



MATERIAL TRACKING PHASES

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USER MANUAL

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Material Tracking Phases

The Material Tracking phases of PharmaSuite represent a series of phases that can be used for tracking materials and their quantities during the execution of a recipe within the framework of PharmaSuite for Production Execution with EBR. They provide functions to identify material sublots, create sublots for produced materials, and account the material quantities of the sublots that have been identified for the executed recipe.

TIP

Please note that even though the material tracking phases can be used in various contexts, they can only display their full functional scope if they are located in recipes with a suitable structure (page [2](#)).

The following phases are available:

- Identify Material (page [9](#))
- Produce Material (page [35](#))
- Account Material (page [57](#))

This section contains important information about using the material phases in master recipes. Please read this section carefully, because it provides a solid background for all operations you may wish to perform with your system.

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 <ul style="list-style-type: none"> ■ window and dialog titles ■ menu functions ■ panel, tab, and button names ■ box labels ■ object properties and their values (e.g., status).
<i>Italic typeface</i>	Designates technical background information, such as <ul style="list-style-type: none"> ■ path, folder, and file names ■ methods ■ classes.
CAPITALS	Designate keyboard-related information, such as <ul style="list-style-type: none"> ■ key names ■ keyboard shortcuts.
Monospaced typeface	Designates code examples.

Structural Context

The phases of material tracking rely on material data provided by their material parameters. They can be run in three very different structural contexts:

- as sequential process where each phase needs to be completed to pass its material data on to the following phase.
- as simultaneous process, where all phases can be concurrently active in different operations and the material data is passed on as soon as it occurs in one of the phases.
- as simultaneous process, where the same phases can be concurrently active in different operations and operators can work on the same material positions, but with different sublots.

The following phases are available for material tracking:

- The **Identify material** phase needs to hold all materials to be processed as MFC-relevant material input parameters.
All listed materials and quantities can either be identified during a single phase run or the phase can be placed in a loop or an event-triggered operation and run several times for identifying the materials in several runs of the phase.
- After material identification, it may be relevant to display the GHS data of an identified material. For this purpose, one (or more) optional **Show GHS data** phases can be added to the operation.
The **Show GHS data** phase belongs to the Dispense and Weighing phases. For more information on the phase, please refer to "Show GHS Data" in "User Manual Dispense and Weighing Phases".
- The **Produce material** phase expects the produced material as MFC-relevant material output parameter. It has an external loop so that it can produce sublots of the output material in several runs and different subplot quality statuses. The phase can also be placed in an event-triggered operation. Thus, it is possible to model a process during which a set of sublots is produced, another phase is used to perform another action on the produced sublots, such as placing them on a pallet, and then the next run of the **Produce material** phase is started to produce another set of sublots.
- The optional **Load logistic unit** phase allows an operator to load sublots or a logistic unit onto a target logistic unit. It is suitable for being placed in the external loop of the **Produce material** phase. For more information on the phase, please refer to "Load Logistic Unit" in "User Manual Dispense and Weighing Phases".

TIP

Please note that the **Load logistic unit** phase is only relevant if PharmaSuite is configured to communicate with Warehouse Management.

- The **Account material** phase expects the same materials as input parameters that were processed in the **Identify material** phase. In this case, however, the input parameters are not MFC-relevant, since the phase only calculates the usage quantities of the materials while the actual material flow has taken place earlier in the **Identify material** and **Produce material** phases.
The listed materials can either be accounted during a single phase run or the phase can be placed in a loop or an event-triggered operation to run several times and thus concurrently account the usage quantities of the identified and processed materials.

