

PharmaSuite®



PRODUCTION EXECUTION

RELEASE 8.4 FUNCTIONAL REQUIREMENT SPECIFICATION

PUBLICATION PSFRSPE-RM008E-EN-E-DECEMBER-2017 Supersedes publication PSFDPE-RM008D-EN-E





Contact Rockwell See contact information provided in your maintenance contract.

Copyright Notice © 2017 Rockwell Automation Technologies, Inc. All rights reserved.

This document and any accompanying Rockwell Software products are copyrighted by Rockwell Automation Technologies, Inc. Any reproduction and/or distribution without prior written consent from Rockwell Automation Technologies, Inc. is strictly prohibited. Please refer to the license agreement for details.

Trademark Notices FactoryTalk, PharmaSuite, Rockwell Automation, Rockwell Software, and the Rockwell Software logo are registered trademarks of Rockwell Automation, Inc.

The following logos and products are trademarks of Rockwell Automation, Inc.:

FactoryTalk Shop Operations Server, FactoryTalk ProductionCentre, FactoryTalk Administration Console, FactoryTalk Automation Platform, and FactoryTalk Security. Operational Data Store, ODS, Plant Operations, Process Designer, Shop Operations, Rockwell Software CPGSuite, and Rockwell Software AutoSuite.

Other Trademarks ActiveX, Microsoft, Microsoft Access, SOL Server, Visual Basic, Visual C++, Visual SourceSafe, Windows, Windows 7 Professional, Windows Server 2008, Windows Server 2012, and Windows Server 2016 are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

> Adobe, Acrobat, and Reader are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

ControlNet is a registered trademark of ControlNet International.

DeviceNet is a trademark of the Open DeviceNet Vendor Association, Inc. (ODVA).

Ethernet is a registered trademark of Digital Equipment Corporation, Intel, and Xerox Corporation.

OLE for Process Control (OPC) is a registered trademark of the OPC Foundation.

Oracle, SQL*Net, and SQL*Plus are registered trademarks of Oracle Corporation.

All other trademarks are the property of their respective holders and are hereby acknowledged.

Warranty This product is warranted in accordance with the product license. The product's performance may be affected by system configuration, the application being performed, operator control, maintenance, and other related factors. Rockwell Automation is not responsible for these intervening factors. The instructions in this document do not cover all the details or variations in the equipment, procedure, or process described, nor do they provide directions for meeting every possible contingency during installation, operation, or maintenance. This product's implementation may vary among users.

> This document is current as of the time of release of the product; however, the accompanying software may have changed since the release. Rockwell Automation, Inc. reserves the right to change any information contained in this document or the software at any time without prior notice. It is your responsibility to obtain the most current information available from Rockwell when installing or using this product.

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Contents

Chapter 1	Introduction	1
	Naming Conventions	1
	Diagrams	2
	Typographical Conventions	3
Chapter 2	Workflows	5
	Inventory Workflows	5
	PEC-WF-0010 - Material Receipt	5
	PEC-WF-0011 - Material Issue	8
	PEC-WF-0012 - Relocation	9
	PEC-WF-0013 - Sublot Split	10
	PEC-WF-0014 - Inventory Correction	12
Chapter 3	Activities	13
	PEC-AC-0053 - Create Batch	13
	PEC-AC-0054 - Select Batch	13
	PEC-AC-0055 - Select Storage Location	14
	PEC-AC-0056 - Select Material	14
	PEC-AC-0057 - Create Sublots	15
	PEC-AC-0058 - Print Labels	15
	PEC-AC-0060 - Filter Sublots	16
	PEC-AC-0061 - Select Multiple Sublots	17
	PEC-AC-0062 - Issue Sublots	17
	PEC-AC-0075 - Relocate Sublots	18
	PEC-AC-0076 - Select Sublot	18
	PEC-AC-0077 - Even Split	19

		F	7
•		•	
,			
•			

	PEC-AC-0078 - Uneven Split	19
	PEC-AC-0079 - Change Quantity	19
	PEC-AC-0080 - Initialization	2 0
Chapter 4	Activity Steps	<mark>2</mark> 1
	GEN-AS-0001 - Single Signature Requested	<mark>2</mark> 1
	GEN-AS-0007 - Label Printed	<mark>21</mark>
	PEC-AS-0035 - Station Check	<mark>21</mark>
	PEC-AS-0043 - Material Data Displayed	21
	PEC-AS-0052 - Enter Batch-specific Data	<mark>2</mark> 1
	PEC-AS-0053 - Batch Data Displayed	<mark>2</mark> 1
	PEC-AS-0054 - Filter Batches	<mark>22</mark>
	PEC-AS-0055 - Batch List Displayed	<mark>22</mark>
	PEC-AS-0056 - Filter Storage Locations	<mark>22</mark>
	PEC-AS-0057 - Storage Location List Displayed	<mark>22</mark>
	PEC-AS-0058 - Enter Sublot-specific Data	<mark>22</mark>
	PEC-AS-0059 - Sublot List Displayed	<mark>22</mark>
	PEC-AS-0060 - Enter Label-specific Data	23
	PEC-AS-0062 - Enter Correction-specific Data	23
	PEC-AS-0064 - Filter Materials	23
	PEC-AS-0068 - Batch Status: Quarantined	23
	PEC-AS-0070 - Sublot Status Set	23
	PEC-AS-0075 - Enter Sublot Filter-specific Data	23
	PEC-AS-0076 - Sublot List Displayed	23
	PEC-AS-0077 - Multiple Sublots Selected	24
	PEC-AS-0078 - Enter Issue-specific Data	24
	PEC-AS-0088 - Ready for Identification by Barcode Scanner	24
	PEC-AS-0092 - Materials List Displayed	24
	PEC-AS-0093 - Enter Relocation-specific Data	24
	PEC-AS-0094 - Sublot Selected	24
	PEC-AS-0095 - Enter Split-specific Data	25
	PEC-AS-0096 - Updated Sublot List Displayed	25

