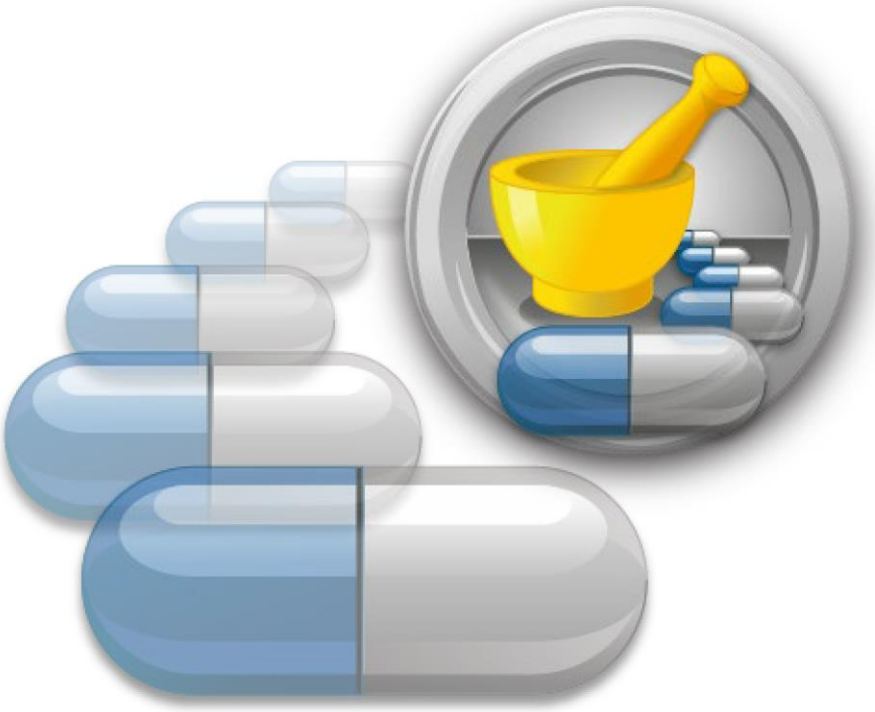
PharmaSuite®



RUNTIME DATA MANAGEMENT

RELEASE 10.02.00

FUNCTIONAL REQUIREMENT SPECIFICATION

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Chapter 1

Introduction

This document details the requirements of the functions implemented for runtime master data management with PharmaSuite. The management includes order management (page 3), workflow management (page 43), as well as archive and purge management (page 55).

Each requirement is composed of a name and a unique identifier (e.g., Workflow attributes (SR1085.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g., Workflow Management (SR1085+)).

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 71) lists the changes made to the document with PharmaSuite 10.02.00 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

Order Management (SR1084+)

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

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

On the basis of its assigned master recipe, material, and quantity, the order is exploded to generate all order-related objects that are necessary for executing the order. This includes order steps based on the respective unit procedures and order step inputs/outputs based on the respective material parameters. The generated order steps have to be released for processing at the specified work centers.

For details about the **Batch Production Report (SR3200.2+)**, see "Functional Requirement Specification Review and Approval" [A3] (page 69).

PMC Order Management (SR3071.3.5)

The Production Management Client provides specific features to support the management of orders.

PMC Workflow Management (SR3071.3.7)

The Production Management Client provides specific features to support the management of workflows.

Supported Order Types (SR1084.1)

PharmaSuite supports batch orders.
An order contains all information necessary to define the resources that are required to produce a target product with the specified order quantity.

At the latest when an order is started, the system checks that the basic information required for executing the order is available in the system and can be accessed.

The minimum information required to start the order execution includes the following attributes:

- Material
- Master recipe
- Planned quantity.

Status Management of Orders and Workflows (SR1084.4)

The system supports the following default transitions for orders and workflows:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Defined	---	Automatic transition.
1.2 - Exploded » Defined	---	---
2.1 - Defined » Exploded	---	---
2.2 - Released » Exploded	---	---
3.1 - Exploded » Released	---	---
4.1 - Released » In process	---	Implicit transition.
4.2 - Reactivated » In process	---	Implicit transition.
5.1 - In process » Finished	---	Implicit transition. See **Order and Workflow Changes (SR1084.30)** for an automatically created exception (page 11).
5.2 - In process » Finished	MES_ES_POI_Status_Trans_FinishWithAborted	See **Finish Order With Aborted Order Steps (SR1084.42)** for details (page 25) and **Order and Workflow Changes (SR1084.30)** for an automatically created exception (page 11).

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
6.1 - Defined » Annulled	MES_Status_Trans_Cancel	---
6.2 - Exploded » Annulled	MES_Status_Trans_Cancel	---
6.3 - Released » Annulled	MES_Status_Trans_Cancel	---
7.1 - In process » Canceled	MES_Status_Trans_Cancel	For orders: In Production Management Client only.
8.1 - Finished » Reactivated	MES_Status_Trans_Reactivate	---
9.1 - Finished » Reviewed	MES_ES_POI_Status_Trans_Reviewed	Manual transition (change status) in Production Response Client. All exceptions with a risk other than **None** that have been recorded must have been set to **Closed**. For orders, appended workflows must be in the **Finished**, **Production-reviewed**, or **Reviewed** status.
9.2 - Finished » Reviewed	---	Automatic transition, see **Automatic Review of an Order (SR1084.4.1.1)** for order-specific details (page 7) and **Automatic Review of a Workflow (SR1084.4.1.2)** for workflow-specific details (page 7).
9.3 - Production-reviewed » Reviewed	MES_ES_POI_Status_Trans_Reviewed (in case of a batch order) MES_ES_POI_Status_Trans_WFReviewed (in case of a workflow)	In Production Response Client only. All exceptions with a risk other than **None** that have been recorded must have been set to **Closed**.
10.1 - Finished » Production-reviewed	MES_ES_POI_Status_Trans_ProductionReviewed (in case of a batch order) MES_ES_POI_Status_Trans_WFProductionReviewed (in case of a workflow)	In Production Response Client only. Exceptions do not need to be set to **Closed**.

The diagram illustrates the **ProcessOrderItemStatus83** flexible state model.

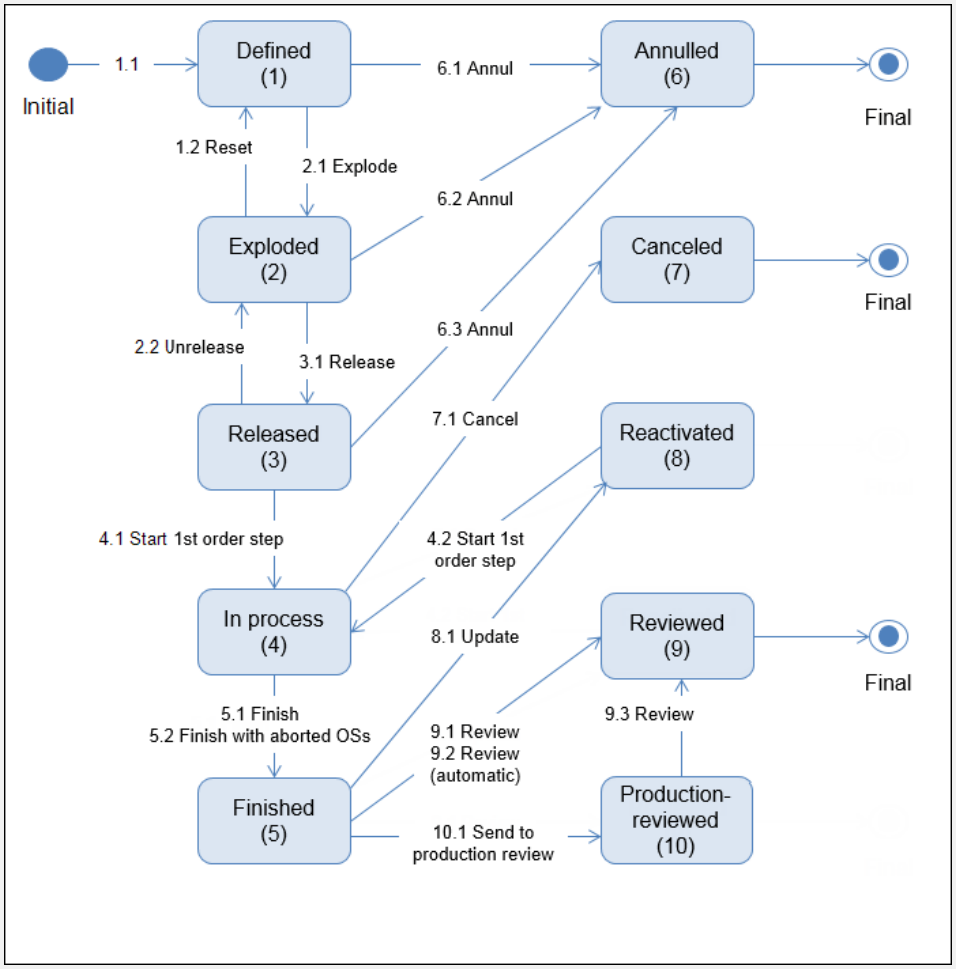

Figure 1: Order and workflow - status graph

Automatic Status Transition to Reviewed (SR1084.4.1+)

Automatic Review of an Order (SR1084.4.1.1)

The status of the order is automatically changed to **Reviewed**, once the order has been set to **Finished** and no exceptions with a risk other than **None** have been recorded for the order or any of its appended workflows (see **Review mode attribute (SR3146.9.3.2)** of the master recipe in "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 69)).

