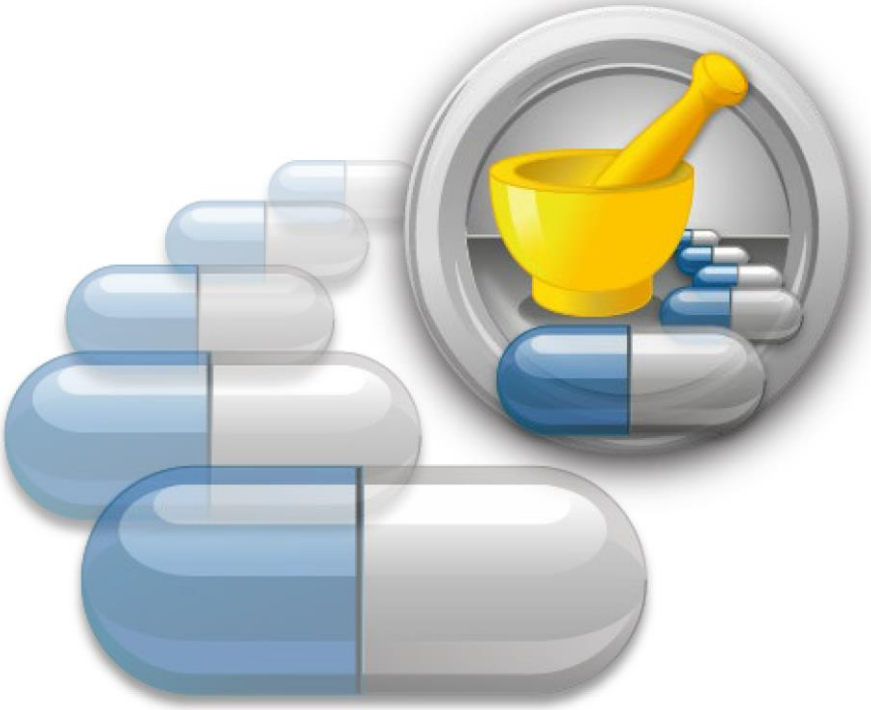
PharmaSuite®



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Rockwell Automation

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Chapter 1

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 37) lists the changes made to the document with PharmaSuite 10.01.00 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:

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).

Chapter 2

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 supports 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 23).
- 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 23).
- The exception dashboard of the **Production Response Client (SR3071.5+)** application (page 33) 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, workflow).
  See **Exception Dashboard (SR3200.3+)** requirements (page 19).

This description is structured in the following sections:

- **Batch Production Record (SR3200.1+)** requirements (page 5)
- **Batch Production Report (SR3200.2+)** requirements (page 7)
- **Workflow Report (SR3200.4+)** requirements (page 11)
- **Dispensing Report (SR1090.4.7)** requirements (page 15)
- **Exception Dashboard (SR3200.3+)** requirements (page 19)
- **Production Response Client (SR3071.5+)** requirements (page 33)

Chapter 3

Batch Production Record (SR3200.1+)

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
- Order-related changes triggered by specific events as defined in the **Order and Workflow Changes (SR1084.30)** requirement (see "Functional Requirement Specification Runtime Data Management" [A2] (page 35)).

Chapter 4

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
- Order-related changes
- 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
- Order-related changes
- Exceptions
- Order-related BOM items
- Appended workflows
- Procedure
  - Unit procedure(s)
    - Operation(s)

Order-related changes (SR3200.2.1.8)

The section for the order-related changes presents the following information, ordered by order step identifier:

- Description of change
- Type of change
- Logged-in user / Signature
  - In case no signature is configured, the data of the logged-in user is tracked.
  - In case a double signature is configured, the data of the second signer is also tracked.
  - With signature(s):
    --- / First signer (first and last name, (login name))
    Timestamp / Reason
    / Comment
    Second signer (first and last name (login name))
    Timestamp / Reason
    / Comment
  - Without signature:
    Logged-in user (first and last name, (login name))
    Timestamp / ---

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, Classification
- Category
- Control recipe element
- Signature (first and last name, (login name), reason, timestamp)

Signature comments of signatures that automatically trigger the creation of an exception are treated as exception-related comments and are marked by "Signature comment:" or "2nd signature comment:", respectively.

Classification only if maintenance of exception classification is not disabled.

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.

Batch report and hidden phases (SR3200.2.1.9)

If a phase has the **Hide in batch/workflow report** attribute flagged and has no exception reference, its phase sub-report is not part of the batch report.