•
•
•
•

	PEC-AS-0097 - Batch Status: Blocked	
Chapter 5	Status Graphs	27
	GEN-SG-0001 - Batch	27
Chapter 6	Function List	29
Chapter 7	Linkage to Implementation	31
	Workflows and Activity Sets	31
Chapter 8	Document Information	35
	Approval	35
	Version Information	35
	Revision History	35
Index	•••••	37

 ${\bf \hat{e}}$ Rockwell Software PharmaSuite ${\bf \hat{e}}$ 8.4 - Functional Requirement Specification Production Execution

Figures

Figure 1: PEC-WF-0010 - Material receipt	6
Figure 2: PEC-WF-0011 - Material issue	8
Figure 3: PEC-WF-0012 - Relocation	9
Figure 4: PEC-WF-0013 - Sublot split	10
Figure 5: PEC-WF-0014 - Inventory correction	12

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Introduction

This document details the pre-defined workflows implemented by the Production Execution Client application. These are:

- Inventory workflows
 - Material receipt (page 5)
 - Material issue (page 8)
 - Relocation (page 9)
 - Sublot split (page 10)
 - Inventory correction (page 12)

The revision history (page 35) lists the changes made to the document.

Naming Conventions

The following naming conventions apply:

Area

Code	Area
PEC	Production Execution Client
PMC	Production Management Client
GEN	General

Object

Code	Object	Process Designer
WF	Workflow (PEC)	Activity set (if applicable)
AC	Activity (PEC)	Activity (if applicable)
AS	Activity step (PEC, GEN)	Form (if applicable)
SG	Status graph (GEN)	Flexible state model
<nnn></nnn>	Function (PMC, PEC)	Form

PSFRSPE-RM008E-EN-E, 1.0

Number

Number	Object	Example
<nnn></nnn>	WF, AC, AS, SG	PEC-WF-8165
<nn></nn>	Characteristic of function	PMC-7468-34

Diagrams

The following elements are used within the activity diagrams:

Element	Name	Meaning
Operator	Swimlane	Represents the logical areas Operator and System where the respective actions are located in the respective swimlane. Identifier: " <name>"</name>
(PEC-AC-0001) Initialization	Activity	Represents a logical step within the workflow. Identifier: "(<number>) <name>"</name></number>
Skip zero —	Control flow	Directed connection between activity diagram elements (activity, decision, merge, initial, final). Bold connectors indicate the main flow (as appropriate to the workflow).
ActivityInitial	Initial	Start of workflow. Identifier: "ActivityInitial"
ActivityFinal	Final	Completion of workflow. Identifier: "ActivityFinal"

Element	Name	Meaning
Print weighing report Canoel order step Select order step Clean room	Decision	Decision how to proceed has to be taken by the operator or the system. A decision has a single incoming connector and multiple outgoing connectors. Identifier: "?" Identifier (control flow): " <action>"</action>
	Merge	Join of alternative flows. A merge has multiple incoming connectors and a single outgoing connector.

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).

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Workflows

This chapter details the pre-defined workflows and provides specific information related to each workflow.

Inventory Workflows

PharmaSuite provides the following Inventory workflows:

- Material receipt (page 5)
- Material issue (page 8)
- Relocation (page 9)
- Sublot split (page 10)
- Inventory correction (page 12)

PEC-WF-0010 - Material Receipt

Material receipt is the pre-defined workflow for introducing materials into small storage areas in a shop-floor environment, such as buffer or line warehouses. It can be used for adding materials to existing batches or to generate new batches. At the end of a successful material receipt the fully identified and labeled material sublots are available for further processing on the shop floor.

During processing the statuses of batches (page 27) to which the sublots belong are changed according to the progress within the workflow.

PSFRSPE-RM008E-EN-E, 1.0

Material receipt at a glance:

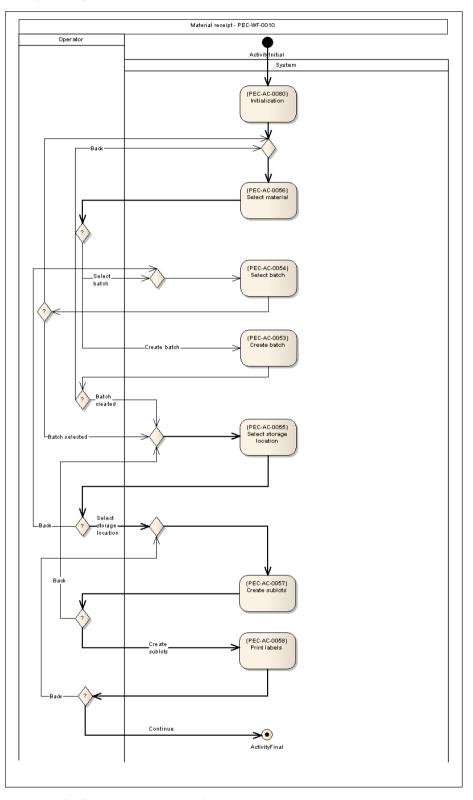


Figure 1: PEC-WF-0010 - Material receipt

- User group: Logistical operator
- Input: Material, storage location
- Output: Batch, sublot(s), labels, report history entry, transaction history entry on batch and sublot level

- 1. PEC-AC-0080 Initialization (page 20)
- 2. PEC-AC-0056 Select material (page 14)
- 3. PEC-AC-0053 Create batch (page 13) PEC-AC-0054 Select batch (page 13)
- 4. PEC-AC-0055 Select storage location (page 14)
- 5. PEC-AC-0057 Create sublots (page 15)
- 6. PEC-AC-0058 Print labels (page 15)

PEC-WF-0011 - Material Issue

Material issue is the pre-defined workflow for removing materials, in the form of individual sublots, from the inventory. This can happen either because the material is required for processing and thus issued for a specific cost center or because the material is not fit for utilization and needs to be destroyed.