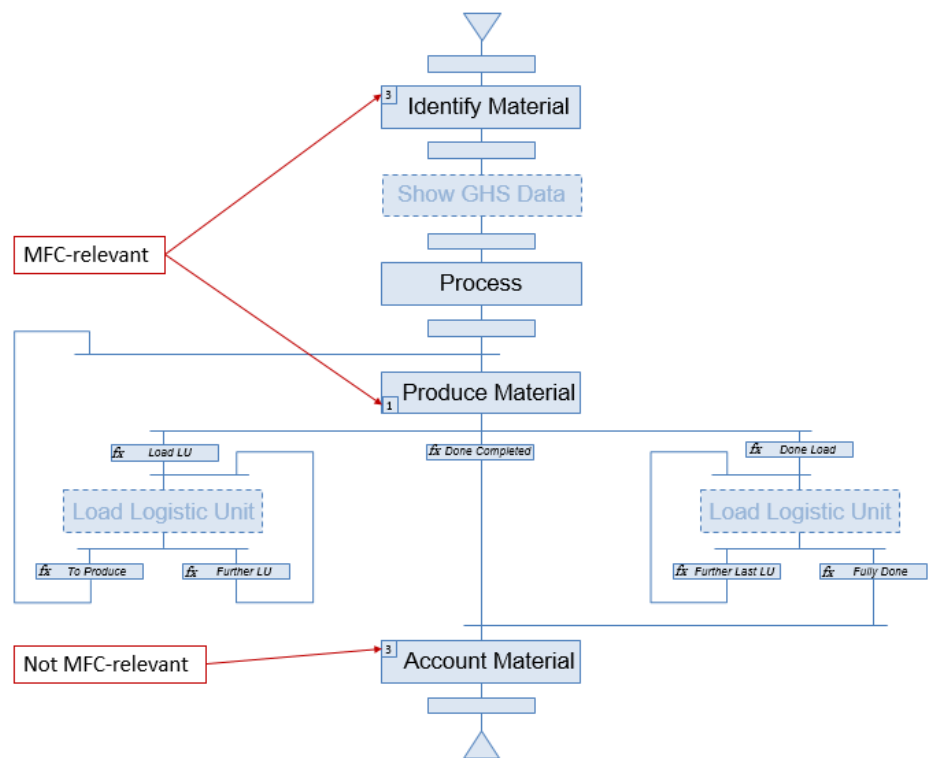


Figure 1: Operation with sequential material tracking

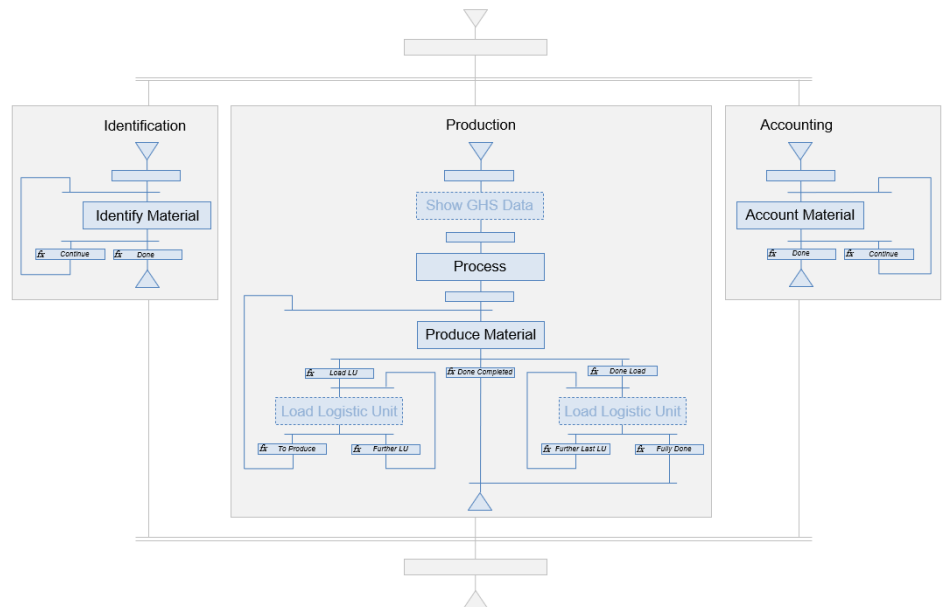


Figure 2: Unit procedure with simultaneous material tracking

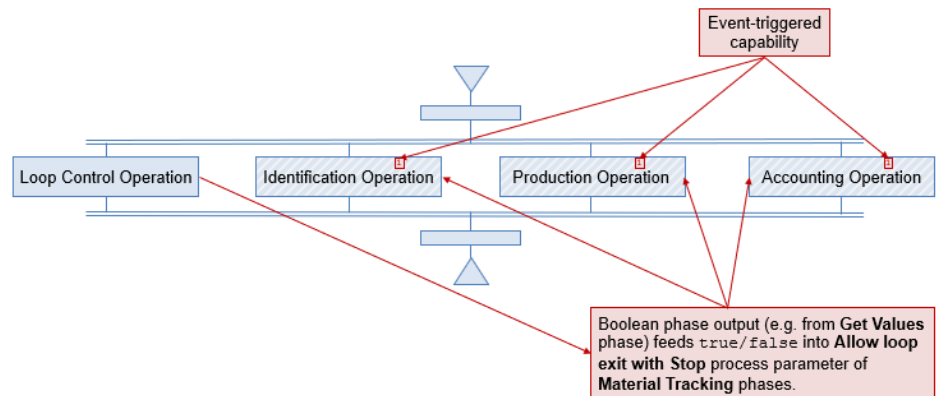


Figure 3: Unit procedure with simultaneous material tracking and event-triggered operations

Transitions of Sequential Material Tracking

The following transition expressions control the material tracking operation:

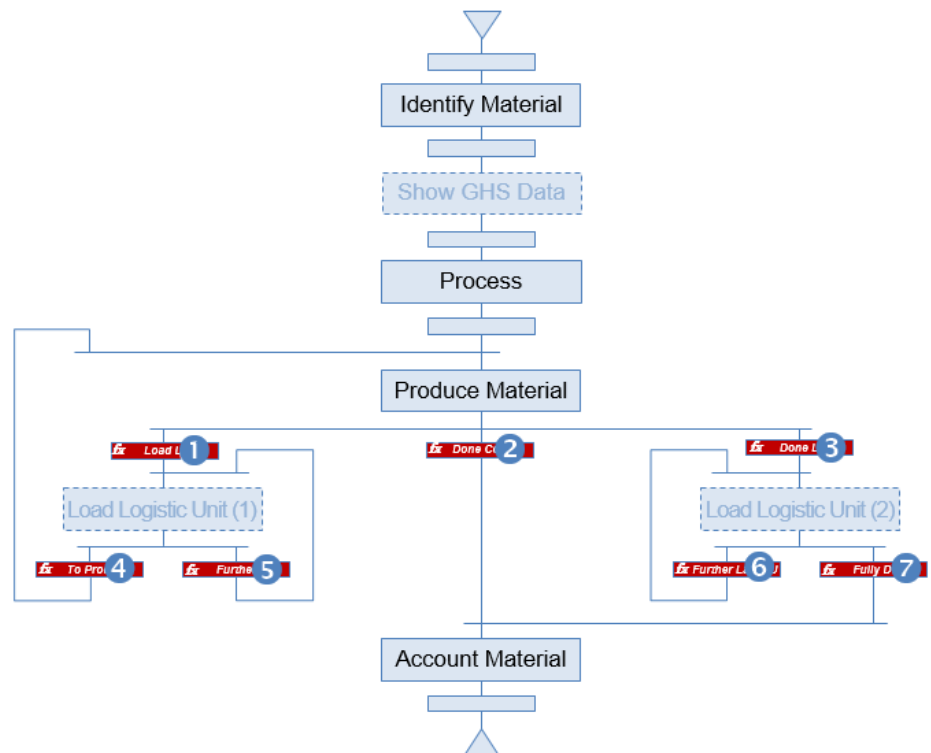


Figure 4: Transitions of a sequential material tracking operation

1 Load LU (Produce material » Load logistic unit (1))

It starts the loop of the **Produce material** phase and provides the chance to move the produced material to a logistic unit.

```
{Produce Material}.{Result} == "CONTINUE"
```

2 **Done Completed** (Produce material » Account material)

It closes the loop of the **Produce material** phase and moves on to material accounting as there are no more sublots to be moved to a logistic unit.

```
{Produce Material}.{Result} == "DONE"
```

3 **Done Load** (Produce Material » Load Logistic Unit (2))