The attribute is maintained in the **element component-specific (SR3146.9.2.12)** property window of the phase (see "Functional Requirement Specification Recipe and Workflow Management" [A9] (page 35)).

Layout per Usage Type (SR3200.2.2+)

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

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.

Chapter 5

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
- Workflow-related changes
- 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
- Workflow-related changes
- Exceptions
- Procedure
  - Unit procedure(s)
    - Operation(s)

Workflow-related changes (SR3200.4.1.8)

The section for the workflow-related changes presents the following information, ordered by workflow step identifier:

- Description of change
- Type of change
- Logged-in user / Signature
  - In case no signature is configured, the data of the logged-in user is tracked.
  - In case a double signature is configured, the data of the second signer is also tracked.
  - With signature(s):
    --- / First signer (first and last name, (login name))
    Timestamp / Reason
    / Comment
    Second signer (first and last name (login name))
    Timestamp / Reason
    / Comment
  - Without signature:
    Logged-in user (first and last name, (login name))
    Timestamp / ---

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
  - Production-reviewed by (login and user name, timestamp)
  - Production review comment
  - 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, Classification
- Category
- Workflow element
- Signature (first and last name, (login name), reason, timestamp)

Signature comments of signatures that automatically trigger the creation of an exception are treated as exception-related comments and are marked by "Signature comment:" or "2nd signature comment:", respectively.

Classification only if maintenance of exception classification is not disabled.

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.

Workflow report and hidden phases (SR3200.4.1.9)

If a phase has the **Hide in batch/workflow report** attribute flagged and has no exception reference, its phase sub-report is not part of the workflow report.

The attribute is maintained in the **element component-specific (SR3146.9.2.12)** property window of the phase (see "Functional Requirement Specification Recipe and Workflow Management" [A9] (page 35)).

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 35) and "Functional Requirement Specification Output Weighing" [A6] (page 35).

Signature Data (SR1090.4.7.5)

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

- Signature meaning
- User (first and last name, (login name))
- 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, Classification
- Category
- Control recipe element
- Signature (first and last name, (login name), reason, timestamp)

Signature comments of signatures that automatically trigger the creation of an exception are treated as exception-related comments and are marked by "Signature comment:" or "2nd signature comment:", respectively.

Classification only if maintenance of exception classification is not disabled.

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**.

Chapter 7

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 have **N/A** as fixed status that cannot and need not be closed to set an order or workflow to **Reviewed**.

Filter (SR3200.3.1)

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 21).

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 21).

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 21).

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]
- Treatment ID (if configured)
- Material description
- Master recipe/workflow identifier
- Unit procedure identifier
- Unit procedure start and completion [dates]
- Has workflows [assigned]
- Exception classification (if configured)
- Exception result
- Exception CAPA ID (if configured)
- Exception has bookmark
- 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 batch-related orders 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 30)
- **Overview panel - Workflow-related (SR3200.3.10)** feature (page 30)

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 22).

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 21).

Workflow appended (SR3200.3.2.6)

For each batch-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-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 21) of the unit procedure and the indicator of not yet closed exceptions (see **color of status indication (SR3200.3.2.2.1)** feature (page 22)).

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 30)
- **Details panel - Workflow-related (SR3200.3.11)** feature (page 31)

Details Panel (SR3200.3.3)

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

- Exception Explorer displays orders, workflows, and started unit procedure down to the phases with the following details:
  - Start and completion times of the elements.
  - Order/workflow identifier
  - Procedure identifier (number of active or completed unit procedures (if > 0))
  - Unit procedure identifier [instance count (if > 1)] / Work center identifier (number of active or completed operations (if > 0))
  - Operation [instance count (if > 1)] (number of active or completed phases (if > 0))
  - Phase identifier [instance count (if > 1)] [(Hidden) if phase is flagged as **Hide in batch/workflow report** and suppressed]
  - Operations and phases for which exceptions have been recorded are indicated by a colored identifier.
  - Operations and phases whose exceptions are selected in the Exception List are indicated by a colored background.