Material issue at a glance:

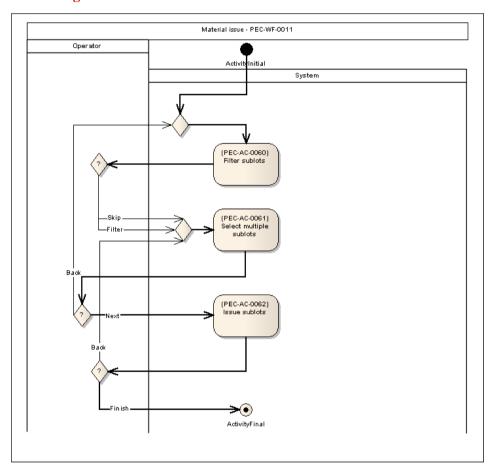


Figure 2: PEC-WF-0011 - Material issue

- User group: Logistical operator
- Input: Sublot
- Output: Transaction history entry on batch and sublot level

- 1. PEC-AC-0060 Filter sublots (page 16)
- 2. PEC-AC-0061 Select multiple sublots (page 17)
- 3. PEC-AC-0062 Issue sublots (page 17)

PEC-WF-0012 - Relocation

Relocation is the pre-defined workflow for moving material, in the form of sublots, from one storage location to another.

Relocation at a glance:

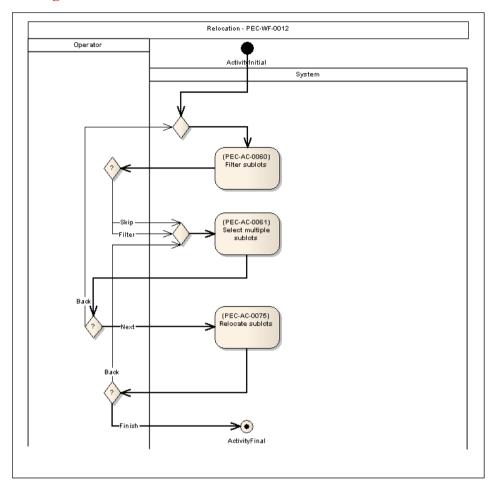


Figure 3: PEC-WF-0012 - Relocation

- User group: Logistical operator
- Input: Sublot, source storage location
- Output: Sublot, target storage location, transaction history entry on batch and sublot level

- 1. PEC-AC-0060 Filter sublots (page 16)
- 2. PEC-AC-0061 Select multiple sublots (page 17)
- 3. PEC-AC-0075 Relocate sublots (page 18)

PEC-WF-0013 - Sublot Split

Sublots occasionally need to be split, for example to make material available simultaneously at two different locations. Splits can be even or uneven. An even split means that the base sublot is split in two or more new sublots with identical quantities, thus using up the base sublot. In an uneven split one or more sublots are split off from the base sublot, which itself also continues to hold material.

Sublot split at a glance:

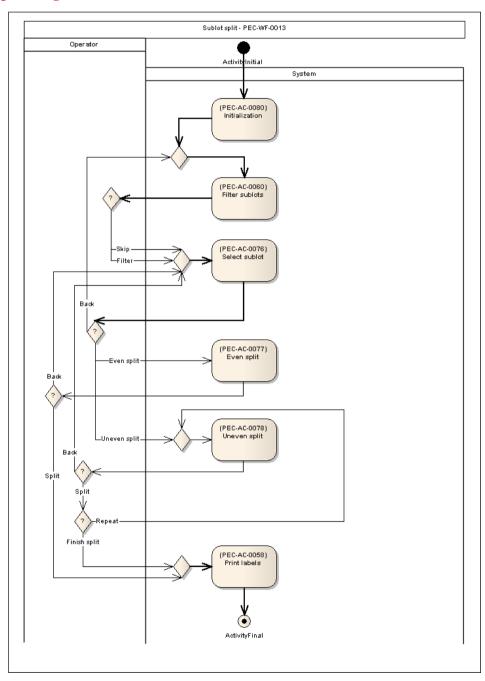


Figure 4: PEC-WF-0013 - Sublot split

- User group: Logistical operator
- Input: Sublot
- Output: Sublots, label(s), report history entry, transaction history entry on batch and sublot level

- 1. PEC-AC-0080 Initialization (page 20)
- 2. PEC-AC-0060 Filter sublots (page 16)
- 3. PEC-AC-0076 Select sublot (page 18)
- 4. PEC-AC-0077 Even split (page 19) PEC-AC-0078 - Uneven split (page 19)
- 5. PEC-AC-0058 Print labels (page 15)

PEC-WF-0014 - Inventory Correction

An inventory correction becomes necessary if, during an inventory check for example, it turns out that a sublot contains more or less material than registered in the system. In these cases the sublot quantity can be changed to the actual quantity of material contained in the sublot.

Inventory correction at a glance:

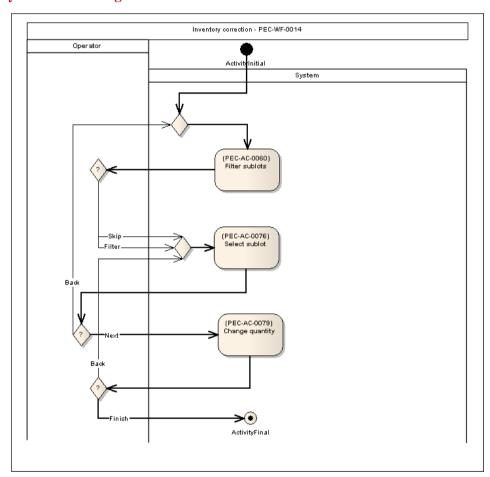


Figure 5: PEC-WF-0014 - Inventory correction

■ User group: Logistical operator

■ Input: Sublot

Output: Sublot, transaction history entry on batch and sublot level

The current workflow comprises the following activities:

1. PEC-AC-0060 - Filter sublots (page 16)

2. PEC-AC-0076 - Select sublot (page 18)

3. PEC-AC-0079 - Change quantity (page 19)

Activities

This chapter details the pre-defined activities listed within the various workflows.