Automatic Review of a Workflow (SR1084.4.1.2)

The status of the workflow is automatically changed to **Reviewed**,

- once the workflow has been set to **Finished** and no exceptions with a risk level other than **None** have been recorded for the workflow (see **Review mode attribute (SR3146.9.12.2)** of the master workflow in "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 69)) and
- for appended workflows in the **Finished** or **Production-reviewed** statuses, if the status of one of the corresponding orders is changed to **Reviewed** in the Production Response Client (see **Review an order (SR3200.3.3.2)** operation in "Functional Requirement Specification Review and Approval" [A3] (page 69)). For this automatic review, no user-related access privilege is verified. If workflows shall always be reviewed by other user groups than orders, the automatic review can be disabled by configuration key (**LibraryHolder/apps-exceptiondashboard-impl.jar/EnableAutomaticReviewOfWorkflowWithOrder**).

  For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Manual Configuration and Extension" [A9] (page 69).

Status Management of Order Steps and Workflow Steps (SR1094.11)

The system supports the following default transitions for order steps and workflow steps:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Generated	---	Automatic transition.
1.2 - Generated » Generated	---	Implicit transition after an order with several order steps was canceled.
2.1 - Generated » In process	---	Start processing of order step (unit procedure), in Production Execution Client only.
2.2 - Reactivated » In process	---	Start processing of order step (unit procedure), in Production Execution Client only.
2.3 - Held » In process	---	Start processing of order step (unit procedure), in Production Execution Client only.
3.1 - In process » Finished	---	Implicit transition after the completion of the last operation.
3.2 - Finished » Finished	---	Implicit transition after an order with several order steps was canceled.
4.1 - Finished » Reactivated	PMC_ES_OS_Non-WD_Reactivate	Reactivation of non-Dispense order step. See **Reactivate Dispense Order Step Manually (SR1084.31)** for Dispense-specific details (page 27).
4.2 - Aborted » Reactivated	PMC_ES_OS_Non-WD_Reactivate	Reactivation of non-Dispense order step.
4.3 - In process » Reactivated	---	Reactivation of order step (unit procedure), in Production Execution Client only.

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
4.4 - Reactivated » Reactivated	---	Implicit transition after an order with several order steps was canceled.
5.1 - Generated » Annulled	MES_Status_Trans_Cancel	Not available in the UI.
6.1 - In process » Canceled	MES_Status_Trans_Cancel	Implicit transition after an order was canceled.
7.1 - In process » Aborted	PMC_ES_OS_Non-WD_Abort	Abortion of non-Dispense order step.
7.2 - Held » Aborted	PMC_ES_OS_Non-WD_Abort	Abortion of non-Dispense order step.
7.3 - Aborted » Aborted	---	Implicit transition after an order with several order steps was canceled.
8.1 - In process » Held	---	Detaching of order step (unit procedure), in Production Execution Client only.
8.2 - Held » Held	---	Implicit transition after an order with several order steps was canceled.
9.1 - Generated » Final aborted	PMC_ES_OS_Final_Abort	Final abort of order step (unit procedure), in Production Management Client only.
9.2 - Reactivated » Final aborted	PMC_ES_OS_Final_Abort	Final abort of order step (unit procedure), in Production Management Client only.
9.3 - Held » Final aborted	PMC_ES_OS_Final_Abort	Final abort of order step (unit procedure), in Production Management Client only.
9.4 - In process » Final aborted	PMC_ES_OS_Final_Abort	Final abort of order step (unit procedure), in Production Management Client only.

The diagram illustrates the **OrderStepStatus92** flexible state model.

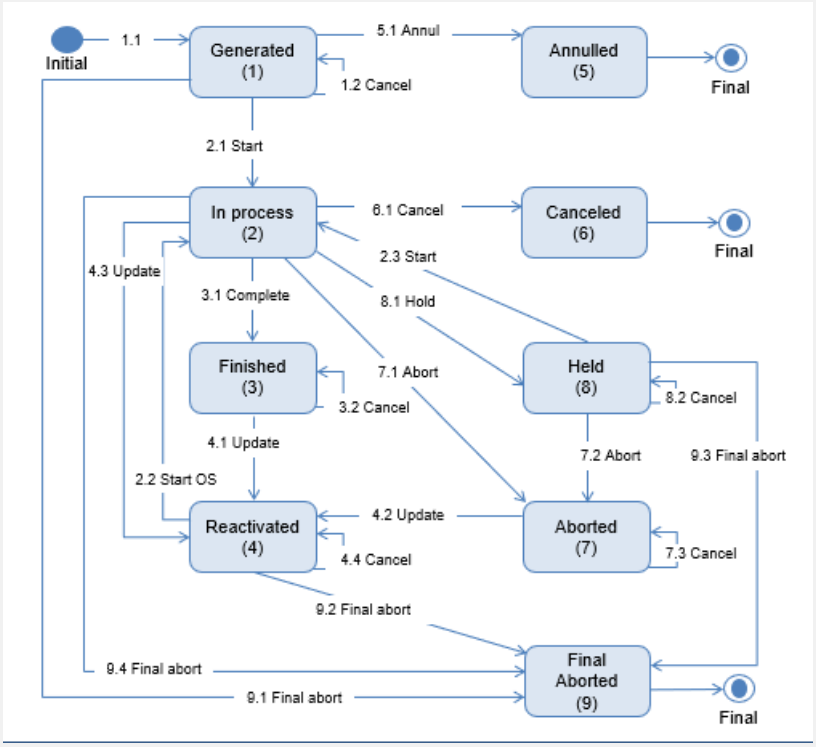

Figure 2: Order step and workflow step - status graph

Propagation of Order Step and Workflow Step Statuses (SR1084.15)

The system propagates status transitions of order steps to the related order. The same applies to workflows and their steps.

Details of the propagation of order step status (SR1084.15.1)

Action	Order step status	Order status
Start first order step of an order	In process	In process
Finish last order step of a recipe path of an order	Finished	Finished
Final abort the last order step of a recipe path of an order	Final aborted	Finished

Order and Workflow Changes (SR1084.30)

For orders or workflows in a status equal to or higher than **Exploded**, the system tracks the following changes.

Orders

- Adding a new **alternative material (order step input) (SR1084.27)** event (page 35)
- Editing the comment of an order
- Editing the comment of an order step
- **Dispatching order steps (SR1084.24)** event (page 26)
- **Allocating batches (SR1084.16)** event (page 33)
- Adding **material-related comments for non-Dispense order steps (SR1084.37)** event (page 41)

Workflows

- Editing the comment of a workflow
- Editing the comment of a workflow step
- **Dispatching workflow steps (SR1085.4.1)** event (page 53)

The system tracks the following data related to the changes:

- Type of the change
- Description of the change
- Reference to the order or workflow
- 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.
- Timestamp (of entry)

When an order or workflow changes its status from **In process** to **Finished,** the system shall check if order or workflow changes have been tracked. If so, the system automatically records an "order/workflow changes"-specific exception for the unit procedure.

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Comparison of Similar Order Step Operations

	Abort OS (SR1084.44) (page 29)	**Abort Non-Dispense OS (SR1084.36) (page 28)**	**Reactivate Non-Dispense OS Manually (SR1084.35) (page 28)**	**Detach UP (SR1089.8.4+) in [A2] (page 69)**	**Reactivate UP (SR1089.8.5) in [A2] (page 69)**
PharmaSuite Client	Production Management Client	Production Management Client	Production Management Client	Production Execution Client	Production Execution Client
Availability depends on	OS status Order status	OS status	OS status	Capability	Capability
Required OS status	Generated, In process, Held, Reactivated	In process	Finished, Aborted	In process	In process
Required UP status	N/A	N/A	Finished, Aborted	Running	Running
UP is paused	Allowed	N/A	N/A	Not allowed.	Allowed
Restrictions related to operations	N/A	N/A	N/A	No running operations.	N/A
Exception handling	Signature with automatic recording of specific exception.	Signature with automatic recording of specific exception.	Signature with automatic recording of specific exception.	Defined in capability.	Defined in capability, added to aborted unit procedure.
Comment to exception	N/A	N/A	N/A	At resume of unit procedure.	N/A
Equipment is bound to UP	Automatic unbind.	Automatic unbind.	N/A	No unbind.	Automatic unbind.

LEGEND

OS	order step
UP	unit procedure

Chapter 3

Batch-specific Order Management

Batch Order Attributes (SR1084.38)

The following attributes are available for batch-specific orders:

- Read-only
  - Order
    - Identifier
    - Status
    - Exported for archive (Exported, Not exported)
    - Actual quantity
    - Planned quantity
    - Usage type
    - Actual start date
    - Actual end date
    - ERP start date
    - ERP end date
    - Planned start date
    - Planned end date
    - Material identifier and description
  - Master recipe
    - Identifier
    - Description
    - Method
    - Method description
    - Review mode

- Editable (depends on the status (page 17))
  - Target batch
  - Comment
  - Treatment ID

Batch Order Operations (SR1084.1.2+)

The following operations are supported for batch orders:

- Create (see **Create order (SR1084.1.2.1)** operation (page 17))
- Filter (see **Filter for Orders (SR1084.1.2.6)** operation (page 17))
- View (see **View order (SR1084.11)** operation (page 22))
- Edit (see **Edit order - Allowed (SR1084.1.2.2)** operation (page 17))
- Create target batch (see **Assign target batch (SR1084.5.3)** operation (page 20))
- Unassign batch from order (see **Assign target batch (SR1084.5.3)** operation (page 20))
- Explode order (see **Explode order (SR1084.9)** operation (page 21))
- Release order (see **Release order (SR1084.25)** operation (page 23))
- Unrelease order (see **Release order (SR1084.25)** operation (page 23))
- Reset order (see **Explode order (SR1084.9)** operation (page 21))
- Cancel order (see **Cancel order (SR1084.3)** operation (page 19))
- Change status
- View status transition history of the order
- Open batch report

  Displays the batch report of the order in a preview window for performing reviews by exception.
  The order must be in the **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status.

- Print batch report

  Displays the batch report of the order in a preview window for printing.
  The order must be in the **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status.