- Exception List displays a list of recorded exceptions and their comments (per unit procedure, order, or workflow). The exceptions can relate to phases, operations, or unit procedures.
  - Comments to an exception are collapsible.
  - The exceptions of the list can be filtered.
    - The following filter attributes are available: Bookmark, Exception text, Status, Risk, Classification (only if configured), Result
    - The last applied filter definition is stored user-specifically and is used automatically the next time the user opens the details panel (even after a client restart).
    - A quick search function can be applied to the search result and reduces the result according to the filter criteria.
- Display and print the batch report or the workflow report in a preview window.
- Display the phase-, operation-, and unit procedure-specific excerpt of the batch report or the workflow report with exceptions (if applicable) 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 35).
  Exceptions can no longer be added to orders or workflows that are already in the **Reviewed** status.
- Comments can be added to the selected exception(s).
  See **Comments related to an Exception (SR1079.2.3)** in "Functional Requirement Specification Execution Framework" [A1] (page 35).
  Comments to exceptions can no longer be added if the order or workflow is already in the **Reviewed** status.
  It is not possible to add a comment to a locked exception. See **Locked Exception (SR1079.2.3.5)** in "Functional Requirement Specification Execution Framework" [A1] (page 35). The lock is made visible to others by displaying the **Under review** indicator text and the user name of the user who holds the lock.
- A single-selected exception 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 27).

  Before the status transition to **Reviewed** is executed on an order, the system checks if there are still operation object locks remaining related to the order. If so, it denies the status transition. This check prevents the creation of an exception in the **Open** status that would be recorded for the order if the operation object lock were removed after the status transition.

- Status of a workflow can be changed to **Production-reviewed** and to **Reviewed**, see **Review a workflow (SR3200.3.3.3)** feature (page 28).

  Before the status transition to **Reviewed** is executed on a workflow, the system checks if there are still operation object locks remaining related to the workflow. If so, it denies the status transition. This check prevents the creation of an exception in the **Open** status that would be recorded for the workflow if the operation object lock were removed after the status transition.

- Multi-selection of exceptions is supported to add a comment and to inform an external QMS.
  - The list of pre-defined texts to be added as a review comment to the exception comment in case multiple exceptions are selected depends on the system configuration.

    For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Manual Configuration and Extension" [A8] (page 35).

  - Multi-selection of exceptions is prevented by the system in case an exception is locked. The user is informed and the locked exceptions are automatically unselected.
  - Multi-selection of exceptions with the **None** risk class and other risk classes than **None** is prevented by the system. The user is informed and exceptions with the **None** risk class are automatically unselected.
  - Multi-selection of exceptions in the **Closed** status and other statuses than **Closed** is prevented by the system if the user does not have the access privileges to comment a closed exception. The user is informed and the closed exceptions are automatically unselected.
- The access to the following features depends on the system configuration:
  - Changing risk or status of exception
  - Changing classification 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 35).
  - 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 29).
  - Disabled in the default configuration.

Signature comments of signatures that automatically trigger the creation of an exception are treated as exception-related comments and are marked by "Signature comment:" or "2nd signature comment:", respectively.

In the report preview window, the report (batch, workflow) is positioned at the start of the report or at the selected unit procedure when called using the standard button.

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 35):

- 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 the selected exception(s).
  Adding a comment to a closed exception is additionally controlled by the **PRC_AccessRight_AddCommentForClosedException** access privilege. Without the access privilege, a closed exception can only be bookmarked. Other input fields and buttons of the exception recording panel are disabled.
- A single-selected exception can be bookmarked to simplify the review process. Bookmarks can be removed.

See "Functional Requirement Specification Execution Framework" [A1] (page 35).

Review an order (SR3200.3.3.2)

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.
- The sensitivity of the button to change the status to **Production-reviewed** is additionally controlled by the **PRC_AccessRight_PerformProductionReview** access privilege.

- 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.
  The automatic review of workflows together with the order can be disabled by configuration key.

  For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Manual Configuration and Extension" [A8] (page 35).

  A decorator indicates the **Reviewed** status.

- The sensitivity of the button to change the status to **Reviewed** is additionally controlled by the **PRC_AccessRight_PerformQAReview** access privilege.

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 35)).

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.

- The sensitivity of the button to change the status to **Production-reviewed** is additionally controlled by the **PRC_AccessRight_PerformWFProductionReview** access privilege.

- 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 sensitivity of the button to change the status to **Reviewed** is additionally controlled by the **PRC_AccessRight_PerformQAWFReview** access privilege.

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 35)).

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 35). **Finished** workflows remain in their status. They never reach the **Production-reviewed** or **Reviewed** status.

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

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 35)).

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 35).

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 and treatment IDs are displayed.