It closes the loop of the **Produce material** phase and allows loading of a final logistic unit.

```
{Produce Material}.{Result} == "DONE"
```

```
AND
```

```
{Produce Material}.{Sublot identifiers} != "Identify"
```

4 **To Produce** (Load logistic unit (1) » Produce Material)

It closes the loop of the **Produce material** phase and allows the production of further sublots.

```
{Load Logistic Unit (1)}. {Result} != "NEXT_LU"
```

5 **Further LU** (Load Logistic Unit (1) » Load Logistic Unit (1))

It loops around the **Load logistic unit** phase to allow to move sublots to an additional logistic unit if the current logistic unit has reached its maximum capacity.

```
{Load Logistic Unit (1)}. {Result} == "FURTHER_LU"
```

6 **Further Last LU** (Load Logistic Unit (2) » Load Logistic Unit (2))

It loops around the **Load logistic unit** phase to allow to move sublots to an additional logistic unit if the current logistic unit has reached its maximum capacity.

```
{Load Logistic Unit (2)}. {Result} == "FURTHER_LU"
```

7 **Fully Done** (Load Logistic Unit (2) » Account Material)

It moves on to material accounting after all remaining sublots have been moved to the logistic unit.

```
{Load Logistic Unit (2)}. {Result} != "FURTHER_LU"
```

Transitions of Simultaneous Material Tracking

The following transition expressions control the material tracking operation:

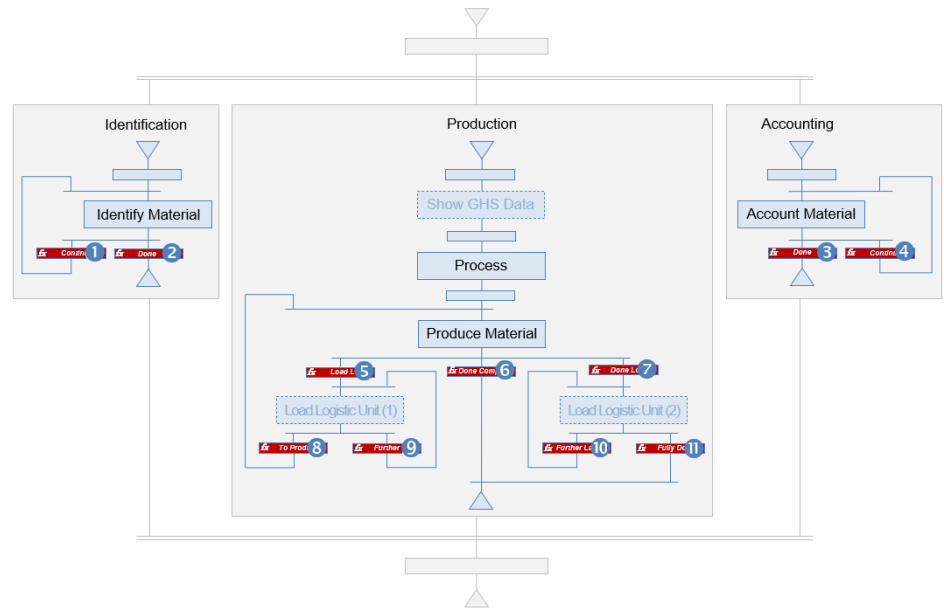


Figure 5: Transitions of a unit procedure with simultaneous material tracking

1 Continue (Identify material » Identify material)

It starts the loop of the **Identify material** phase and provides the chance to identify another subplot.

```
{Identify Material}.{Result} == "CONTINUE"
```

2 Done (Identify material » End step)

It closes the loop of the **Identify material** phase and completes the operation.

```
{Identify Material}.{Result} == "DONE"
```

3 Done (Account material » End step)

It closes the loop of the **Account material** phase and completes the operation.

```
{Account Material}.{Result} == "DONE"
```

4 Continue (Account material » Account material)

It starts the loop of the **Account material** phase and provides the chance to account another subplot.

```
{Account Material}.{Result} == "CONTINUE"
```

5 **Load LU** (Produce material » Load logistic unit (1))

It starts the loop of the **Produce material** phase and provides the chance to move the produced material to a logistic unit.

```
{Produce Material}.{Result} == "CONTINUE"
```

6 **Done Completed** (Produce material » End step)

It closes the loop of the **Produce material** phase and moves on to the next operation as there are no more sublots to be moved to a logistic unit.

```
{Produce Material}.{Result} == "DONE"
```

7 **Done Load** (Produce Material » Load Logistic Unit (2))

It closes the loop of the **Produce material** phase and allows loading of a final logistic unit.

```
{Produce Material}.{Result} == "DONE"
```

AND

```
{Produce Material}.{Sublot identifiers} != "Identify"
```

8 **To Produce** (Load logistic unit (1) » Produce Material)

It closes the loop of the **Produce material** phase and allows the production of further sublots.

```
{Load Logistic Unit (1)}. {Result} != "NEXT_LU"
```

9 **Further LU** (Load Logistic Unit (1) » Load Logistic Unit (1))

It loops around the **Load logistic unit** phase to allow to move sublots to an additional logistic unit if the current logistic unit has reached its maximum capacity.

```
{Load Logistic Unit (1)}. {Result} == "FURTHER_LU"
```

10 **Further Last LU** (Load Logistic Unit (2) » Load Logistic Unit (2))

It loops around the **Load logistic unit** phase to allow to move sublots to an additional logistic unit if the current logistic unit has reached its maximum capacity.

```
{Load Logistic Unit (2)}. {Result} == "FURTHER_LU"
```

11 **Fully Done** (Load Logistic Unit (2) » End step)

It moves on to the next operation after all remaining sublots have been moved to the logistic unit.

```
{Load Logistic Unit (2)}. {Result} != "FURTHER_LU"
```


Identify Material

The **Identify material** phase allows an operator to identify material on subplot and logistic unit level for further processing.

TIP

Please note that the **Identify material** phase is only available for use in master recipes, not in workflows.