- Export order (see **Export order for archive (SR1084.40)** operation (page 23))
- Purge order (see **Purge order (SR1084.41)** operation (page 25))

- Finish order with aborted order steps (see **Finish order with aborted order steps (SR1084.42)** operation (page 25))
- Force execution transition (see **Force execution transition (SR1084.43)** operation (page 26))

In an exceptional situation it may be necessary to repair a corrupted process (order) by unloading it from the EBR server. For an unloaded order or its order steps, operations are not disabled even though they cannot be performed. For details related to unloaded processes, see **Unload and Reload Procedures of Orders and Workflows (SR1200.2.2)** in "Functional Requirement Specification Execution Framework" [A2] (page 69).

The following operations are also supported for order steps:

- View status transition history of the order step

Filter for Orders (SR1084.1.2.6)

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

Create Order (SR1084.1.2.1)

During order creation, the system allows the supervisor to initially define the following attributes:

- Order identifier (mandatory, unique, insert only)
  Uniqueness of order identifier includes purged orders.
- Target material (mandatory, insert only).

An order is of the Production usage type if it has not been defined on the shop floor. The usage type of shop floor-defined orders reflects their respective use cases (e.g. Cost center).

Edit Order - Allowed (SR1084.1.2.2)

The system allows the supervisor to change the following editable attributes or to perform the following operations depending on the order's status (page 4):

Attribute/Operation	Order status
Master recipe (see **Select master recipe (SR1084.1.2.2.1)** operation (page 18))	Defined
Planned quantity	Defined
Scheduling data	Defined, Exploded
Comment	Defined, Exploded

Attribute/Operation	Order status
Target batch (see **Assign target batch (SR1084.5.3)** operation (page 20))	Defined, Exploded
Work centers (of order steps)	Defined, Exploded
Treatment ID	Defined (no target batch assigned)
Batch allocations (of order step inputs, see **Allocate batches SR1084.16** operation (page 33))	Defined, Exploded
Explode order (SR1084.9) operation (page 21)	Defined
Reset order (see **Explode order (SR1084.9)** operation (page 21))	Exploded

SELECT MASTER RECIPE (SR1084.1.2.2.1)

The system allows to define an access privilege for the protection of master recipes from unauthorized access. Subsequently, it shall only allow to select a master recipe whose access privilege matches the access privilege of the logged-in user.

The system allows to select a batch master recipe depending on the following conditions:

- If an order is **production-related** (usage type is empty or **Production**), only those master recipes are available for selection that are production-related (usage type is empty or **Production**).
- If an order is **not production-related**, only master recipes of the specific usage type can be selected (e.g. **Cost center**). Only applicable if an order was created as a shop floor-defined order and the order explosion has been reset.

Edit Order - Restricted (SR1084.1.2.3)

The system allows the supervisor to change the following editable attributes or to perform the following operations depending on the order's status (page 4):

Attribute/Operation	Order status
Comment	Released, In process
Work centers (of order steps, only in the **Generated**, **Held**, or **Reactivated** status (page 8) of the order step, see **Dispatch order steps (SR1084.24)** operation (page 26))	Released, In process
Batch allocations (of order step inputs, only in the **Generated** or **Reactivated** status (page 8) of the order step, see **Allocate batches SR1084.16** operation (page 33))	Released, In process
Reset order (sets the status to **Exploded**)	Released
Annul order (sets the status to **Annulled**)	Defined, Exploded, Released

Attribute/Operation	Order status
Cancel order (SR1084.3) operation (page 19) (sets the status to **Canceled**)	In process
Change the status to **Production-reviewed** (This operation is only available in the Production Response Client (see **Review an order (SR3200.3.3.2)** operation in "Functional Requirement Specification Review and Approval" [A3] (page 69).)	Finished
Change the status to **Reviewed** (This operation is only available in the Production Response Client (see **Review an order (SR3200.3.3.2)** operation in "Functional Requirement Specification Review and Approval" [A3] (page 69).)	Finished, Production-reviewed
Export order for archive (SR1084.40) operation (page 23)	Canceled, Reviewed
Purge order (SR1084.41) operation (page 25)	Annulled With restrictions: Canceled, Reviewed
Finish order with aborted order steps (SR1084.42) operation (page 25)	In process

Edit Order - Not Allowed (SR1084.1.2.4)

The system does not allow the supervisor to change attributes of an order or order step when they are in the following order statuses (page 4) or order step statuses (page 8):

Object	Order status	Order step status
Order and its order steps	Canceled, Annulled, Reviewed	Any
Order step	Any	Finished

Cancel Order (SR1084.3)

The system allows to cancel an order.

The system automatically records a "cancel order"-specific exception for all active phases of the order. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

CANCEL ORDER - CONSTRAINTS (SR1084.3.1)

The system allows to cancel an order when the order is in the **In process** status (page 4).

The potential cleanup of already produced sublots of intra materials is not automatically performed.

By default, the cancelation of an order is treated as an exception and must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

A system integrator can configure whether an electronic signature is required.

CANCEL ORDER - STATUS PROPAGATION (SR1084.3.1.2)

When an order is canceled, the status transition is propagated to its order steps in the **In process** status (page 8).

CANCEL ORDER - NO ORDER STEP EXECUTION (SR1084.3.2)

When an order is canceled, the system ensures that its order steps cannot be started and/or executed anymore.

CANCEL ORDER - TERMINATION OF PROCEDURAL ELEMENTS (SR1084.3.2.1)

When an order is canceled, all related phases, operations, unit procedures, and procedures are terminated automatically and are no longer visible as running processes in the Cockpit of the Production Execution Client.
At each of the related Production Execution Clients, the system displays an appropriate message.
Termination of related phases and operations also applies to server-run operations, which run on the Operation Execution server without any user interaction.

Assign Target Batch (SR1084.5.3)

The system allows the supervisor to create a target batch for an order when the order is in the **Defined** or **Exploded** statuses (page 4).

The batch identifier is a non-editable attribute of the order.

However, if a target batch has been assigned to an order, a supervisor can unassign the batch from an order in the **Defined** or **Exploded** statuses. After the target batch has been unassigned, a new assignment is possible for orders in the **Defined** or **Exploded** statuses.

The system sets the batch status to **Quarantined**.
See also **Batch - Initial Status (SR1076.4.1.2)** in "Functional Requirement Specification Data Management" [A7] (page 69).

Target Batch Generation (SR1084.1.1)

Unless defined or generated before, the batch is created at the latest by the system during the start of the first order step on the shop-floor level.

Target Batch Treatment ID Assignment (SR1084.1.1.1)

At the time of target batch creation, the treatment ID is passed on from the order to the batch.

Intra Material Batch Treatment ID Assignment (SR1084.1.1.2)

Any time an outgoing batch for an order step is created, the treatment ID is passed on from the order to the batch.

Assign Target Batch Manually (SR1084.5.3.1)

The system allows the supervisor to define a target batch identifier manually. It verifies that the assigned batch identifier is unique.

Assign Target Batch Automatically (SR1084.5.3.2)

The system can create a target batch identifier automatically based on a pre-defined algorithm that can be configured.

Explode Order (SR1084.9)

The system allows to explode orders manually.

The order explosion can be reset as long as the order has not been started. Along with a reset, the system cleans up all data that has been generated during the order explosion.

The system sets the order status to **Exploded**.
The assignment of a master recipe to the order is a prerequisite for exploding orders.

Default Order Step Numbering (SR1084.9.1)

By default, the numbering of order steps is as follows:

Order step number = [order number]-[unit procedure name]

SEPARATE CONTROL RECIPE (SR1084.9.3)

The system can be configured to behave as follows during the order explosion: The system keeps the created control recipe completely separated from the original master recipe, so that the master recipe can be updated even if a related control recipe has already been executed.

For details, see section "Exploding Orders Based on Simulation Master Recipes" in chapter "Adapting the Order Explosion Service" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

NON-VALID MASTER RECIPE (SR1084.9.4)

The system can be configured to behave as follows: The order explosion is also possible for orders that refer to non-valid master recipes. Master recipes in the **Valid** or **Verification** status can be assigned to an order.

For details, see section "Exploding Orders Based on Simulation Master Recipes" in chapter "Adapting the Order Explosion Service" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

View Order (SR1084.11)

The system allows to view an order including the following attributes:

- Order steps
- Target batch
- Scheduling data
- Treatment ID.

Progress Information (SR1084.12)

The system allows to show the current information regarding the progress of an order on user request. This includes at least the following attributes:

- Actual start and end of the order
- Actual start and end of the order steps
- Data collected during processing, at least the identified sublots for the input materials and the produced sublots for the output materials.
- Quantity of the target batch that has been produced, if applicable.

Release Order (SR1084.25)

The system allows the supervisor to release an order to work centers according to the definition in the master recipe.
That means that order steps are not available at a work center as long as the order is not released.

The order must be in the **Exploded** status (page 4).The system sets the order status to **Released**. Releasing an order starts its control recipe on the EBR server for distributed execution.

If required, orders can be unreleased. The order must be in the **Released** status. The system sets the order status to **Exploded**. Unreleasing an order terminates its control recipe on the EBR server for distributed execution.

Export Order for Archive (SR1084.40)

The system allows to export an order for archiving purposes into a pre-configured folder when the order is in the **Canceled** or **Reviewed** status (page 4).

The order cannot be exported if at least one of its appended workflows is also appended to another order that is not in the **Canceled** or **Reviewed** status (page 4).

The export of an order for archive must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

Available attributes are:

- Display of pre-defined target directory
- Export result (only filled after export)

After the first successful export of an order, the system sets the **Exported for archive** status to **Exported**.

To view the meta data of an export, see the **Archive and Purge Management (SR1088+)** feature (page 55).

Handling of Appended Workflows (SR1084.40.1)

Along with the export of an order, the system exports all currently appended workflows as well unless a workflow was already exported. The workflows are exported into a separate pre-configured folder (per system configuration).