Details Panel - Product-related (SR3200.3.6)

In its Object Information panel, the product-related Details panel provides the following filter options to display the structure of the selected elements and its list of recorded exceptions:

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

Details Panel - Workflow-related (SR3200.3.11)

In its Object Information panel, the workflow-related Details panel provides the following filter options to the structure of the selected element and its list of recorded exceptions:

- The **workflow** element displays the structure of the workflow and the exceptions of its unit procedure.
- The **workflow-related unit procedure** element displays the structure and the exceptions of this 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 35)
- Adding the Print FDA Report Function to PharmaSuite Clients in Volume 5 of the "Technical Manual Configuration and Extension" [A4] (page 35)

Column (SR3200.3.4.1)

An additional column can be added to the **Overview panel (SR3200.3.2)** view (page 21), 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.

Chapter 8

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+)

Synchronization (SR3071.5.1.1)

PharmaSuite supports the synchronization between Production Response, Production Management, Production Execution clients, and Data Manager 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-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 19).

Views (SR3071.5.2.1)

The exception dashboard provides

- an **Overview panel (SR3200.3.2)** view (page 21) with high-level information based on **filter (SR3200.3.1)** settings (page 19) and
- a **Details panel (SR3200.3.3)** view (page 23) with more detailed data.

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 21): Filter Selection panel.
- In the **Details panel (SR3200.3.3)** view (page 23), below the Exception List: Exception Recording 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-RM006C-EN-E
A2	PharmaSuite Functional Requirement Specification Runtime Data Management	PSFRSRT-RM006C-EN-E
A3	PharmaSuite Technical Manual Configuration & Extension - Volume 3	PSCEV3-GR010C-EN-E
A4	PharmaSuite Technical Manual Configuration & Extension - Volume 5	PSCEV5-GR007B-EN-E
A5	PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM008B-EN-E
A6	PharmaSuite Functional Requirement Specification Output Weighing	PSFRSOW-RM004B-EN-E
A7	PharmaSuite Functional Requirement Specification Non-functional Requirements	PSFRSNF-RM003C-EN-E
A8	PharmaSuite Technical Manual Configuration & Extension - Volume 4	PSCEV4-GR010C-EN-E
A9	PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM010C-EN-E

TIP

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

Appendix A

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
Norbert Ern	Product Owner
Fabian Hofsäß	Technical Lead
Ignaz Wangler	Test Lead

Version Information

Object	Version
PharmaSuite	10.02.00
Functional Requirement Specification	1.1

Revision History

The following tables describe 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
---	---	---

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 "Workflow Report" (page 11):

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

Changes related to "Dispensing Report" (page 15):

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

Changes related to "Exception Dashboard" (page 19):

Object	Description	Document
Exception Dashboard (SR3200.3+) (page 19)	Context information-related The latter are indicated by the **None** risk level and have **N/A** as fixed status that cannot and need not be closed to set an order or workflow to **Reviewed**.	1.0
Details Panel (SR3200.3.3) (page 23)	Editorial A single-selected exception can be bookmarked to simplify the review process. Update Multi-selection of exceptions is prevented by the system in case an exception is locked. The user is informed and the locked exceptions are automatically unselected. Multi-selection of exceptions with the **None** risk class and other risk classes than **None** is prevented by the system. The user is informed and exceptions with the **None** risk class are automatically unselected. Multi-selection of exceptions in the **Closed** status and other statuses than **Closed** is prevented by the system if the user does not have the access privileges to comment a closed exception. The user is informed and the closed exceptions are automatically unselected.	1.0
Exception Management (SR3200.3.3.1) (page 27)	Update Adding a comment to a closed exception is additionally controlled by the **PRC_AccessRight_AddCommentForClosedException** access privilege. Without the access privilege, a closed exception can only be bookmarked. Other input fields and buttons of the exception recording panel are disabled. Editorial A single-selected exception can be bookmarked to simplify the review process.	1.0
Details Panel (SR3200.3.3) (page 23)	Editorial Information added to the status change to **Reviewed** for orders and workflows, respectively: Before the status transition to **Reviewed** is executed on an order/a workflow, the system checks if there are still operation object locks remaining related to the order/workflow. If so, it denies the status transition. This check prevents the creation of an exception in the **Open** status that would be recorded for the order/workflow if the operation object lock were removed after the status transition.	1.1

Changes related to "Production Response Client" (page 33):

Object	Description	Document
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