079.2.8)** in "Functional Requirement Specification Execution Framework" [A1] (page 33).

## Product-related Panels

### Overview Panel - Product-related (SR3200.3.5)

The product-related exception dashboard provides an Overview panel that is grouped by products and master recipes. The panel displays a representation of orders with their batches and their related unit procedures.

For batch-specific orders, the order and batch identifiers are displayed. For device-specific orders, also the serial numbers are displayed.

### Details Panel - Product-related (SR3200.3.6)

➤ For recent changes, see revision history (page 35).

The product-related Details panel provides the following filter options to display a list of recorded exceptions:

- First row
  - The **order** element displays the exceptions of all order-related unit procedures, including the exceptions of their appended workflows.
  - The **order-related unit procedure** element displays only the exceptions of this unit procedure, including the exceptions of its appended workflows.
- Second row
  - The **order-related unit procedure** element displays only the exceptions of this unit procedure, excluding the exceptions of its appended workflows.

- The **appended workflow-related unit procedure** element displays only the exceptions of this unit procedure. In this case it is not required that the access privilege of the master workflow matches the access privilege of the logged-in user.

## Workflow-related Panels

### Overview Panel - Workflow-related (SR3200.3.10)

The workflow-related exception dashboard provides an Overview panel that is grouped by the workflow's processing name and master workflow. The panel displays a representation of workflows with their work center and their unit procedure.

### Details Panel - Workflow-related (SR3200.3.11)

The workflow-related Details panel displays the exceptions of the unit procedure.

## Extensibility (SR3200.3.4+)

The exception dashboard can be extended in the following areas.

Refer to Technical Manuals for further dashboard-related extension capabilities:

- Adding Filter Attributes to the Exception Dashboard of the Production Response Client in Volume 3 of the "Technical Manual Configuration and Extension" [A3] (page 33)
- Adding the Print FDA Report Function to PharmaSuite Clients in Volume 5 of the "Technical Manual Configuration and Extension" [A4] (page 33)

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### Column (SR3200.3.4.1)

An additional column can be added to the **Overview panel (SR3200.3.2)** view (page 23), so that a system integrator can fill this column and thereby enhance the overview.

The additional column is only visible when it is used, i.e. set up by a system integrator.

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## Production Response Client (SR3071.5+)

The Production Response Client provides access to production response-related data.

### Access Control (SR3071.5.3)

The access control of the Production Response Client enables the definition of user-specific access rights.

### Framework (SR3071.5.1+)

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#### Synchronization (SR3071.5.1.1)

PharmaSuite supports the synchronization between Production Response, Production Management, and Production Execution clients that run in parallel. This applies to:

- Status of orders and workflows
- Creation of exceptions
- Creation of exception-related comments
- Status of exceptions
- Status of order steps/unit procedures
- Append/remove workflows to/from batch- or device-specific order steps

### Exception Dashboard Framework (SR3071.5.2+)

The system provides an Exception Dashboard-specific framework as part of the Production Response Client.

See also **Exception Dashboard (SR3200.3+)** requirements (page 21).

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#### Views (SR3071.5.2.1)

The exception dashboard provides

- an **Overview panel (SR3200.3.2)** view (page 23) with high-level information based on **filter (SR3200.3.1)** settings (page 21) and
- a **Details panel (SR3200.3.3)** view (page 24) with more detailed data.

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### **Docking (SR3071.5.2.2)**

The docking configuration is available as a default layout and a user-specific layout.

In the default docking configuration the panels are arranged as follows:

- To the left of the **Overview panel (SR3200.3.2)** view (page [23](#)): Filter Selection panel.

The following functions are available to maintain the docking configuration:

- Save the window layout (user-specific).
- Load the last saved window layout (user-specific).
- Reset the window layout to the default layout.

## Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM004E-EN-E
A2	PharmaSuite Functional Requirement Specification Runtime Data Management	PSFRSRT-RM004E-EN-E
A3	PharmaSuite Technical Manual Configuration & Extension - Volume 3	PSCEV3-GR008E-EN-E
A4	PharmaSuite Technical Manual Configuration & Extension - Volume 5	PSCEV5-GR005E-EN-E
A5	PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM006E-EN-E
A6	PharmaSuite Functional Requirement Specification Output Weighing	PSFRSOW-RM002E-EN-E
A7	PharmaSuite Functional Requirement Specification Non-functional Requirements	PSFRSNF-RM001E-EN-E

### TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

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## Document Information

The document information covers various data related to the document.

### Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Martin Dittmer	Product Manager
Steffen Landes	Development Manager
Martin Irmisch	Test Manager

In addition, the electronic document approval via DMS is confirmed by a handwritten signature of all approvers in the Quality Document when the release is completed. The Quality Document summarizes the quality-related planning activities and results of a PharmaSuite release.

### Version Information

Object	Version
PharmaSuite	8.4
Functional Requirement Specification	1.0

### Revision History

The following table describes the history of this document.

Changes related to the document:

Object	Description	Document
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Changes related to "Review and Approval" (page 3):

Object	Description	Document
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Changes related to "Batch Production Record" (page 5):

Object	Description	Document
---	---	---

Changes related to "Batch Production Report" (page 7):

Object	Description	Document
---	---	---

Changes related to "Device History Report" (page 11):

Object	Description	Document
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Changes related to "Workflow Report" (page 15):

Object	Description	Document
---	---	---

Changes related to "Dispensing Report" (page 19):

Object	Description	Document
---	---	---

Changes related to "Exception Dashboard" (page 21):

Object	Description	Document
Filter (SR3200.3.1) (page 21)	Update PharmaSuite supports the concept of confidential objects to protect the intellectual property of recipes, workflows, orders, and related data from unauthorized access.	1.0

Object	Description	Document
Details Panel (SR3200.3.3) (page 24)	Update Multi-selection of exceptions is supported to inform an external QMS. The availability of the adding a CAPA ID feature depends on the system configuration. New features whose availability depends on the system configuration: Display of the <b>Communication status</b> and <b>External ID</b> of an external QMS, Sending exceptions to an external QMS.	1.0
Review an Order (SR3200.3.3.2) (page 26)	Update PharmaSuite supports the concept of confidential objects to protect the intellectual property of recipes, workflows, orders, and related data from unauthorized access.	1.0
Manually Inform an External QMS about an Exception (SR3200.3.3.4) (page 27)	New New feature to manually inform an external QMS about an exception.	1.0
Details Panel - Product-related (SR3200.3.6) (page 28)	Update PharmaSuite supports the concept of confidential objects to protect the intellectual property of recipes, workflows, orders, and related data from unauthorized access.	1.0

Changes related to "Production Response Client" (page 31):

Object	Description	Document
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