For the files exported into the workflow-specific folder, see the **Exported Files (SR1085.2.10.1)** feature (page 51).

To view the meta data of an export, see the **Archive and Purge Management (SR1088+)** feature (page 55).

EXPORTED FILES (SR1084.40.2)

The result of a successful export of an order is the following set of folders and files.

- Folder
  Name: Batch_Orders
  - Folder
    Name: BR_<OrderID>_<BatchID>_<Date>_<Time>
    Example: BR_O123456_BX1234_2015-10-14_16-23-56
    - Export event meta data (XML)
      Name: LOG_BR_<OrderID>_<BatchID>_<Date>_<Time>
      Example: LOG_BR_O123456_BX1234_2015-10-14_16-23-56.xml
    - Batch record (XML)
      Name: Batch_Record_<OrderID>_<BatchID>
      Example: Batch_Record_O123456_BX1234.xml
    - Batch report (PDF/A)
      Name: Batch_Report_<OrderID>_<BatchID>
      Example: Batch_Report_O123456_BX1234.pdf
    - Folder
      Name: Labels
      Sublot labels (PDF/A)
      Name: Sublot_<SublotID>_<LabelID>
      Example: Sublot_SL00000802_501.pdf
      Reprinted sublot labels (PDF/A, only if a label has been reprinted)
      Name: Sublot_<SublotID>_<LabelID>_<Copy No.>
      Example: Sublot_ SL00000802_501_01.pdf
    - Folder
      Name: B2MML_V0600
      Data definition (XSDs)

If the order identifier contains a character that is not allowed within a folder or file name, the system replaces the character.

Purge Order (SR1084.41)

The system allows to purge an order when the order is in the **Annulled**, **Canceled**, or **Reviewed** status (page 4) and there is no current relationship.
For **Canceled** and **Reviewed** orders, the order must have been successfully exported first with the **Export Order for Archive (SR1084.40)** operation (page 23).

The purge of an order must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" in [A8] (page 69)).

The purge operation deletes all order data including reports, labels, and context data written by the **Write Context Data Phase (SR0140+)** (see "Functional Requirement Specification EBR Phases" [A4] (page 69))with the order identifier as context identifier from the system. Data objects that contain references to a purged order, such as its appended workflows or equipment used during processing remain unchanged and retain their references to the deleted order.

Not Subject to Purge (SR1084.41.1)

The following order-related data is not subject to purge in case an order is purged:

- Batches that were created in the context of the order.
- Sublots that were created in the context of the order.

Finish Order With Aborted Order Steps (SR1084.42)

The system allows the supervisor to manually finish an order with aborted order steps if

- the order is in the **In process** status (page 4) and
- the order steps of a recipe path of the order are in the **Finished**, **Final aborted**, or **Aborted** statuses (page 8).

Finish Order With Aborted Order Steps - Related Exceptions (SR1084.42.1)

Finishing an order with aborted order steps is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "finish order with aborted order step"-specific exception for each unit procedure in the **Aborted** status. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Force Execution Transition (SR1084.43)

The system allows to force a transition in case it is stalled during execution.

For a given order, the system displays a list of stalled transitions that are related to XOR branches.

The force action must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" in [A8] (page 69)).

Force Execution Transition - Related Exceptions (SR1084.43.1)

Forcing a transition within the execution is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "Force execution transition"-specific exception that is assigned as follows:

- A transition between **phases** is forced:
  The exception is assigned to the related operation.
- A transition between **operations** is forced:
  The exception is assigned to the related unit procedure.
- A transition between **unit procedures** is forced:
  The exception is added to the unit procedure that was performed prior to the forced transition. If there is no such unit procedure, the transition cannot be forced.

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Batch Order Step Operations

Dispatch Order Steps (SR1084.24)

The system allows order steps to be assigned to one or more specific work centers.

The work centers that are assigned to a unit procedure define the work centers at which the order step will be available for processing. The list of work centers is populated automatically from the respective unit procedure.

DISPATCH ORDER STEPS MANUALLY (SR1084.24.1)

The system allows the supervisor to manually rework the list of assigned work centers for a specific order step. Work centers can be added and removed. Access to both actions can be controlled by two different signature classes.

The system tracks the adding and removal of work centers in the **order and workflow changes (SR1084.30)** table (page 11).

The order must be in the **Exploded**, **Released**, or **In process** status (page 4).

The order step must be in the **Generated**, **Held**, or **Reactivated** status (page 8).

DISPATCH ORDER STEPS - CONSTRAINTS (SR1084.24.2)

Changing work center assignments will affect the station assignments that may have been defined during recipe creation for order step dispatching.
In case the original work center assignment is restored by the user, also the original station assignments are in place again.
Only in case the work center assignment is different compared to the recipe definition (work center added, removed, or changed), station assignments are completely ignored during execution. Then, the order step is startable at all stations of the assigned work centers.

The system displays an appropriate message and allows to cancel the action.

Reactivate Dispense Order Step Manually (SR1084.31)

The system allows to manually reactivate an order step if

- the order step is a Dispense order step, and
- the order step is in the **Finished** status (page 8), and
- the order is in the **In process** status (page 4), and
- an already open split position of an order step input exists (e.g. due to a replacement of a sublot done in the Production Execution Client).

The operation can be used to prevent deadlock situations that could occur if a Dispense order step has processed all materials, has therefore its concluding **Print report** phase active, and then has an exception recorded to replace a sublot.

The Dispense order step must contain a yet unprocessed material input.

The system sets the order step status to **Reactivated**.

Reactivate Non-Dispense Order Step Manually (SR1084.35)

The system allows to manually reactivate a non-Dispense order step if

- the order step is in the **Finished** or **Aborted** status (page 8) and
- the order is in the **In process** status (page 4).

Reactivate Non-Dispense Order Step - Related Exceptions (SR1084.35.1)

Reactivating a non-Dispense order step is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "reactivate order step"-specific exception for the unit procedure. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Abort Non-Dispense Order Step for Reactivation (SR1084.36)

The system allows to abort a non-Dispense order step that is in the **In process** or **Held** statuses (page 8).

When an order step is aborted, any inventory object (e.g. sublot) identified and bound to the order step during its aborted run has to be unbound manually in order to make them available again for identification with the **Unidentify Sublot (SR1084.200.2)** function (page 65).

The cleanup of already produced sublots of intra material that may be necessary after having aborted an order step is not performed automatically.

ABORT NON-DISPENSE ORDER STEP FOR REACTIVATION - RELATED EXCEPTIONS (SR1084.36.1)

Aborting an order step is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records an "abort order step"-specific exception for the unit procedure and for all active phases of the unit procedure. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

ABORT NON-DISPENSE ORDER STEP FOR REACTIVATION - NO ORDER STEP EXECUTION (SR1084.36.2)

When an order step is aborted, all related phases, operations, and unit procedures are terminated automatically and are no longer visible as running processes in the Cockpit of the Production Execution Client.
At each of the related Production Execution Clients, the system displays an appropriate message.
Termination of related phases and operations also applies to server-run operations, which run on the Operation Execution server without any user interaction.

Abort Order Step (SR1084.44)

The system allows to abort an order step if

- the order step is in the **Generated** (and listed as startable in the Cockpit of the Production Execution Client), **In process**, or **Held**, or **Reactivated** statuses (page 8) and
- the order is in the **In process** status (page 4).

When an order step is aborted, any inventory object (e.g. sublot) identified and bound to the order step during its aborted run has to be unbound manually in order to make them available again for identification with the **Unidentify Sublot (SR1084.200.2)** function (page 65).

The cleanup of already produced sublots of intra material that may be necessary after having aborted an order step is not performed automatically.

ABORT ORDER STEP - RELATED EXCEPTIONS (SR1084.44.1)

Aborting an order step is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "final abort order step"-specific exception for the unit procedure and for all active phases of the unit procedure. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

ABORT ORDER STEP - NO ORDER STEP EXECUTION (SR1084.44.2)

When an order step is aborted, all related phases, operations, and unit procedures are terminated automatically and are no longer visible as running processes in the Cockpit of the Production Execution Client.
At each of the related Production Execution Clients, the system displays an appropriate message.
Termination of related phases and operations also applies to server-run operations, which run on the Operation Execution server without any user interaction.

Append Workflows (SR1084.34)

The system allows to define an access privilege for the protection of master workflows from unauthorized access. Subsequently, it shall only allow to select a workflow whose access privilege matches the access privilege of the logged-in user.

The system allows the supervisor to manually append and remove workflows to and from specific order steps depending on the order's status (page 4), the order step's status (page 8) and the workflow's status (page 4):

Workflow	Order status	Order step status
They are not available for an assignment if ■ they have not been released yet or ■ they are in the **Canceled** status.	In process, Finished, Production-reviewed, Canceled	In process, Held, Finished, Canceled, Reactivated

Workflows that have not been released yet or that are in the **Canceled** status (page 4) cannot be appended.

Workflows are either created manually with the **Workflow Management (SR1085+)** feature (page 43) based on a master workflow designed with Workflow Designer [A1] (page 69), generated when the processing of a one-click startable workflow has been started in the Production Execution Client [A2] (page 69), or generated by executing the **Create Workflow Phase (SR01300+)** (see "Functional Requirement Specification EBR Phases" [A4] (page 69)).
In general, workflows can be executed independently from orders. However, they can be appended to the respective order steps in order to include them in the batch record.

The batch-specific order must be in the **In process**, **Finished**, **Production-reviewed**, **Canceled**, or **Reactivated** status (page 4).

Usually workflows can only be appended to batch-specific unit procedures in the Production Execution Client. In the Production Management Client, appending or removing of workflows is allowed for batch-specific unit procedures and always considered to be an exceptional situation according to the **Append Workflow - Related Exceptions (SR1084.34.1)** feature (page 31).