PEC-AC-0053 - Create Batch

- The operator creates a new batch for further processing.
- Used by workflows: PEC-WF-0010 Material receipt (page 5)

The following activity steps are executed when creating a batch:

Step 1

PEC-AS-0052 - Enter batch-specific data

The system requests the operator to enter batch-specific data.

The operator triggers the system to create a batch.

Step 2a

ONLY IF THE EXPIRY DATE OF THE BATCH IS IN THE PAST OR THE ACTUAL DATE.

PEC-AS-0097 - Batch status: Blocked

The system sets the batch status to **Blocked** (see **GEN-SG-0001 - Batch** status graph (page 27)).

Step 2b

ONLY IF THE EXPIRY DATE OF THE BATCH IS IN THE FUTURE.

PEC-AS-0068 - Batch status: Quarantined

The system sets the batch status to **Quarantined** (see **GEN-SG-0001 - Batch** status graph (page 27)).

Step 3

PEC-AS-0053 - Batch data displayed

The system displays the batch data.

PEC-AC-0054 - Select Batch

- The operator selects an existing batch for further processing.
- Used by workflows: PEC-WF-0010 Material receipt (page 5)

PSFRSPE-RM008E-EN-E, 1.0 13

The following activity steps are executed when selecting a batch:

Step 1

PEC-AS-0054 - Filter batches

The system displays the filter criteria for batches.

Step 2

PEC-AS-0055 - Batch list displayed

The system displays the batch list according to the filter criteria.

Step 3

PEC-AS-0053 - Batch data displayed

The system displays the batch data.

PEC-AC-0055 - Select Storage Location

- The operator selects a storage location for further processing.
- Used by workflows: PEC-WF-0010 Material receipt (page 5)

The following activity steps are executed when selecting a storage location:

Step 1

PEC-AS-0056 - Filter storage locations

The system displays the filter criteria for storage locations.

Step 2

PEC-AS-0057 - Storage location list displayed

The system displays the storage location list according to the filter criteria.

PEC-AC-0056 - Select Material

- The operator selects a material for further processing.
- Used by workflows: PEC-WF-0010 Material receipt (page 5)

The following activity steps are executed when selecting a batch:

Step 1

PEC-AS-0064 - Filter materials

The system displays the filter criteria for materials.

Step 2

PEC-AS-0092 - Materials list displayed

The system displays all materials available for receiving according to the filter criteria.

Step 3

PEC-AS-0043 - Material data displayed

The system displays the data of the selected material.

PEC-AC-0057 - Create Sublots

- The operator creates sublots for further processing.
- Used by workflows: PEC-WF-0010 Material receipt (page 5)

The following activity steps are executed when creating sublots:

Step 1

PEC-AS-0058 - Enter sublot-specific data

The system requests the operator to enter sublot-specific data.

The operator triggers the system to create sublots.

System verification:

- Number of sublots between 1 and 9999.
- Quantity is larger than 0.
- If a unit conversion is required whether the conversion is defined.

Default setting:

Unit of measure of batch is taken over. This setting can be overwritten by the operator.

Step 2

PEC-AS-0070 - Sublot status set

The system sets the status to the status of the batch.

Step 3

PEC-AS-0059 - Sublot list displayed

The system displays a list of the created sublots.

PEC-AC-0058 - Print Labels

- The system prints labels for the created sublots.
- Used by workflows: PEC-WF-0010 Material receipt (page 5), PEC-WF-0013 Sublot split (page 10)

The following activity steps are executed when printing labels:

PEC-AS-0060 - Enter label-specific data

The system requests the operator to enter label-specific data.

The operator triggers the system to print the labels.

Default setting:

- Number of labels per sublot = 1.
- Printing sequence: Not collated

Reprinting labels: The system allows to reprint the labels according to the settings.

Step 2

Step 1

GEN-AS-0007 - Label printed

The system prints the label(s) to the configured printer.

PEC-AC-0060 - Filter Sublots

- The system displays the filter criteria for sublots.
- Used by workflows: PEC-WF-0011 Material issue (page 8), PEC-WF-0012 Relocation (page 9), PEC-WF-0013 Sublot split (page 10), PEC-WF-0014 Inventory correction (page 12)

The following activity steps are executed when filtering sublots:

Step 1

PEC-AS-0075 - Enter sublot filter-specific data

The system requests the operator to enter sublot filter-specific data.

Step 2

PEC-AS-0088 - Ready for identification by barcode scanner

The system is ready to accept at any time the identification of a sublot or container (if applicable) by barcode scanning. This automatically triggers

- in the Material issue context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0062 Issue sublots (page 17)
- in the Relocation context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0075 Relocate sublots (page 18)
- in the Sublot split context: PEC-AC-0076 Select sublot (page 18), selection of the sublot in PEC-AC-0076 Select sublot (page 18)
- in the Inventory correction context: PEC-AC-0076 Select sublot (page 18), PEC-AC-0079 Change quantity (page 19)

PEC-AC-0061 - Select Multiple Sublots

- The operator selects sublots for further processing.
- Used by workflows: PEC-WF-0011 Material issue (page 8), PEC-WF-0012 Relocation (page 9)

The following activity steps are executed when selecting sublots:

Step 1

PEC-AS-0076 - Sublot list displayed

The system displays the sublot list according to the filter criteria.

Step 2

PEC-AS-0077 - Multiple sublots selected

The system requests the operator to select specific sublots for further processing.

Step 3

PEC-AS-0088 - Ready for identification by barcode scanner

The system is ready to accept at any time the identification of a sublot or container (if applicable) by barcode scanning. This automatically triggers

- in the Material issue context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0062 Issue sublots (page 17)
- in the Relocation context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0075 Relocate sublots (page 18)
- in the Sublot split context: PEC-AC-0076 Select sublot (page 18), selection of the sublot in PEC-AC-0076 Select sublot (page 18)
- in the Inventory correction context: PEC-AC-0076 Select sublot (page 18), PEC-AC-0079 Change quantity (page 19)

PEC-AC-0062 - Issue Sublots

- The operator issues the selected sublots.
- Used by workflows: PEC-WF-0011 Material issue (page 8)

The following activity steps are executed when issuing sublots:

Step 1

PEC-AS-0078 - Enter issue-specific data

The system requests the operator to enter issue-specific data.