It can be used for processing requirements, such as:

- **Identify material prior to dispensing**
The batch status of the materials must be **Released**. This material-specific requirement can be defined and corresponding violations can be tracked as exceptions.
- **Identify material before mixing**
Only allocated batches are allowed to be utilized in the mixing process. An allocation check is specified in the phase. Identification of other batches can be tracked as exceptions.
- **Unidentify material**
Material that has been identified is bound to an order step. As long as none of the previously identified sublots has been accounted, their identification can be revoked. This unbinds the material from the order step and makes it available for identification elsewhere.

Execution

The **Identify material** phase lists all materials that are to be used for processing the ensuing order. An operator can scan the listed materials in any order. It is also possible to place the phase into a loop or an event-triggered operation, so that the operator can scan one or several materials of the list to identify them for immediate processing with concurrent accounting, confirm the phase for subsequent continuation, and later identify further materials in the next run of the phase.

The operator can either scan the label of a single subplot or that of a logistic unit to identify all sublots located on the logistic unit.

TIPS

Please note that 10 is the maximum number of materials you can assign as parameters to the phase.

Please note that handling of logistic units is only available if PharmaSuite is configured to communicate with Warehouse Management.

Once the operator has scanned a material subplot, the phase checks the following data to make sure that it is fit and available for use:

- Batch and subplot status
- Retest and expiry date
- Batch allocation
- Material is marked as MFC-relevant
- Sublot has been produced for the current order step (only for intra materials)
- Sublot is exclusively used by the current order.

TIP

Please note that if any one subplot of a logistic unit fails one of the checks, the system rejects the entire logistic unit. Suitable sublots need to be identified individually.

If the phase is configured to run without a loop and the operator has registered the materials available for identification, he can unlock the **Confirm** button and complete the identification.

If the phase is configured to run in a loop, the operator has registered the materials required for the current phase run, and there will be further phase runs to identify further materials, he selects the **Continue** option, and can **Confirm** the partial identification.

If the phase is configured to run in a loop or an event-triggered-operation, the operator has registered the materials required for the moment, but there will be additional sublots identified elsewhere for the same position, he selects the **Stop** option, and can **Confirm** the partial identification.

If the operator has registered the materials required for the final phase run, he selects the **Done** option, and can **Confirm** and thus complete the identification.

TIP

Please note that the **Unlock** button that enables phase confirmation is not present when the phase has been configured to request a phase completion signature. When the phase is configured for looping, it provides the **Continue** and **Done** options instead of an **Unlock** button.

As long as the phase is active, it provides user-triggered exceptions

- to identify material manually, by typing its subplot identifier.
- to unidentify a material subplot that was erroneously identified and thus bound to the order step, by typing its subplot identifier.
- to force the completion of the identification, even if the system would otherwise prevent that, for instance due to a structural issue with simultaneous processing.

If PharmaSuite is configured to communicate with Warehouse Management, the phase provides an additional user-triggered exception to record warehouse-related errors. If a warehouse-related error occurs, the operator cannot confirm the phase unless he records the exception. The operator, however, can continue to identify materials.

After phase completion, it provides post-completion exceptions

- to identify an additional material subplot, by typing its subplot identifier
- to unidentify a material subplot that was erroneously identified and thus bound to the order step, by typing its subplot identifier.

The exception is only available until the material subplot has been accounted.

TIP

Please note that if the phase is configured for simultaneous processing, the post-completion exceptions are only available for the final run of the phase.

After completion, the phase displays the identified material with the following data in the Execution Window:

- batch and/or subplot identifiers
 - In case a logistic unit has been identified, the phase also displays the logistic unit identifier.
- planned quantity
- identified quantity
- accounted quantity with accounting status (if available).

The Navigator displays the processing result and provides access to the post-completion exceptions.

TIP

When an irregular occurrence during processing, such as loss of material during transport, requires the phase to be fully or partially reworked, the phase's order step can be **Aborted** and **Reactivated** by supervisor action from PharmaSuite for Production Management. Under these circumstances the supervisor can include a comment to execution for each material to detail the actions the operator needs to perform when he restarts the **Reactivated** order step. The phase displays the comment like an instruction text below the list of materials.

Identify the materials for tableting.

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g		
		BX194 / SL00008697		10.0 g		
20	D005-04 / Talc		(20.0 g)	0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	0 g		

Figure 6: Identify material during execution (sequential processing)

Identify the materials for tableting. Refresh

Pos.	Material	Allocated or identified batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	20.0 g	10.0 g	Accounted
		BX238 / SL00008770		10.0 g		
		BX194 / SL00008697		10.0 g		
20	D005-04 / Talc		(20.0 g)	100.0 g	20.0 g	Accounted
		BX196 / SL00008706		100.0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g	1,015.0 g	Accounted
		BX201 / SL00008725		200.0 g		
		BX197 / SL00008716		400.0 g		
		BX219 / SL00008750		505.0 g		

D003-04: Re-Identify 10.0 g
D005-04: Re-Identify 20.0 g
D130-01: Re-Identify 200.0 g

Confirm

Figure 7: Reactivated Identify material during execution with Comment to execution (sequential processing)

Identify the product for packaging. Refresh

Pos.	Material	Allocated or identified batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	1,200.0 g	900 g	
		BX176 / SL00008654		300.0 g		

Confirm

Figure 8: Identify material during execution (simultaneous processing)

Identify the product for packaging. Refresh

Pos.	Material	Allocated or identified batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600.0 g		
		BX10 / SL00000010		300.0 g		

Confirm


Figure 9: Identify material during execution (simultaneous processing with Stop)


Identify the materials for tableting. Refresh

Pos.	Material	Allocated or identified logistic unit / batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	0 g		
20	D005-04 / Talc		(20.0 g)	0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	0 g		

Confirm

Figure 10: Identify material during execution with warehouse connection

To undo the identification, enter the identifier of the affected subplot. Confirm 

To identify manually, enter the subplot identifier. Confirm 



Force the completion. Confirm 

Figure 11: User-triggered exceptions of Identify material

Confirm to record the warehouse error. Confirm 

Figure 12: User-triggered warehouse error exception

Identify the materials for tableting. Refresh 

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %	BX194 / SL00008697	(10.0 g)	10.0 g		
20	D005-04 / Talc	BX196 / SL00008706	(20.0 g)	100.0 g		
30	D130-01 / Sonolin 100 mg premix	BX201 / SL00008725	(1,000.0 g)	1,105.0 g		
		BX197 / SL00008716		200.0 g		
		BX219 / SL00008750		400.0 g		
				505.0 g		