Appended workflows are considered as **Production-relevant**. This affects the **Purge workflow (SR1085.2.11)** operation (page 51).

Exported workflows cannot be appended to an order and if appended, cannot be removed according to the **Export Workflow for Archive (SR1085.2.10)** operation (page 50).

Append Workflows - Related Exceptions (SR1084.34.1)

Workflows can be appended and removed. Changing the list of appended workflows is controlled by one signature class.
Per default configuration, the change action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records an "append workflow list changed"-specific exception for the unit procedure. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Batch Order Step Input/Output Operations

Definition of Outgoing Materials (SR1084.5)

The system creates one main product and potentially 0..n co-products and by-products for an order by consuming some materials as defined in the master recipe.

The runtime BOM is related to a defined total quantity of the main product.

In a multi-staged process, additional WIP materials are produced in an order step that are conceptually neither part of the overall BOM nor outgoing materials of the overall work order (they will be consumed internally). Nevertheless, they are regarded as outgoing materials at the level of the order step and will be used as incoming materials of the **WIP** type in a later order step.

ONE MAIN PRODUCT (SR1084.5.1)

PharmaSuite supports only one main product.
Co-products, by-products, and multiple products are not supported.

Planned Quantity-related Data of Order Step Inputs and Outputs (SR1084.39)

The system supports a planned quantity (original), which represents the planned quantity as defined in the master recipe, and a planned quantity (execution). The latter may be updated during execution depending on the definition of the planned quantity mode and the application of a prorate factor.

Planned quantity mode	Planned quantity (Execution)	Planned quantity (Original)
None	N/A	N/A
As defined	Planned quantity taken over from recipe, updated by the application of a prorate factor (for order step inputs: before a position is started; for order step outputs: before a position is completed).	Planned quantity taken over from recipe (not updated).
As produced (not supported for order step outputs)	Planned quantity calculated according to the produced material of the related MFC transfer output material.	N/A

Allocate Batches (SR1084.16)

In case the system manages materials, it allows to pre-define the batches to be used during processing as a preparatory step for the execution. The batches are allocated to order step inputs.

The system tracks the allocation of batches in the **order and workflow changes (SR1084.30)** table (page 11).

If required, batches can be removed from the list of allocated batches.

Batch Allocation - Source System (SR1076.3.10)

The system supports the batch allocation to be performed by either an MES or ERP system.

Replace Target Sublot (SR1084.26+)

- Does not apply to Inline Weighing

The system supports the replacement of an outgoing sublot of Dispense order steps by the same material.

The weighing material type of the replaced target sublot defines whether additional sublots must be replaced first:

- To replace **Active substances**, all subsequent **Compensator** and **Filler substances** must be replaced first.
- To replace other materials, all subsequent existing **Filler** substances must be replaced first.

Access Control (SR1084.26.5)

The system provides access control for replacing a target sublot.
By default, a supervisor has access and an operator has no access.

Reactivated Status of the Related Order Step (SR1084.26.2)

The following status-related prerequisites apply:

- The order must be in the **In process** status (page 4).
- The Dispense order step must be in the **Finished** or **Reactivated** status (page 8).

When the replacement item has been created, the system sets the order step status to **Reactivated**.

Split Position for the Target Sublot (SR1084.26.3)

The system replaces the sublot of the order step output by re-creating its order step input as a new split position.

Properties of the Split Position (SR1084.26.4)

For a new split position, the system applies the following properties:

- A batch allocation that equals the batch allocation of the original order step input (if applicable).
  The batch allocation can be updated by the supervisor.
- The remaining quantity to be dispensed after the sublot has been replaced.
  For **Active substances**, this includes a potency correction compared to the actual quantity of the replaced sublot.
- The tolerances and weighing method of the original order step input.

Ignore Increased Quantity (SR1084.26.4.1)

After the calculation of the remaining quantity, the system displays appropriate warning messages in the following cases:

- The quantity of the position has been increased before.

  The calculation of the remaining quantity, however, is based on the material's original planned quantity as defined in the recipe. If the new remaining quantity needs to reflect the previous quantity increase, the quantity of the new order step input must be increased.

- The remaining quantity of the position is 0 or negative due to high tolerances or overweight situations.

  The quantity of the new order step input must be increased to correct the remaining quantity manually.

REPLACE TARGET SUBLOT - RELATED EXCEPTIONS (SR1084.26.7)

Replacing a target sublot is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "replace target sublot"-specific exception for the unit procedure. The exception text displays the details of the change.

- Target sublot <identifier> replaced for:
  Material: <identifier>
  Position: <number>)

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Add New Alternative Order Step Input (SR1084.27)

➢ Applies to Dispense order steps only

The system allows the supervisor to add an alternative material (order step input) to the order-related items that replaces an existing material. This includes:

- The alternative material is assigned to the same material position.
- The status of the replaced order step input is set to **Aborted** and the input is marked as replaced.
- There is no planned quantity defined for the alternative material if the planned quantity mode of the replaced order step input was set to **None**.
- The attributes are inherited from the replaced order step input, but can be overwritten.
- If a weighing sequence is inherited from the replaced order step input, it cannot be removed, but it can be overwritten. If the replaced order step input had no weighing sequence defined, it can also not be defined for the alternative order step input.
- Batch allocations can be defined.
- The definition of an alternative material must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

The status of the alternative order step input is set to **Created**.

WEIGHING MATERIAL TYPE OF AN ALTERNATIVE ORDER STEP INPUT (SR1084.27.1)

The material of the order step input must be of the **Active substance**, **Compensation substance**, **Auxiliary substance**, or **Filler substance** weighing material type and cannot be changed.

REQUIRED ORDER STATUS FOR AN ALTERNATIVE ORDER STEP INPUT (SR1084.27.2)

The following status-related prerequisites apply:

- The order must be in the **Exploded** status (page 4).

MFC DATA FOR THE ALTERNATIVE ORDER STEP INPUT (SR1084.27.3)

The system automatically updates the MFC-related data for the alternative order step input.

CHANGE HISTORY (SR1084.27.4)

The system tracks the creation of an alternative order step input in the **order and workflow changes (SR1084.30)** table (page 11).

Increase Quantity of Order Step Input (SR1084.28)

- Applies to Dispense order steps only

The system allows the supervisor to add additional quantity to an already finished position.

The quantity can also be decreased and new batch allocations can be defined.

INCREASE QUANTITY-RELATED REACTIVATION OF THE ORDER STEP (SR1084.28.1)

The following status-related prerequisites apply:

- The order must be in the **In process** status (page 4).
- The Dispense order step must be in the **Finished** or **Reactivated** status (page 8).

When the quantity has been increased, the system sets the order step status to **Reactivated**.

Business Logic (SR1084.28.2)

The system supports the following business logic:

- If there is no open split position, the system creates a new split position.
- If an open split position already exists, the quantity of the existing split position is increased by the newly defined quantity.
- The operator must define the additional quantity.
- Default batch allocations are populated from the original order step input and can be updated.
- The weighing material type of the **Completed** order step input to be increased and the weighing material types of the not yet completed order step inputs of the order step define whether the quantity can be increased:
  - To increase **Active substances**, there must be no **Compensation substances** at all and no subsequent **Filler substances**.
  - To increase **Auxiliary substances**, there must be no subsequent **Filler substances**.
  - An order step input of the **compensator substance** weighing material type cannot have its quantity increased.
  - An order step input of the **filler substance** weighing material type cannot have its quantity increased.

Increase Quantity - Related Exceptions (SR1084.28.4)

Increasing the quantity is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records an "increase quantity of order step input"-specific exception for the unit procedure. The exception text displays the details of the change.

- Quantity increased for:
  Material: <identifier>
  Position: <number>
  Old value:
  Planned quantity (execution): <old value> <UoM>
  New value:
  Planned quantity (execution): <new value> <UoM>

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Add New Additional Order Step Input (SR1084.29)

- Applies to Dispense order steps only

The system allows the supervisor to add an additional item (order step input) to the order-related items.

Weighing Material Type of a New Additional Item (SR1084.29.1)

The system supports new additional items of the **Auxiliary substance** weighing material type only, and as long as no subsequent item of the **Filler substance** is defined as order-related item.

Additional Item-related Reactivation of the Order Step (SR1084.29.2)

The following status-related prerequisites apply:

- The order must be in the **In process** status (page 4).
- The Dispense order step must be in the **Finished** or **Reactivated** status (page 8).

When the additional item has been created, the system sets the order step status to **Reactivated**.

MFC Data for the New Additional Item (SR1084.29.3)

The system automatically generates a respective MFC output item for the new additional item.

Weighing Sequence of a New Additional Item (SR1084.29.6)

In case the existing order-related items have a weighing sequence defined, the system requires a weighing sequence for the new additional item. Otherwise a weighing sequence cannot be defined.

Additional Item - Related Exceptions (SR1084.29.5)

Creating an additional item is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records an "add new order step input"-specific exception for the unit procedure. The exception text displays the details of the change.

- New additional order step input added to order step <identifier>:
  Material: <identifier>
  Planned quantity (execution): <value> <UoM>
  Lower tolerance (absolute): <value>
  Upper tolerance (absolute): <value>
  Lower tolerance (relative): <value> %
  Upper tolerance (relative): <value> %
  Planned potency: <value> %
  Position: <number>
  Weighing Sequence: <number>
  Allowed weighing methods: <list of weighing methods>
  Default weighing method: <weighing method>

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Reactivate Aborted Order Step Input (SR1084.32)

➢ Does not apply to Inline Weighing

The system allows the supervisor to reactivate an aborted order step input.

The operation can be used to resolve situations when a Dispense order step input had to be **Aborted** during execution on the shop floor.

Aborted Order Step Input-related Reactivation of the Order Step (SR1084.32.1)

The following status-related prerequisites apply:

- The order must be in the **In process** status (page 4).
- The **Aborted** Dispense order step must be in the **Finished** or **Reactivated** status (page 8).