The operator triggers the system to issue the sublots.

Step 2

GEN-AS-0001 - Single signature requested

The system requests a confirmation via single signature.

PEC-AC-0075 - Relocate Sublots

- The operator relocates the selected sublots.
- Used by workflows: PEC-WF-0012 Relocation (page 9)

The following activity steps are executed when relocating sublots:

Step 1

PEC-AS-0093 - Enter relocation-specific data

The system requests the operator to enter relocation-specific data.

The operator triggers the system to relocate the sublots.

PEC-AC-0076 - Select Sublot

- The operator selects a sublot for further processing.
- Used by workflows: PEC-WF-0013 Sublot split (page 10), PEC-WF-0014 Inventory correction (page 12)

The following activity steps are executed when selecting a sublot:

Step 1

PEC-AS-0076 - Sublot list displayed

The system displays the sublot list according to the filter criteria.

Step 2

PEC-AS-0094 - Sublot selected

The system requests the operator to select a specific sublot for further processing.

Step 3

PEC-AS-0088 - Ready for identification by barcode scanner

The system is ready to accept at any time the identification of a sublot or container (if applicable) by barcode scanning. This automatically triggers

- in the Material issue context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0062 Issue sublots (page 17)
- in the Relocation context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0075 Relocate sublots (page 18)

- in the Sublot split context: PEC-AC-0076 Select sublot (page 18), selection of the sublot in PEC-AC-0076 Select sublot (page 18)
- in the Inventory correction context: PEC-AC-0076 Select sublot (page 18), PEC-AC-0079 Change quantity (page 19)

PEC-AC-0077 - Even Split

- The operator performs an even split on the selected sublot.
- Used by workflows: PEC-WF-0013 Sublot split (page 10)

The following activity steps are executed when performing sublot split:

Step 1

PEC-AS-0095 - Enter split-specific data

The system requests the operator to enter split-specific data.

The operator triggers the system to perform the sublot split.

Step 2

PEC-AS-0096 - Updated sublot list displayed

The system displays an updated sublot list after performing the sublot split.

PEC-AC-0078 - Uneven Split

- The operator performs an uneven split on the selected sublot.
- The steps can be repeated.
- Used by workflows: PEC-WF-0013 Sublot split (page 10)

The following activity steps are executed when performing sublot split:

Step 1

PEC-AS-0095 - Enter split-specific data

The system requests the operator to enter split-specific data.

The operator triggers the system to perform the sublot split.

Step 2

PEC-AS-0096 - Updated sublot list displayed

The system displays an updated sublot list after performing the sublot split.

PEC-AC-0079 - Change Quantity

- The operator changes the quantity of the selected sublot.
- Used by workflows: PEC-WF-0014 Inventory correction (page 12)

The following activity steps are executed when changing the quantity:

Step 1

PEC-AS-0062 - Enter correction-specific data

The system requests the operator to enter the correction-specific data.

The operator triggers the system to correct the quantity.

Step 2

GEN-AS-0001 - Single signature requested

The system requests a confirmation via single signature.

PEC-AC-0080 - Initialization

- The system checks whether all prerequisites for the current activity are fulfilled. If the requirements are not fulfilled, the system displays a message.
- Used by workflows: PEC-WF-0010 Material receipt (page 5), PEC-WF-0013 Sublot split (page 10)

The following activity steps are executed when initializing the system.

Step 1

PEC-AS-0035 - Station check

The system checks whether a station is available.

Activity Steps

This chapter lists all pre-defined activity steps.

GEN-AS-0001 - Single Signature Requested

GEN-AS-0001 - Single signature requested

The system requests a confirmation via single signature.

GEN-AS-0007 - Label Printed

GEN-AS-0007 - Label printed

The system prints the label(s) to the configured printer.

PEC-AS-0035 - Station Check

PEC-AS-0035 - Station check

The system checks whether a station is available.

PEC-AS-0043 - Material Data Displayed

PEC-AS-0043 - Material data displayed

The system displays the data of the selected material.

PEC-AS-0052 - Enter Batch-specific Data

■ PEC-AS-0052 - Enter batch-specific data

The system requests the operator to enter batch-specific data.

The operator triggers the system to create a batch.

PEC-AS-0053 - Batch Data Displayed

■ PEC-AS-0053 - Batch data displayed

The system displays the batch data.

PSFRSPE-RM008E-EN-E, 1.0 21

PEC-AS-0054 - Filter Batches

PEC-AS-0054 - Filter batches

The system displays the filter criteria for batches.

PEC-AS-0055 - Batch List Displayed

PEC-AS-0055 - Batch list displayed

The system displays the batch list according to the filter criteria.

PEC-AS-0056 - Filter Storage Locations

PEC-AS-0056 - Filter storage locations

The system displays the filter criteria for storage locations.

PEC-AS-0057 - Storage Location List Displayed

PEC-AS-0057 - Storage location list displayed

The system displays the storage location list according to the filter criteria.

PEC-AS-0058 - Enter Sublot-specific Data

PEC-AS-0058 - Enter sublot-specific data

The system requests the operator to enter sublot-specific data.

The operator triggers the system to create sublots.

System verification:

- Number of sublots between 1 and 9999.
- Quantity is larger than 0.
- If a unit conversion is required whether the conversion is defined.

Default setting:

■ Unit of measure of batch is taken over. This setting can be overwritten by the operator.

PEC-AS-0059 - Sublot List Displayed

PEC-AS-0059 - Sublot list displayed

The system displays a list of the created sublots.

PEC-AS-0060 - Enter Label-specific Data

PEC-AS-0060 - Enter label-specific data

The system requests the operator to enter label-specific data.

The operator triggers the system to print the labels.