Lock  Confirm 

Figure 13: Identify material after phase completion (sequential processing)

Identify the materials for tableting. Refresh 

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %	BX238 / SL00008770	(10.0 g)	20.0 g	10.0 g	Accounted
		BX194 / SL00008697		10.0 g		
20	D005-04 / Talc	BX237 / SL00008760	(20.0 g)	200.0 g	20.0 g	Accounted
		BX196 / SL00008706		100.0 g		
30	D130-01 / Sonolin 100 mg premix	BX201 / SL00008724	(1,000.0 g)	1,305.0 g	1,015.0 g	Accounted
		BX219 / SL00008750		200.0 g		
		BX197 / SL00008716		505.0 g		
		BX201 / SL00008725		400.0 g		
				200.0 g		

D003-04: Re-identify 10.0 g
D005-04: Re-identify 20.0 g
D130-01: Re-identify 200.0 g



Lock  Confirm 

Figure 14: Reactivated Identify material after phase completion with Comment to execution (sequential processing)

Identify the product for packaging. Refresh

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	1,200.0 g	900 g	
		BX176 / SL00008654		300.0 g		

Continue Done Confirm

Figure 15: Identify material after phase completion (simultaneous processing)

Identify the product for packaging. Refresh

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600.0 g	300.0 g	
		BX10 / SL00000010		300.0 g		

Continue Stop Confirm

Figure 16: Identify material after phase completion (simultaneous processing with Stop)

Identification
Identify Tableting Inputs

Done Identify Undo

Figure 17: Identify material in the Navigator (sequential processing)

Identification
Identify Product

Continue

Figure 18: Identify material in the Navigator (simultaneous processing - Continue)

Identification
Identify Product [2]

Stop

Figure 19: Identify material in the Navigator (simultaneous processing - Stop)

Identification
Identify Product [4]

Done Identify Undo

Figure 20: Identify material in the Navigator (simultaneous processing - Done)

To identify an additional subplot, enter the subplot identifier. Confirm

Figure 21: Post-completion exception of Identify material (Identify)

To undo the identification, enter the identifier of the affected subplot. Confirm

Figure 22: Post-completion exception of Identify material (Undo)

Phase Design

The characteristics of the **Identify material** phase are defined via process parameters and their attributes.

TIP

To have a material listed in the table for identification, you need to assign it as material input parameter to the phase and mark it as MFC-relevant.

Its user interface is designed in three columns that span several rows. When the phase is active, the merged columns of the first row provide space for textual instructions. The center column holds a text box that displays the scanned input. The rightmost of the next row displays a **Refresh** button that updates the data shown in the list of materials. In the next rows, the phase displays the list of materials available for identification, spanning all columns. Once a material has been identified, its data appears as new row of the table. The center column of the bottom row provides the **Unlock** button, while the right column holds the **Confirm** button. If the phase is configured for looping, the phase shows the **Continue** and the **Stop** or **Done** options instead of the **Unlock** button.

When the phase is completed it shows the same three-column, three-row layout with the data of the identified materials listed in the table.

Exception handling during execution is controlled by a risk assessment classification and an exception message that are both defined by the recipe author in the exception's process parameter.

Process Parameters

The following process parameters are available to configure the phase's behavior during execution:

Instruction

Represents the instruction text that is visible on the preview, the active, and the completed view of the phase.

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	Not used.

Loop configuration

Defines if the phase is intended for a single run or to allow looping with several phase runs.

Attribute	Type	Comment
Loop configuration	Choice list	Defines if the phase shall use a loop or static mode. Available settings: No loop , Can loop , Must loop . Default setting: No loop .

Allow loop exit with Stop

Defines if the phase allows to exit its loop without performing the checks that are triggered by the **Done** button. To enable the looping behavior of the phase, make sure the **Loop configuration** process parameter (page 17) is set to **Can loop** or **Must loop**.

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Batch status check configuration

Defines whether the batch status of a material must be checked to determine if the material is fit for use.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum batch status attribute of the Batch check definition process parameter (page 20) is set.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Expiry date check configuration

Defines whether the expiry date of a material must be checked to determine if the material is fit for use.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum time to expire attribute of the Batch check definition process parameter (page 20) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Allocation check configuration

Defines whether existing batch allocation requirements are relevant to determine if the material is suitable for use.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, the check is only performed if there are allocation requirements.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Consumption configuration

Intended for sublots that are fully used up during processing, such as pre-dispensed materials.

Attribute	Type	Comment
Auto consume	Flag	Controls if the identified subplot is registered as fully consumed when the phase is completed with the Confirm button. If you have more than one phase sharing the same material within one operation, all sublots will be consumed even if the flag is set only for one of the phases. A subplot that is marked as fully consumed is no longer displayed in any inventory lists.

Batch check definition

Defines the settings required to enable the configuration of the batch status (page 17) and expiry date (page 18) checks.

Attribute	Type	Comment
Minimum batch status	Choice list	Defines the minimum batch status required for material identification. Available settings: Blocked , Quarantined , Released . Default setting: Released .
Minimum time to expire	Numeric	Defines the number of days allowed between the actual identification date and expiry date, excluding the expiry date.

Sublot status check configuration

Defines whether the sublot status of a material must be checked to determine if the material is fit for use.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum sublot status attribute of the Sublot check definition process parameter (page 21) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Sublot check definition

Defines the setting required to enable the configuration of the subplot status check (page 20).

Attribute	Type	Comment
Minimum subplot status	Choice list	Defines the minimum subplot status required for material identification. Available settings: Blocked, Quality Inspection, Unrestricted. Default setting: Unrestricted.