The system sets the order step status to **Reactivated**.

Business Logic (SR1084.32.2)

The system supports the following business logic:

- If sublots have been created during previous weighing, the system takes over the remaining quantity as planned quantity of the reactivated order step input.
- If no sublots have been created during previous weighing, the system takes over originally planned quantity as planned quantity of the reactivated order step input.
- The weighing material type of the **Aborted** order step input defines whether sublots of other order step inputs must be replaced first (see **Replace Target Sublot (SR1084.26)** operation (page 33)):
- To reactivate **Active substances**, all subsequent **Compensator** and **Filler substances** must be replaced first.
- To reactivate other materials, all subsequent existing **Filler substances** must be replaced first.

Reactivate Aborted Order Step Input - Related Exceptions (SR1084.32.4)

Reactivating an aborted order step input is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "reactivate aborted order step input"-specific exception for the unit procedure. The exception text displays the details of the change.

- Order step input reactivated:
  Material: <identifier>
  Position: <number>

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Material-related Comments for Non-Dispense Order Steps (SR1084.37)

The system allows the supervisor to add material-related comments for order step inputs and outputs.

The comments are not editable for order steps in the **In process** status (page 8) and are no longer editable for orders in the **Finished** or **Production-reviewed** status (page 4). However, they are editable for order steps in the **Held** status (page 8).

The system tracks the adding of material-related comments in the **order and workflow changes (SR1084.30)** table (page 11).

The maximum length of a comment is 500 characters.

The character of this comment is a "comment to execution" in support of the Rework use cases. Planned quantity-related comments can be added for material inputs and outputs. The system displays them during the execution of the **Identify material (SR0050+)** and **Produce material (SR0060+)** phases. For details, see "Functional Requirement Specification Material Tracking Phases" [A6] (page 69).

Unlock Order Step Input (SR1084.45)

Material identification and accounting for material positions can be synchronized and can be used simultaneously in ETOs. To prevent inconsistent quantities and status values, the function locks and unlocks the material position to process. If due to an exceptional situation a material position remains locked, it can be unlocked manually. This is controlled by a signature class (PMC_ES_OSI_Release).

After the electronic signature has been performed successfully, the system automatically records a "manual unlock of input position"-specific exception for the phase that owns the lock. The exception text contains the material position.

The risk level of the exception can be configured by configuration key (**LibraryHolder/services-order-ifc.jar/ReleaseOSILockExcRisk**).

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

If unlocking the material position is not possible since it is not locked, the user is informed accordingly.

Chapter 4

Workflow Management (SR1085+)

In PharmaSuite, workflows are either created manually based on a master workflow designed with Workflow Designer [A1] (page 69) or generated when the processing of a one-click startable workflow has been started in the Production Execution Client [A2] (page 69). They are managed in the Production Management Client.
For details about the **Workflow Report (SR3200.4+)**, see "Functional Requirement Specification Review and Approval" [A3] (page 69).

Workflow Attributes (SR1085.1)

The following attributes are available for workflows:

- Read-only
  - Workflow
    - Identifier
    - Status
    - Exported for archive (Exported, Not exported)
    - Actual start date
    - Actual end date
    - Planned start date
    - Planned end date
  - Master workflow
    - Identifier
    - Processing name
    - Short description
    - Description
    - Reason for creation
    - Review mode
    - Production-relevant
    - Appendable during processing

- Editable (depends on the status (page 45))
  - Treatment ID
  - Comment

A workflow is **Production-relevant**, if

- the corresponding master workflow is defined as **Production-relevant**, or
- the workflow has been appended to an order, or
- there is a reference to the workflow in an equipment entity logbook.

The **Comment** attribute of an exported workflow is not editable according to the **Export Workflow for Archive (SR1085.2.10)** operation (page 50).

Workflow Operations (SR1085.2+)

The following operations are supported for workflows:

- Create (see **Create workflow (SR1085.2.4)** operation (page 45))
- Filter (see **Filter for Workflows (SR1085.2.12)** operation (page 45))
- View (see **View workflow (SR1085.2.5)** operation (page 45))
- Edit (see **Edit workflow (SR1085.2.6+)** operation (page 45))
- Explode workflow (see **Explode workflow (SR1085.2.7)** operation (page 47))
- Release workflow (see **Release workflow (SR1085.2.8)** operation (page 48))
- Unrelease workflow (see **Release workflow (SR1085.2.8)** operation (page 48))
- Reset workflow (see **Explode workflow (SR1085.2.7)** operation (page 47))
- Cancel workflow (see **Cancel workflow (SR1085.2.1)** operation (page 49))
- Change status
- View status transition history of the workflow
- Open workflow report

  Displays the workflow report in a preview window for performing reviews by exception.
  The workflow must be in the **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status.

- Print workflow report

  Displays the workflow report in a preview window for printing.
  The workflow must be in the **Exploded**, **Released**, **In process**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status.

- Export workflow (see **Export Workflow for Archive (SR1085.2.10)** operation (page 50))
- Purge workflow (see **Purge Workflow (SR1085.2.11)** operation (page 51))
- Force execution transition (see **Force execution transition (SR1085.2.13)** operation (page 52))

In an exceptional situation it may be necessary to repair a corrupted workflow (order) by unloading the workflow from the EBR server. For an unloaded workflow or its workflow steps, operations are not disabled even though they cannot be performed. For details related to unloaded processes, see **Unload and Reload Procedures of Orders and Workflows (SR1200.2.2)** in "Functional Requirement Specification Execution Framework" [A2] (page 69).

Filter for Workflows (SR1085.2.12)

The system allows to define an access privilege for the protection of master workflows from unauthorized access. Subsequently, it shall only allow to filter for workflows whose master workflow's access privilege matches the access privilege of the logged-in user.

Create Workflow (SR1085.2.4)

During workflow creation, the system allows the supervisor to initially define the following attribute:

- Workflow identifier (mandatory, unique, insert only).
  Uniqueness of workflow identifier includes purged workflows.

View Workflow (SR1085.2.5)

The system allows to view a workflow including the following attributes:

- Workflow steps
- Scheduling data
- Batch-specific order steps to which the workflow is appended
- Treatment ID.

Edit Workflow (SR1085.2.6+)

The workflow and workflow step statuses define which editable attributes can be changed (page 46) and which operations can be performed (page 46).

EDIT WORKFLOW - CHANGE ATTRIBUTES (SR1085.2.6.1)

The system allows the supervisor to change the following editable attributes depending on the workflow's status (page 4):

Attribute	Workflow status
Master workflow (see **Select master workflow (SR1085.2.6.3)** operation (page 47))	Defined
Treatment ID	Defined
Scheduling data	Defined, Exploded
Comment	Defined, Exploded, Released, In process, Finished, Production-reviewed
Work centers (of workflow steps in the **Generated**, **Held**, or **Reactivated** status (page 8), see **Dispatch workflow steps (SR1085.4.1)** operation (page 53))	Exploded, Released, In process

The system does not allow the supervisor to change attributes of a workflow or workflow step when they are in the following workflow statuses (page 4) or workflow step statuses (page 8):

Object	Workflow status	Workflow step status
Workflow and its workflow steps	Canceled, Annulled, Reviewed	Any
Workflow step	Any	Finished

EDIT WORKFLOW - PERFORM OPERATIONS (SR1085.2.6.2)

The system allows the supervisor to perform the following operations depending on the workflow's status (page 4):

Operation	Workflow status
Explode workflow (SR1085.2.7) operation (page 47)	Defined
Reset workflow (see **Explode workflow (SR1085.2.7)** operation (page 47))	Exploded
Undo workflow release (sets the status to **Exploded**)	Released
Annul workflow (sets the status to **Annulled**)	Defined, Exploded, Released
Cancel workflow (SR1085.2.1) operation (page 49) (sets the status to **Canceled**)	In process

Operation	Workflow status
Change status to **Production-reviewed** (This operation is only available in the Production Response Client (see **Review a workflow (SR3200.3.3.3)** operation in "Functional Requirement Specification Review and Approval" [A3] (page 69).)	Finished
Change status to **Reviewed** (This operation is only available in the Production Response Client (see **Review a workflow (SR3200.3.3.3)** operation in "Functional Requirement Specification Review and Approval" [A3] (page 69).)	Finished, Production-reviewed
Export workflow for archive (SR1085.2.10) operation (page 50)	Finished, Canceled, Production-reviewed, Reviewed
Purge workflow (SR1084.2.11) operation (page 51)	Annulled With restrictions: Finished, Canceled, Production-reviewed, Reviewed

SELECT MASTER WORKFLOW (SR1085.2.6.3)

The system allows to define an access privilege for the protection of master workflows from unauthorized access. Subsequently, it shall only allow to select a master workflow whose access privilege matches the access privilege of the logged-in user.

The system allows to select a master workflow that was created with Workflow Designer.

Explode Workflow (SR1085.2.7)

The system allows to explode workflows manually.

The workflow explosion can be reset as long as the workflow has not been started. Along with a reset, the system cleans up all data that has been generated during the workflow explosion.

The system sets the workflow status to **Exploded**.

The assignment of a master workflow to the workflow is a prerequisite for exploding workflows.

DEFAULT WORKFLOW STEP NUMBERING (SR1085.2.7.1)

By default, the numbering of workflow steps is as follows:

Workflow step number = [workflow number]-[unit procedure name]

SEPARATE CONTROL WORKFLOW (SR1085.2.7.2)

The system can be configured to behave as follows during the workflow explosion: The system keeps the created control workflow completely separated from the original master workflow, so that the master workflow can be updated even if a related control workflow has already been executed.

For details, see section "Exploding Orders Based on Simulation Master Recipes" in chapter "Adapting the Order Explosion Service" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

NON-VALID MASTER WORKFLOW (SR1085.2.7.3)

The system can be configured to behave as follows: The workflow explosion is also possible for workflows that refer to non-valid master workflows. Master workflows in the **Valid** or **Verification** status can be assigned to a workflow.