Default setting:

- Number of labels per sublot = 1.
- Printing sequence: Not collated

Reprinting labels: The system allows to reprint the labels according to the settings.

PEC-AS-0062 - Enter Correction-specific Data

PEC-AS-0062 - Enter correction-specific data

The system requests the operator to enter the correction-specific data.

The operator triggers the system to correct the quantity.

PEC-AS-0064 - Filter Materials

PEC-AS-0064 - Filter materials

The system displays the filter criteria for materials.

PEC-AS-0068 - Batch Status: Quarantined

PEC-AS-0068 - Batch status: Quarantined

The system sets the batch status to **Quarantined** (see **GEN-SG-0001 - Batch** status graph (page 27)).

PEC-AS-0070 - Sublot Status Set

PEC-AS-0070 - Sublot status set

The system sets the status to the status of the batch.

PEC-AS-0075 - Enter Sublot Filter-specific Data

PEC-AS-0075 - Enter sublot filter-specific data

The system requests the operator to enter sublot filter-specific data.

PEC-AS-0076 - Sublot List Displayed

PEC-AS-0076 - Sublot list displayed

The system displays the sublot list according to the filter criteria.

PSFRSPE-RM008E-EN-E, 1.0

PEC-AS-0077 - Multiple Sublots Selected

PEC-AS-0077 - Multiple sublots selected

The system requests the operator to select specific sublots for further processing.

PEC-AS-0078 - Enter Issue-specific Data

PEC-AS-0078 - Enter issue-specific data

The system requests the operator to enter issue-specific data.

The operator triggers the system to issue the sublots.

PEC-AS-0088 - Ready for Identification by Barcode Scanner

PEC-AS-0088 - Ready for identification by barcode scanner

The system is ready to accept at any time the identification of a sublot or container (if applicable) by barcode scanning. This automatically triggers

- in the Material issue context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0062 Issue sublots (page 17)
- in the Relocation context: PEC-AC-0061 Select multiple sublots (page 17), PEC-AC-0075 Relocate sublots (page 18)
- in the Sublot split context: PEC-AC-0076 Select sublot (page 18), selection of the sublot in PEC-AC-0076 Select sublot (page 18)
- in the Inventory correction context: PEC-AC-0076 Select sublot (page 18), PEC-AC-0079 Change quantity (page 19)

PEC-AS-0092 - Materials List Displayed

PEC-AS-0092 - Materials list displayed

The system displays all materials available for receiving according to the filter criteria.

PEC-AS-0093 - Enter Relocation-specific Data

PEC-AS-0093 - Enter relocation-specific data

The system requests the operator to enter relocation-specific data.

The operator triggers the system to relocate the sublots.

PEC-AS-0094 - Sublot Selected

PEC-AS-0094 - Sublot selected

The system requests the operator to select a specific sublot for further processing.

PEC-AS-0095 - Enter Split-specific Data

PEC-AS-0095 - Enter split-specific data

The system requests the operator to enter split-specific data.

The operator triggers the system to perform the sublot split.

PEC-AS-0096 - Updated Sublot List Displayed

PEC-AS-0096 - Updated sublot list displayed

The system displays an updated sublot list after performing the sublot split.

PEC-AS-0097 - Batch Status: Blocked

PEC-AS-0097 - Batch status: Blocked

The system sets the batch status to **Blocked** (see **GEN-SG-0001 - Batch** status graph (page 27)).

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Status Graphs

This chapter details the status graphs applied by the inventory workflows.

GEN-SG-0001 - Batch

Batches are maintained within PharmaSuite for Production Management. However, for details, see "Functional Requirement Specification Data Management".

PSFRSPE-RM008E-EN-E, 1.0 27

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Function List

The table below lists all workflows and their related activities.

Workflow	Activities
PEC-WF-0010 - Material receipt (page 5)	PEC-AC-0080 - Initialization (page 20)
	PEC-AC-0056 - Select material (page 14)
	PEC-AC-0053 - Create batch (page 13) PEC-AC-0054 - Select batch (page 13)
	PEC-AC-0055 - Select storage location (page 14)
	PEC-AC-0057 - Create sublots (page 15)
	PEC-AC-0058 - Print labels (page 15)
PEC-WF-0011 - Material issue (page 8)	PEC-AC-0060 - Filter sublots (page 16)
	PEC-AC-0061 - Select multiple sublots (page 17)
	PEC-AC-0062 - Issue sublots (page 17)
PEC-WF-0012 - Relocation (page 9)	PEC-AC-0060 - Filter sublots (page 16)
	PEC-AC-0061 - Select multiple sublots (page 17)
	PEC-AC-0075 - Relocate sublots (page 18)
PEC-WF-0013 - Sublot split (page 10)	PEC-AC-0080 - Initialization (page 20)
	PEC-AC-0060 - Filter sublots (page 16)
	PEC-AC-0076 - Select sublot (page 18)
 	PEC-AC-0077 - Even split (page 19) PEC-AC-0078 - Uneven split (page 19)
	PEC-AC-0058 - Print labels (page 15)
PEC-WF-0014 - Inventory correction (page 12)	PEC-AC-0060 - Filter sublots (page 16)
	PEC-AC-0076 - Select sublot (page 18)
	PEC-AC-0079 - Change quantity (page 19)

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

Linkage to Implementation

The tables below provide the linkage of workflows, activities, activity steps, and status graphs to their implementation.

Workflows and Activity Sets

The workflows are implemented by the following activity sets.