Identify manually

Represents a user-triggered exception that is accessible from the Exception Window. The exception allows an operator to enter the required subplot identifier manually. It covers incidents when it is not possible to scan the respective label.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Undo identification

Represents a user-triggered exception that is accessible from the Exception Window.
 The exception allows an operator to unidentify a subplot that has been identified before for the phase.
 It covers incidents when a subplot has been identified by mistake.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Post - Identify additionally

Represents a post-completion exception that is accessible from the Navigator.
 The exception allows an operator to manually enter the subplot identifier of a subplot that needs to be identified after the phase has been completed.
 It covers incidents when an identified subplot turns out to be unfit for use and needs to be replaced.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Post - Undo identification

Represents a post-completion exception that is accessible from the Navigator.

The exception allows an operator to unidentify an identified subplot after the phase has been completed.

It covers incidents when a subplot has been identified by mistake.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Quantity out of tolerance

Represents a system-triggered exception that is displayed in the Exception Window to prevent the use of identified quantities that violate the quantity range defined for a material. It is only relevant to material positions with the **As defined** planned quantity mode and if the **Auto consume** attribute of the **Consumption configuration** process parameter (page 19) is set to **Yes**.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Force completion

Represents a user-triggered exception that is accessible from the Exception Window. The exception allows an operator to force the phase to complete even though one or more errors would otherwise prevent the completion of the phase. It covers incidents when the phase needs to be completed in spite of potential errors such as

- not all identified materials have been accounted yet,
- not all materials listed for identification have been identified yet,
- at least one predecessor of a position with the **As produced** planned quantity mode has not been processed yet,
- the **Auto consume** attribute of the **Consumption configuration** process parameter (page 19) is set to **Yes** and not for all required positions material has been identified.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Warehouse error

TIP

Please note that warehouse-related errors can only occur if PharmaSuite is configured to communicate with Warehouse Management. If not, the **Warehouse error** process parameter is not relevant and you can skip its configuration.

Represents a user-triggered exception that is accessible from the Exception Window. It allows an operator to record a warehouse-related error that has occurred during phase processing.

It must be registered before the phase can be confirmed.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Instruction links

In addition to the permanent process parameters that are always present, the **Identify material** phase provides instruction links as optional process parameters, which you can insert if required.

You can add up to ten instruction link parameters.

TIP

Instruction links are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.







ADDING INSTRUCTION LINKS

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
2. Select the **Instruction Link** type.
The system opens the **Add Instruction Link** dialog to define the instruction link's identifier.
3. Type an identifier and click the **OK** button.
The system adds the instruction link parameter and the first link definition row to the list of parameters.
Instruction link parameters are generally inserted below all other parameters. Where within the block of instruction link parameters the system adds a new link parameter depends on the current selection in the Parameter Panel:
 - If no parameter is selected, the system adds the new instruction link parameter as last parameter.
 - If an instruction link parameter is selected, the system adds the new instruction link parameter below the selected one.
 - If any other parameter is selected, the system adds the new instruction link parameter as first parameter of the instruction link parameter block.

TIPS

Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa. The identifier of the instruction link parameter is shown as **Identifier** of the link's instruction text parameter.

4. Specify the instruction text to be displayed and mark the link texts by enclosing them in curly brackets.
5. Specify the list of link definitions. Each row of the list defines one hyperlink. The button bar above the list provides the following functions:
 -  adds a new row to the list. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.
 -  deletes the currently selected rows.
 -  moves the currently selected row one row up.
 -  moves the currently selected row one row down.



REMOVING INSTRUCTION LINKS

1. In the list of parameters, select the instruction link parameter you wish to remove.
2. Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction link parameter.

The following process parameters are available to configure the phase's behavior during execution:

Instruction text with links

Defines the text of the optional instruction link that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (page 27).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

Instruction link definition

Defines all links to be available within the instruction text defined with the **Instruction text with links** process parameter (page 27). You can either access a file on the web, such as your intranet, by using the web access syntax or a file on your file system, by using the file access syntax.

Examples:

`https://rockwellautomation.com`

`file:///c:/SOP/SOP1492.pdf`

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

Instruction tables

In addition to the permanent process parameters that are always present, the **Identify material** phase provides instruction tables as optional process parameters, which you can insert if required.

You can add up to ten instruction tables with up to 50 table rows.

TIP

Instruction tables are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.



ADDING INSTRUCTION TABLES

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
2. Select the **Instruction Table** type.
The system opens the **Add Instruction Table** dialog to define the instruction table's identifier.

3. Type an identifier and click the **OK** button.

The system adds the parameter definition and the first table row to the list of parameters.

Instruction table parameters are generally inserted below all other parameters. Where within the block of instruction table parameters the system adds a new table depends on the current selection in the Parameter Panel:

- If no parameter is selected, the system adds the new instruction table as last parameter.
- If an instruction table parameter is selected, the system adds the new instruction table below the selected one.
- If any other parameter is selected, the system adds the new instruction table as first parameter of the instruction table parameter block.

TIPS


Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa.

The identifier of the instruction table is shown as **Identifier** of the table's definition parameter. The identifiers of the individual table rows (**Row-1**, **Row-2**, etc.) are system-defined and not editable.


4. Specify the overall appearance of the table:


- Select the number of columns to define the layout.
- Set the width of the first column. If you do not set it to narrow, all columns have equal widths. If you set the first column to narrow, the remaining columns will have equal widths.
- Define if your table needs to have borders. You can either show all borders of the table and its cells or none.

5. Specify the table rows and their content. The button bar above the rows table provides the following functions:

 adds a new row to the table. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.

 deletes the currently selected rows.

 moves the currently selected row one row up.

 moves the currently selected row one row down.

TIP

Please note that the system always retains the consecutive numbering of the rows. If you reorder the table rows or delete rows, the row identifiers are updated accordingly.



REMOVING INSTRUCTION TABLES

1. In the list of parameters, select the instruction table parameter you wish to remove.
2. Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction table with its definition and rows.

The following process parameters are available to configure the phase's behavior during execution:

Instruction table definition

Defines the appearance of the optional instruction table that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns. Default setting: 1 column.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text

Specifies the instruction texts to be displayed in the individual cells of the instruction table.

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

Output Variables

Instead of specifying a fixed value to be displayed or used during execution, you can also use an expression created in the Expression editor to draw the output of another phase or operation or the calculated result of several outputs as value into a parameter attribute.