For details, see section "Exploding Orders Based on Simulation Master Recipes" in chapter "Adapting the Order Explosion Service" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Release Workflow (SR1085.2.8)

The system allows the supervisor to release a workflow to work centers according to the definition in the master workflow.
That means that workflow steps are not available at a work center as long as the workflow is not released.

The workflow must be in the **Exploded** status (page 4).The system sets the workflow status to **Released**. Releasing a workflow starts its control workflow on the EBR server for distributed execution.

If required, workflows can be unreleased. The workflow must be in the **Released** status and cannot be appended to a batch order step. The system sets the workflow status to **Exploded**. Unreleasing a workflow terminates its control workflow on the EBR server for distributed execution.

Cancel Workflow (SR1085.2.1)

The system allows to cancel a workflow.

The system automatically records a "cancel workflow"-specific exception for all active phases of the order. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

A workflow can also be canceled in the Production Execution Client, see the **Cancel a workflow (SR1089.8.6)** context-related action in "Functional Requirement Specification Execution Framework" [A2] (page 69).

Cancel Workflow - Constraints (SR1085.2.1.1)

The system allows to cancel a workflow when the workflow is in the **In process** status (page 4).

By default, the cancelation of a workflow within the Production Management Client is treated as an exception and must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" in [A8] (page 69)).

A system integrator can configure whether an electronic signature is required.

Cancel Workflow - Status Propagation (SR1085.2.1.2)

When a workflow is canceled, the status transition is propagated to its workflow steps in the **In process** status (page 8).

Cancel Workflow - No Workflow Step Execution (SR1085.2.1.3)

When a workflow is canceled, the system ensures that its workflow steps cannot be started and/or executed anymore.

Cancel Workflow - Termination of Procedural Elements (SR1085.2.1.3.1)

When a workflow is canceled, all related phases, operations, unit procedures, and procedures are terminated automatically and are no longer visible as running processes in the Cockpit of the Production Execution Client.
At each of the related Production Execution Clients, the system displays an appropriate message.
Termination of related phases and operations also applies to server-run operations, which run on the Operation Execution server without any user interaction.

Progress Information (SR1085.2.9)

The system allows to show the current information regarding the progress of a workflow on user request. This includes at least the following attributes:

- Actual start and end of the workflow
- Actual start and end of the workflow steps

Export Workflow for Archive (SR1085.2.10)

The system allows to export a workflow for archiving purposes into a pre-configured folder when the workflow is in the **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status (page 4).

Additionally, appended workflows can only be exported, if their corresponding orders are in the **Reviewed** or **Canceled** status (page 4).

The export of a workflow for archive must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

Available attributes are:

- Display of pre-defined target directory
- Export result (only filled after export)

After the first successful export of a workflow, the system sets the **Exported for archive** status to **Exported**.

An exported workflow cannot be modified anymore. This implies that:

- The workflow cannot be appended to an order.
- If appended to an order, the workflow cannot be removed.
- 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.
- The **Comment** attribute of the workflow is not editable.

To view the meta data of an export, see the **Archive and Purge Management (SR1088+)** feature (page 55).

EXPORTED FILES (SR1085.2.10.1)

The result of a successful export of a workflow is the following set of folders and files.

- Folder
  Name: Workflows
  - Folder
    Name: WF_<WorkflowID>_<Date>_<Time>
    Example: WF_WF123456_2015-10-14_16-23-56
    - Export event meta data (XML)
      Name: LOG_WF_<WorkflowID>_Date>_<Time>
      Example: LOG_WF_WF123456_2015-10-14_16-23-56.xml
    - Workflow record (XML)
      Name: Workflow_Record_<WorkflowID>
      Example: Workflow_Record_WF123456.xml
    - Workflow report (PDF/A)
      Name: Workflow_Report_<WorkflowID>
      Example: Workflow_Report_WF123456.pdf
    - Folder
      Name: B2MML_V0600
      Data definition (XSDs)

If the workflow identifier contains a character that is not allowed within a folder or file name, the system replaces the character.

Purge Workflow (SR1085.2.11)

The system allows to purge a workflow when the workflow is in the **Annulled**, **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status (page 4) and there is no current relationship.
Only in case the workflow is Production-relevant and in the **Finished**, **Canceled**, **Production-reviewed**, or **Reviewed** status, the workflow must have been successfully exported first with the **Export Workflow for Archive (SR1085.2.10)** operation (page 50).

Additionally, appended workflows can only be purged, if their corresponding orders have been purged.

The purge of a workflow must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

Production-relevant in the context of purge means that

- the corresponding master workflow is defined as **Production-relevant**, or
- the workflow has been appended to an order, or
- there is a reference to the workflow in an equipment entity logbook.

The purge operation deletes all workflow data including reports and context data written by Write Context Data Phase (SR0140+) (see "Functional Requirement Specification EBR Phases" [A4] (page 69)) with the workflow identifier as context identifier from the system. Data objects that contain references to a purged workflow, such as orders, assigned work centers, or equipment used during processing remain unchanged and retain their references to the deleted workflow.

Force Execution Transition (SR1085.2.13)

The system allows to force a transition in case it is stalled during execution.

For a given workflow, the system displays a list of stalled transitions that are related to XOR branches.

The force action must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" in [A8] (page 69)).

Force Execution Transition - Related Exceptions (SR1085.2.13.1)

Forcing a transition within the execution is controlled by a signature class.
Per default configuration, the action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A8] (page 69)).

After the electronic signature has been performed successfully, the system automatically records a "force execution transition"-specific exception that is assigned as follows:

- A transition between **phases** is forced:
  The exception is assigned to the related operation.
- A transition between **operations** is forced:
  The exception is assigned to the related unit procedure.

The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

Workflow Step Operations (SR1085.4+)

The following operations are supported for workflow steps:

- Assign work centers (see **Dispatch work centers (SR1085.4.1)** operation (page 53))
- View status transition history of the order step

Dispatch Workflow Steps (SR1085.4.1)

The system allows workflow steps to be assigned to one or more specific work centers.

The work centers that are assigned to a unit procedure define the work centers at which the workflow step will be available for processing. The list of work centers is populated automatically from the respective unit procedure.

Dispatch Workflow Steps Manually (SR1085.4.1.1)

The system allows the supervisor to manually rework the list of assigned work centers for a specific workflow step. Work centers can be added and removed. Access to both actions can be controlled by two different signature classes.

The system tracks the adding and removal of work centers in the **order and workflow changes (SR1084.3)** table (page 11).

The workflow must be in the **Exploded**, **Released**, or **In process** status (page 4).

The workflow step must be in the **Generated**, **Held**, or **Reactivated** status (page 8).

Dispatch Workflow Steps - Constraints (SR1085.4.1.2)

Changing work center assignments will affect the station assignments that may have been defined during workflow creation for workflow step dispatching.
In case the original work center assignment is restored by the user, also the original station assignments are in place again.
Only in case the work center assignment is different compared to the recipe definition (work center added, removed, or changed), station assignments are completely ignored during execution. Then, the workflow step is startable at all stations of the assigned work centers.

The system displays an appropriate message and allows to cancel the action.

Workflow Step Input/Output Operations (SR1085.5+)

The following operations are supported for workflow step input/outputs:

- Allocate material (see **Allocate batches (SR1084.5.1)** operation (page 54))
- Add comment (see **Add material-related comment (SR1084.5.2)** operation (page 54))

Allocate Batches (SR1085.5.1)

In case the system manages materials, it allows to pre-define the batches to be used during processing as a preparatory step for the execution. The batches are allocated to workflow step inputs.

If required, batches can be removed from the list of allocated batches.

Batch Allocation - Source System (SR1085.5.1.1)

The system supports the batch allocation to be performed by either an MES or ERP system.

Add Material-related Comment (SR1085.5.2)

The system allows the supervisor to add material-related comments for workflow step inputs and outputs.

The comments are not editable for workflow steps in the **In process** status (page 8) and are no longer editable for workflows in the **Finished** or **Production-reviewed** status (page 4). However, they are editable for workflow steps in the **Held** status (page 8).

The maximum length of a comment is 500 characters.

Chapter 5

Archive and Purge Management (SR1088+)

Archive and Purge Events (SR1088.1)

Archive- and purge-related events can be filtered and sorted.

The following attributes are available for archive- and purge-related events:

- Event identifier
- Event type (Export for archive, Purge)
- Execution type (Manual, Automated)
- Processing status (Preparing, In progress, Success, Failure)
- Start timestamp
- Finish timestamp
- Object type (Order (Batch), Workflow)
- Object identifier
- Object status
- Object context
- Logged-in user
- Signature data (user and login names, signature timestamp)
- Signature comment

Chapter 6

Labeling and Reports (SR1090+)

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

- reports on **dispensing** performed for a given order
  (see **Dispensing Report (SR1090.4.7)** in "Functional Requirement Specification Review and Approval" [A3] (page 69)),
- **batch production** reports for a given order
  (see **Batch Production Report (SR3200.2+)** in "Functional Requirement Specification Review and Approval" [A3] (page 69)),
- **workflow** reports for a given workflow
  (see **Workflow Report (SR3200.4+)** in "Functional Requirement Specification Review and Approval" [A3] (page 69)),
- **labels** created for a given sublot.

Tracking the Output (SR1090.1)

The system shall keep track of generated documents (e.g. labels, dispensing reports, etc.) and allow to re-generate the documents.

The document history (audit trail) contains the following information:

1. Logged-in user.
2. Data of executed electronic signatures including timestamps.
3. Number of reprinted items.
4. Work center at which the document was printed.

The system shall store the contents of the printed documents in a non-changeable format, a reprint is only possible with the **Reprint (SR1090.6)** function (page 62).