Material receipt

■ Workflow: PEC-WF-0010 - Material receipt (page 5)

Activity set	Activity set step	Activity	Form/Activity/Other
GoodsReceipt	asCheckStationIsSet	PEC-AC-0080 - Initialization (page 20)	PreconditionCheckActiv ity
GoodsReceipt	$as {\tt StepCreateTHC} on text$		Generator
GoodsReceipt	asSelectPart		MacroStep: as_wip_GoodsReceiptSe lectPart
as_wip_GoodsReceiptSelectPart	asMarkUnfinished		Constants
as_wip_GoodsReceiptSelectPart	asFilterParts	PEC-AC-0056 - Select material (page 14)	FormActivity: pec_FilterPartsForm
as_wip_GoodsReceiptSelectPart	asSelectPart	PEC-AC-0056 - Select material (page 14)	FormActivity: pec_GoodsReceiptSelec tPart
as_wip_GoodsReceiptSelectPart	asMarkFinished		Constants
GoodsReceipt	asCreateBatch	PEC-AC-0053 - Create batch (page 13)	FormActivity: pec_GoodsReceiptCreat eBatch
GoodsReceipt	asSelectBatch		MacroStep: as_wip_GoodsReceiptSe lectBatch
as_wip_GoodsReceiptSelectBa tch	asMarkUnfinished		Constants

PSFRSPE-RM008E-EN-E, 1.0

•	
•	
•	

Activity set	Activity set step	Activity	Form/Activity/Other
as_wip_GoodsReceiptSelectBa tch	asFilterBatches	PEC-AC-0054 - Select batch (page 13)	FormActivity: pec_FilterBatchesForm
as_wip_GoodsReceiptSelectBa tch	asSelectBatch	PEC-AC-0054 - Select batch (page 13)	FormActivity: pec_GoodsReceiptSelec tBatch
as_wip_GoodsReceiptSelectBatch	asMarkFinished		Constants
GoodsReceipt	asSelectStorageLocatio n		MacroStep: as_wip_GoodsReceiptSe lectStorageLocation
as_wip_GoodsReceiptSelectSt orageLocation	asMarkUnfinished		Constants
as_wip_GoodsReceiptSelectSt orageLocation	asFilterStorageLocation s	PEC-AC-0055 - Select storage location (page 14)	FormActivity: pec_FilterLocationsFor m
as_wip_GoodsReceiptSelectSt orageLocation	asSelectStorageLocatio n	PEC-AC-0055 - Select storage location (page 14)	FormActivity: pec_GoodsReceiptSelec tStorageLocation
as_wip_GoodsReceiptSelectSt orageLocation	asMarkFinished		Constants
GoodsReceipt	asStepPrepareSublotCr eation		Constants
GoodsReceipt	asStepAfterRestore		Null step
GoodsReceipt	asCreateSublots	PEC-AC-0057 - Create sublots (page 15)	FormActivity: pec_GoodsReceiptCreat eSublots
GoodsReceipt	asStepRestoreUnprinte dSublots		UnprintedSublotActivity
GoodsReceipt	asPrintLabels	PEC-AC-0058 - Print labels (page 15)	FormActivity: pec_GoodsReceiptPrint Labels

•

Material issue

■ Workflow: PEC-WF-0011 - Material issue (page 8)

Activity set	Activity set step	Activity	Form/Activity/Other
GoodsIssue	asFilterSublots	PEC-AC-0060 - Filter sublots (page 16)	FormActivity: pec_FilterSublotsForm
GoodsIssue	asClearSelectableSublo ts		Constants
GoodsIssue	asSelectSublots	PEC-AC-0061 - Select multiple sublots (page 17)	FormActivity: pec_GoodsIssueSelectS ublots
GoodsIssue	asIssueSublots	PEC-AC-0062 - Issue sublots (page 17)	FormActivity: pec_GoodsIssueIssueSu blots

Relocation

■ Workflow: PEC-WF-0012 - Relocation (page 9)

Activity set	Activity set step	Activity	Form/Activity/Other
SublotRelocation	asFilterSublots	PEC-AC-0060 - Filter sublots (page 16)	FormActivity: pec_FilterSublotsForm
SublotRelocation	$as {\it Clear Available Sublots}$		Constants
SublotRelocation	asSelectSublots	PEC-AC-0061 - Select multiple sublots (page 17)	FormActivity: pec_SublotRelocationSe lectSublots
SublotRelocation	asRelocateSublots	PEC-AC-0075 - Relocate sublots (page 18)	FormActivity: pec_SublotRelocationR elocateSublots

Sublot split

■ Workflow: PEC-WF-0013 - Sublot split (page 10)

Activity set	Activity set step	Activity	Form/Activity/Other
SublotSplit	asCheckStationIsSet	PEC-AC-0080 - Initialization (page 20)	PreconditionCheckActiv ity
SublotSplit	$as {\tt StepCreateTHC} on text$		Generator
SublotSplit	asFilterSublots	PEC-AC-0060 - Filter sublots (page 16)	FormActivity: pec_FilterSublotsForm

•

Activity set	Activity set step	Activity	Form/Activity/Other
SublotSplit	asClearSelectableSublo ts		Constants
SublotSplit	asSelectSublot	PEC-AC-0076 - Select sublot (page 18)	FormActivity: pec_SublotSplitSelectS ublot
SublotSplit	asStepPrepareSplit		Constants
SublotSplit	asStepAfterRestore		Null step
SublotSplit	asEvenSplit	PEC-AC-0077 - Even split (page 19)	FormActivity: pec_SublotSplitSplitSub lot
SublotSplit	asUnevenSplit	PEC-AC-0078 - Uneven split (page 19)	FormActivity: pec_SublotSplitSplitSub lot
SublotSplit	asPrintLabels	PEC-AC-0058 - Print labels (page 15)	FormActivity: pec_PrintSublotsWrapp er
SublotSplit	asStepRestoreUnprinte dLabels		UnprintedSublotActivity

Inventory correction

■ Workflow: PEC-WF-0014 - Inventory correction (page 12)

Activity set	Activity set step	Activity	Form/Activity/Other
InventoryCorrection	asFilterSublots	PEC-AC-0060 - Filter sublots (page 16)	FormActivity: pec_FilterSublotsForm
InventoryCorrection	asClearSelectableSublo ts		Constants
InventoryCorrection	asStepSelectSublot	PEC-AC-0076 - Select sublot (page 18)	FormActivity: pec_InvCorrSelectSublo t
InventoryCorrection	asStepChangeSublot	PEC-AC-0079 - Change quantity (page 19)	FormActivity: pec_InvCorrChangeSubl ot

Document Information

The document information covers various data related to the document.