When you reference outputs in this manner you need to be aware of the following restrictions:

- Only when a component has been processed does it provide an output that can be fed into another component as attribute value. For this reason, you can never reference an output of a component that is a strict successor of the component in which you try to use the output.
- Branches and loops, however, require special notice in this context, since they are only potentially passed through and/or completed during processing, so their outputs are not reliably available. Thus, you can reference any such potentially available outputs, but need to be aware of the fact that the provided value may be **Undefined** so that the component into which you are feeding the output must be able to deal with such an **Undefined** input value.

The **Identify material** phase provides the following output variables:

Result

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Values: CONTINUE, STOP, DONE
- Usage: The output variable provides the result of the phase processing:
 - The value is CONTINUE if the phase was completed with **Continue**.
 - The value is STOP if the phase was completed with **Stop**.
 - The value is DONE if the phase was completed with **Done** or the **Loop configuration** process parameter (page 17) is set to **No loop**.

Identifier

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Usage: The output variable provides the identifier of the phase.

Instance count

- Data type: Long, used for integral numbers:
12345
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

Start time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the start time of the phase.

Completion time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the completion time of the phase.

TIP

To calculate a duration from two timestamps and display it in a specific format, you need to use two conversion functions on the calculation:

- **Convert to Unitless Number (convertTo)** takes the calculated duration and converts it into the duration's value for one of its units (e.g., minutes or seconds).
- **Convert to String for Display (convertToDisplayString)** takes the converted value and displays it as string to which you can add the unit, also as string.

Example:

Sample Phase with Start time = 14-Nov-2014@10:15

Sample Phase with Completion time = 14-Nov-2014@11:47

The duration is to be displayed in minutes.

```
convertToDisplayString
(
  convertTo
    ({Sample Phase}.{Completion time}-{Sample Phase}.{Start time},
    "min")
)
+ " min"
```

As result of the expression, the system displays "92 min".

Produce Material

The **Produce material** phase allows an operator to produce intra materials or the final product during recipe execution.

TIP

Please note that the **Produce material** phase is only available for use in master recipes, not in workflows.

It can be used for processing requirements, such as:

- **Produce intra materials**
The intra materials produced in a processing step will be used in a subsequent processing step. Create the sublots of the intra materials and print their labels. Now, the intra materials are prepared for identification in the next processing step.
- **Produce intra materials with defined quality status**
The quality status of the intra materials must be **Released**. This requirement can be defined and will be assigned to the produced sublots.
- **Produce final product**
For final products, the quantity can be declared and labels printed per subplot. Then, the product can be delivered to the warehouse.
- **Produce final product using packaging levels**
The packaging levels defined for an ERP BOM or a material are visible during phase execution in order to support the operator when he enters the produced quantity. In case **Blister** and **Shipping carton** packaging levels are defined, he can quantify the quantity in the packaging levels even if the outgoing material is accounted in each.
- **Reprint a subplot label**
If there was a problem during label printing that renders the printed labels unusable, the required labels can be printed again.

Execution

The Produce material phase displays the data of the material defined with its material output parameter. An operator can indicate and register the quantity of the produced material.

If the phase is run for a material without packaging levels, the operator enters the number of produced sublots and the material quantity per subplot.

If the phase is run for a material with packaging levels, the operator enters the numbers of units produced for the respective packaging levels.

The system calculates the total of the material produced and checks it against the planned quantity.

Below the input boxes, the system displays a materials table with the following information per subplot:

- Material ID
- Material short description
- Batch ID of material to be produced
- Planned quantity
- Produced quantity (total)
- List of sublots produced with this phase instance including quantities

TIP

The phase provides a **Refresh** button to refresh the data displayed in the table. If the phase is run simultaneously at several production stations, this allows an operator to ensure that the produced quantity does not exceed the planned quantity range before he registers further produced sublots.

If the planned quantity range has not been reached yet, the operator selects the **Continue** option and can afterwards confirm the phase. For each of the produced sublots the system prints a subplot label. Thus, the material produced in this phase run is ready to be transported to either a subsequent processing step or into the warehouse. The phase enters the loop, starts another run, and can register further material quantities.

If the operator has registered produced sublots, but there will be additional sublots produced elsewhere for the same position, he selects the Stop option, and can Confirm the partial production.

When the total quantity of the material produced during all runs of the phase reaches the planned quantity range, the operator selects the **Done** option and confirms the phase.

Again, the system prints labels for the produced sublots. Then the phase exits the loop and the system moves on to the next phase of the process.

TIP

Please note that the phase can also be placed into an event-triggered operation.

If PharmaSuite is configured to communicate with Warehouse Management, the phase provides a user-triggered exception to record warehouse-related errors. If a warehouse-related error occurs, the operator cannot confirm the phase unless he records the exception. Once he has recorded the exception, the phase completes automatically.

After phase completion, it provides post-completion exceptions

- to reprint a subplot label, by typing the identifier of the produced subplot,
- to cancel a subplot, by typing the identifier of the produced subplot.

After completion the phase displays the produced material with the following data in the Execution Window:

- batch identifiers
 - planned quantity
 - already produced quantity
 - subplot identifier and quantity (of newly produced sublots)
 - number of sublots
- or
- packaging level data.

The Navigator displays the quantity produced during this run and provides access to the post-completion exceptions.

TIP

When an irregular occurrence during processing, such as loss of material during transport, requires the phase to be fully or partially reworked, the phase's order step can be **Aborted** and **Reactivated** by supervisor action from PharmaSuite for Production Management. Under these circumstances the supervisor can include a comment to execution to detail the actions the operator needs to perform when he restarts the **Reactivated** order step. The phase displays the comment like an instruction text below the list of materials.

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot

t
g
kg

Limits: [1,009.0 g .. 1,011.0 g]

Total = 500.0 g

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix			1,010.0 g	0 g	

Continue

Done

Confirm

Figure 23: Produce material during execution

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot

t
g
kg

Limits: [1,009.0 g .. 1,011.0 g]

Total = 0 g

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix	BX1601		1,010.0 g	1,011.0 g	

D130-01: SL00006922 contaminated, re-produce 250.0 g.