Sublot Label Output (SR1090.1.1)

The system allows to track the printing of sublot labels. In addition to the data listed in the **Tracking the output (SR1090.1)** requirement (page 57), the following data is relevant for sublot labels:

- Label identifier
- Batch identifier
- Sublot identifier
- Label type (order-related sublot label, inventory-related sublot label)

Dispensing Report Output (SR1090.1.2)

The system allows to track the printing of Dispensing reports. In addition to the data listed in the **Tracking the output (SR1090.1)** requirement (page 57), the following data is relevant for Dispensing reports:

- Order step identifier

Label Printing (SR1090.3+)

The system shall support label printing.

Barcode and Barcode Types (SR1090.3.2)

The system shall allow a system integrator or administrator to configure/customize a project-specific format of the barcode in an easy way.

The system shall support the barcode types which are commonly used in the Life Sciences industry.

Examples:

- Code 128
- Code 39

The default barcode type is Code 128.

Trigger Label Printing for Batches and Sublots (Create New Target) (SR1090.3.3)

The system shall allow to print a label at any moment when an external trigger is executed. This shall be a hidden functionality. It allows a system integrator to trigger a label printout from a customization routine.

Label Design - Customization (SR1090.3.4)

The system shall allow a system integrator to create or modify label designs.

LABEL DESIGN - REVISION MANAGEMENT (SR1090.3.4.1)

The system shall ensure that label layouts are under revision management.

Print Sublot Label (SR1076.40)

The system shall be able to print sublot labels at material receipt, which contain the following data:

- Rockwell Automation logo
- Up to 4 hazard symbols
- Material (identifier, description)
- Batch and sublot identifier
- Expiry date
- Barcode for identification (EAN128)
- Printing context data (who has when printed the label, label ID)

Dispensing Sublot Label (SR1090.5)

A sublot label in the context of dispensing shall contain the following information:

- Footer: user who has printed the label; timestamp; reprint marker
- Material definition and batch identifier.
- Barcode of target sublot.
- GHS
  Up to 8 hazard pictograms (in the sequence as displayed in the materials master data form, the 9th pictogram is not printed on the label)
  Signal word
- Work center where the label was generated.
- Sublot quantity (including UoM) and container tare.
  In case of the **Only identification** and **Removal weighing** weighing methods, no tare is available.
- Order step identifier
- Target batch
- Expiry date

Sublot Label for Cost Center-related Dispensing (SR1090.5.3)

The system provides a specific dispensing sublot label layout in the context of orders of the **Cost center-related** usage type.

The label holds the following additional information, according to the related shop floor-defined order:

- Cost center number
- Comment

Reports (SR1090.4+)

The system shall support reports.

Font (SR1090.4.1)

Reports shall support the Arial Unicode font.

The default font for reports shall be Arial.

Paper Size (SR1090.4.2)

The default paper size for reports shall be **Letter** to define the **paper length** and **DIN A4** to define the **paper width**.

Database Context (SR1090.4.3)

Each report shall contain the information to clearly recognize the data source (system information) of a report. This means that it shall be possible to differentiate between production data, historical data, test data, etc.

The database context is printed in the **footer (SR1090.7)** area (page 61).

User Context (SR1090.4.4)

Each report shall contain the user name and login name of the user, who was logged in during the report printing.

The user context is printed in the **footer (SR1090.7)** area (page 61).

Timestamp (SR1090.4.5)

Each report shall contain the global time (GT) and the local time (LT). The timestamps are taken at the moment of the report generation.

The timestamps are printed in the **footer (SR1090.7)** area (page 61).

Footer (SR1090.7)

The footer of a report includes at least following data:

- Rockwell Automation logo
- Printed by: <user name and login>
- Printed from: <station/work center>
- Database: <database name>
- Printed on: <local time and server time>
- Page x of y

Report Design - Customization (SR1090.4.8)

The system shall allow a system integrator to create or modify report designs.

Report Design - Revision Management (SR1090.4.8.1)

The system shall ensure that report layouts are under revision management.

Reprint Labels and Reports (SR1090.6)

The system allows to reprint labels and reports.

Reprint Last Printed Label (SR1090.6.2)

The system allows to reprint the last printed label. Reprinting is restricted to the respective work center at which the label has been printed.

Electronic Signature for Reprint (SR1090.6.6)

The system allows to request an electronic signature from the user before reprinting a label. Default configuration is:

- single signature and
- comment is mandatory.

Reprint History Data (SR1090.6.3)

The system shall track every label reprint and log at least following data for each reprint:

- Logged-in user
- Timestamp of reprint
- Number of reprinted items

Select Label to be Reprinted (SR1090.6.4)

The reprint function allows to search for a specific label with the following search criteria (only possible if the respective context information is available for the label):

- Related object identifier (e.g. sublot identifier)
- Batch identifier (if available)

Reprint Report (SR1090.6.5)

The system allows to reprint operational reports. Operational reports are:

- Dispensing reports
- Applies to scale tests and scale calibration tests that were performed prior to PharmaSuite 8.1.
  - Scale test reports
  - Scale calibration reports

Since PharmaSuite 8.1, scales and rooms are maintained in the system based on the flexible S88 equipment management capability (see "Functional Requirement Specification Data Management" [A7] (page 69)). As a consequence, the **Scale test** and **Scale calibration** pre-defined and non-S88 workflows are no longer available in the system. The related functionality is covered by phases and their capabilities that allow to build adequate S88-based workflows in Workflow Designer. Thus, both reports are included in the workflow report as phase-specific sub-reports.

The system allows to define an access privilege for the protection of master recipes from unauthorized access. Subsequently, it shall only allow to select a report whose master recipe's access privilege matches the access privilege of the logged-in user.

The reprint function allows to search for a specific report with at least the following search criteria (only possible if the respective context information is available for the report):

- Order step identifier
- Work center identifier
- Scale identifier (for scale-specific reports)

Reprint Marker (SR1090.6.7)

The system shall mark reprinted reports and labels with a reprint marker and the number of the reprint. This means that e.g. the first reprint is marked with **Copy 1**, the second with **Copy 2** and so on.

The reprint is based on the non-changeable format stored in the original print history record. The document shall provide a free area to add and print the reprint information.

Chapter 7

Unidentify Objects (SR1084.200)

In the Production Management Client, the system shall provide specific administrator functionality that allows to proceed with processing on the shop floor in case data-related issues occur.

When an object such as a sublot is identified during processing, the system links it to the order step that is being processed. Under specific circumstances, it may become necessary to revoke this link and make the object available for identification again elsewhere. Unidentify objects revokes the order step links of an object and makes it available for re-identification.

This administrative function should be used with care and only as last resort as it can impact the material flow of an order.

Unidentify Sublot (SR1084.200.2)

The system shall provide a functionality that allows to unidentify (release) a sublot from the order step for which it has been identified.

At the same time, the corresponding order step input is reset to allow identification of new material in the context of reactivated unit procedures (rework scenarios).

A system integrator can configure whether an electronic signature is required.

Removal of Object Locks (SR3071.3.6)

The system shall allow to remove object locks, authorized by user authentication.

An object is locked when it is currently being edited or processed elsewhere. It is available then for read-only output to prevent a situation where users or the system access the same object simultaneously and overwrite changes made by the other party. Under specific circumstances, however, it may become necessary to unlock such an object manually and make it available for work again. This administrative function should only be used as a last resort for scenarios such as

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

Unlock S88 Runtime Operation (SR3071.3.6.1)

In case a lock of an S88 runtime operation is removed, the system shall detach the operation from its device and automatically record a detach-specific exception for all running phases of the operation. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A5] (page 69).

At each of the related PharmaSuite for Production Executions, the system displays an appropriate message.

Remove Object Lock History (SR3071.3.6.2)

In case an object lock is removed, the system shall record it. The information available in the history includes (but is not limited to) the following properties:

- Unlock timestamp
- Object type
- Object
- Object details (contains in case of unlocking a runtime operation the related order and order step)
- Lock user
- Lock timestamp
- Signature data from unlock

The history can be filtered by the following criteria:

- Unlock timestamp (after, before)
- Object type
- Object
- Object details (in case of unlocking a runtime operation, it contains the related order and order step)

Chapter 9

Reference Documents

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

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM010C-EN-E
A2	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM006C-EN-E
A3	PharmaSuite Functional Requirement Specification Review and Approval	PSFRSRA-RM006C-EN-E
A4	PharmaSuite Functional Requirement Specification EBR Phases	PSFRSEB-RM006C-EN-E
A5	PharmaSuite Technical Manual Configuration & Extension - Volume 2	PSCEV2-GR010C-EN-E
A6	PharmaSuite Functional Requirement Specification Material Tracking Phases	PSFRSMT-RM007B-EN-E
A7	PharmaSuite Functional Requirement Specification Data Management	PSFRSDM-RM006C-EN-E
A8	PharmaSuite Functional Requirement Specification Non-functional Requirements	PSFRSNF-RM003C-EN-E
A9	PharmaSuite Technical Manual Configuration & Extension - Volume 4	PSCEV4-GR010C-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
Martin Kühne	Technical Lead
Ignaz Wangler	Test Lead

Version Information

Object	Version
PharmaSuite	10.02.00
Functional Requirement Specification	1.0

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 "Order Management" (page 3):

Object	Description	Document
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Changes related to "Batch-specific Order Management" (page 15):

Object	Description	Document
Replace Target Sublot (SR1084.26+) (page 33)	Editorial Requirement number updated to grouping requirement. No change of code.	1.0

Changes related to "Workflow Management" (page 43):

Object	Description	Document
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Changes related to "Archive and Purge Management" (page 55):

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

Changes related to "Labeling and Reports" (page 57):

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

Changes related to "Unidentify Objects" (page 65):

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

Changes related to "Removal of Object Locks" (page 67):

Object	Description	Document
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