Approval

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

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

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

Version Information

Object	Version
PharmaSuite	8.4
Functional Requirement Specification	1.0

Revision History

The following table describes the history of this document.

Object	Description	Document

PSFRSPE-RM008E-EN-E, 1.0 35

 $\ref{eq:continuous}$ Rockwell Software PharmaSuite $\ref{eq:continuous}$ 8.4 - Functional Requirement Specification Production Execution

В	I
	Initialization - PEC-AC-0080 • 20
Batch - GEN-SG-0001 • 27	Inventory correction - PEC-WF-0014 • 12
Batch data displayed - PEC-AS-0053 • 21	Issue sublots - PEC-AC-0062 • 17
Batch list displayed - PEC-AS-0055 • 22	
Batch status	L
Blocked - PEC-AS-0097 • 25	Label printed - GEN-AS-0007 • 21
Quarantined - PEC-AS-0068 • 23	M
С	M
	Material data displayed - PEC-AS-0043 • 21
Change quantity - PEC-AC-0079 • 19	Material issue - PEC-WF-0011 • 8
Conventions (typographical) • 3	Material receipt - PEC-WF-0010 • 5
Create batch - PEC-AC-0053 • 13	Materials list displayed - PEC-AS-0092 • 24
Create sublots - PEC-AC-0057 • 15	Multiple sublots selected - PEC-AS-0077 • 24
E	Р
Enter batch-specific data - PEC-AS-0052 • 21	PEC-AC-0053 - Create batch • 13
Enter correction-specific data - PEC-AS-0062 • 23	PEC-AC-0054 - Select batch • 13
Enter issue-specific data - PEC-AS-0078 • 24	PEC-AC-0055 - Select storage location • 14
Enter label-specific data - PEC-AS-0060 • 23	PEC-AC-0056 - Select material • 14
Enter relocation-specific data - PEC-AS-0093 • 24	PEC-AC-0057 - Create sublots • 15
Enter split-specific data - PEC-AS-0095 • 25	PEC-AC-0058 - Print labels • 15
Enter sublot filter-specific data - PEC-AS-0075 • 23	PEC-AC-0060 - Filter sublots • 16
Enter sublot-specific data - PEC-AS-0058 • 22	PEC-AC-0061 - Select multiple sublots • 17
Even split - PEC-AC-0077 • 19	PEC-AC-0062 - Issue sublots • 17
F	PEC-AC-0075 - Relocate sublots • 18
F	PEC-AC-0076 - Select sublot • 18
Filter batches - PEC-AS-0054 • 22	PEC-AC-0077 - Even split • 19
Filter materials - PEC-AS-0064 • 23	PEC-AC-0078 - Uneven split • 19
Filter storage locations - PEC-AS-0056 • 22	PEC-AC-0079 - Change quantity • 19
Filter sublots - PEC-AC-0060 • 16	PEC-AC-0080 - Initialization • 20
G	PEC-AS-0035 - Station check • 21
GEN-AS-0001 - Single signature requested • 21 GEN-AS-0007 - Label printed • 21 GEN-SG-0001 - Batch • 27	PEC-AS-0043 - Material data displayed • 21
	PEC-AS-0052 - Enter batch-specific data • 21
	PEC-AS-0053 - Batch data displayed • 21
	PEC-AS-0054 - Filter batches • 22
	PEC-AS-0055 - Batch list displayed • 22
	PEC-AS-0056 - Filter storage locations • 22

PSFRSPE-RM008E-EN-E, 1.0

```
PEC-AS-0057 - Storage location list displayed • 22
  PEC-AS-0058 - Enter sublot-specific data • 22
  PEC-AS-0059 - Sublot list displayed • 22
  PEC-AS-0060 - Enter label-specific data • 23
  PEC-AS-0062 - Enter correction-specific data • 23
  PEC-AS-0064 - Filter materials • 23
  PEC-AS-0068 - Batch status
     Quarantined • 23
  PEC-AS-0070 - Sublot status set • 23
  PEC-AS-0075 - Enter sublot filter-specific data • 23
  PEC-AS-0076 - Sublot list displayed • 23
  PEC-AS-0077 - Multiple sublots selected • 24
  PEC-AS-0078 - Enter issue-specific data • 24
  PEC-AS-0088 - Ready for identification by barcode
     scanner • 24
  PEC-AS-0092 - Materials list displayed • 24
  PEC-AS-0093 - Enter relocation-specific data • 24
  PEC-AS-0094 - Sublot selected • 24
  PEC-AS-0095 - Enter split-specific data • 25
  PEC-AS-0096 - Updated sublot list displayed • 25
  PEC-AS-0097 - Batch status
     Blocked • 25
  PEC-WF-0010 - Material receipt • 5
  PEC-WF-0011 - Material issue • 8
  PEC-WF-0012 - Relocation • 9
  PEC-WF-0013 - Sublot split • 10
  PEC-WF-0014 - Inventory correction • 12
  Print labels - PEC-AC-0058 • 15
R
  Ready for identification by barcode scanner -
     PEC-AS-0088 • 24
  Relocate sublots - PEC-AC-0075 • 18
  Relocation - PEC-WF-0012 • 9
  Select batch - PEC-AC-0054 • 13
  Select material - PEC-AC-0056 • 14
  Select multiple sublots - PEC-AC-0061 • 17
  Select storage location - PEC-AC-0055 • 14
  Single signature requested - GEN-AS-0001 • 21
  Station check - PEC-AS-0035 • 21
```

Storage location list displayed - PEC-AS-0057 • 22 Sublot list displayed - PEC-AS-0059 • 22 Sublot list displayed - PEC-AS-0076 • 23 Sublot selected - PEC-AS-0094 • 24 Sublot split - PEC-WF-0013 • 10 Sublot status set - PEC-AS-0070 • 23

U

Uneven split - PEC-AC-0078 • 19 Updated sublot list displayed - PEC-AS-0096 • 25

S