Continue

Done

Confirm

Figure 24: Reactivated Produce material during execution with Comment to execution

Move packaged product to one or more sublots.

Pallet(s) (LU) containing 5 shipping cartons = 0 ea

Shipping carton(s) (SL) containing 20 bundles = 2,000 ea

Bundle(s) containing 5 folding cartons = 750 ea

Folding carton(s) containing 1 blister = 0 ea

Blister(s) containing 10 tablets = 0 ea

Tablet(s) = 0 ea

Limits: [5,500 ea .. 5,500 ea]

Total (tablets) = 2,750 ea

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets			5,500 ea	0 ea	

Continue

Done

Confirm


Figure 25: Produce material with packaging levels during execution

Move packaged product to one or more sublots.

<input type="text"/>	Pallet(s)	(LU)	containing	5 shipping cartons	=	0 ea
<input type="text" value="1"/>	Shipping carton(s)	(SL)	containing	20 bundles	=	1,000 ea
<input type="text" value="2"/>	Bundle(s)		containing	5 folding cartons	=	100 ea
<input type="text"/>	Folding carton(s)		containing	1 blister	=	0 ea
<input type="text"/>	Blister(s)		containing	10 tablets	=	0 ea
<input type="text"/>	Tablet(s)				=	0 ea

Limits: [5,500 ea .. 5,500 ea]
Sublot status: Quality Inspection

Total (tablets) = 1,100 ea



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets	BX9		5,500 ea	350 ea	




Figure 26: Produce material with packaging levels during execution (simultaneous processing with Stop)

Confirm to record the warehouse error.



Figure 27: User-triggered warehouse error exception

Move verified output material to one or more sublots.

Number of sublots

Quantity per sublot t g kg

Total = 500.0 g

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix	BX1601		1,010.0 g	500.0 g	
			SL00006921			250.0 g
			SL00006922			250.0 g




Figure 28: Produce material after phase completion

Move verified output material to one or more sublots.

Number of sublots

1

Quantity per sublot

250.0

g

kg

Total = 250.0 g

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix	BX1601		1,010.0 g	1,261.0 g	
			SL00006926			250.0 g

D130-01: SL00006922 contaminated, re-produce 250.0 g.

Continue

Done

Confirm

Figure 29: Reactivated Produce material after phase completion with Comment to execution

Move packaged product to one or more sublots.

Pallet(s)

(LU)

containing

5 shipping cartons

=

0 ea

2

Shipping carton(s)

(SL)

containing

20 bundles

=

2,000 ea

15

Bundle(s)

containing

5 folding cartons

=

750 ea

Folding carton(s)

containing

1 blister

=

0 ea

Blister(s)

containing

10 tablets

=

0 ea

Tablet(s)

=

0 ea

Total (tablets) = 2,750 ea

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets	BX1708		5,500 ea	2,750 ea	
			SL00007104			1,000 ea
			SL00007105			1,000 ea
			SL00007106			750 ea

Continue

Done

Confirm

Figure 30: Produce material with packaging levels after phase completion

Move packaged product to one or more sublots.

<input type="text"/>	Pallet(s)	(LU)	containing	5 shipping cartons =	0 ea
<input type="text" value="1"/>	Shipping carton(s)	(SL)	containing	20 bundles =	1,000 ea
<input type="text" value="2"/>	Bundle(s)		containing	5 folding cartons =	100 ea
<input type="text"/>	Folding carton(s)		containing	1 blister =	0 ea
<input type="text"/>	Blister(s)		containing	10 tablets =	0 ea
<input type="text"/>	Tablet(s)			=	0 ea

Sublot status: Quality Inspection Total (tablets) = 1,100 ea

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets	BX9		5,500 ea	1,450 ea	
			SL00000026			1,000 ea
			SL00000027			100 ea

Figure 31: Produce material with packaging levels after phase completion (simultaneous processing with Stop)

Production
Verify Tableting Output

500.0 g

Figure 32: Produce material in the Navigator

Packaging Process
Package Product

2,750 ea

Figure 33: Produce material with packaging levels in the Navigator

To reprint a sublot label, enter the ID of the produced sublot.



Figure 34: Post-completion exception of Produce material - Reprint sublot label

To cancel a sublot, enter the ID of the produced sublot.



Figure 35: Post-completion exception of Produce material - Cancel sublot

Phase Design

The characteristics of the **Produce material** phase are defined via process parameters and their attributes.

TIP

To have a material listed in the table for production, you need to assign it as material output parameter to the phase and mark it as MFC-relevant.

Its user interface is designed in three columns that span several rows. When the phase is active, the merged columns of the first row provide space for textual instructions. In the next rows, the phase layout depends on whether there are packaging levels defined for the produced material:

- If the material does not have packaging levels, the system displays input boxes to type the number and quantity of the sublots produced in the center column. The right column of the row with the quantity text box provides the **Toggle unit of measure** button.
- If the material has packaging levels, the system uses the merged first and center columns to displays input boxes for the packaging levels defined for the material and in the recipe including the basic quantities per level. The right column of each row shows the actual quantity per level calculated from the entered number of units and the basic quantity per level.

The left columns in the next row contain the tolerance range for the planned quantity and the subplot status, if defined. In the right column, the system calculates the total quantity of material from the operator's input.

The rightmost of the next row displays a **Refresh** button that updates the data shown in the list of materials.

In the next rows, the phase displays the list of materials available for production, spanning all columns. After phase completion, the sublots and their data appear as new rows of the table. The left column of the bottom row contains the option buttons for **Continue** and **Done** or **Stop**, respectively, and the rightmost column provides the **Confirm** button.

When the phase is completed it shows the same three-column, multi-row layout with the data of the produced material sublots listed in the table.

Exception handling during execution is controlled by a risk assessment classification and an exception message that are both defined by the recipe author in the exception's process parameter.

Process Parameters

The following process parameters are available to configure the phase's behavior during execution:

Instruction

Represents the instruction text that is visible on the preview, the active, and the completed view of the phase.

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. Restriction: Maximum length is 2000 characters (including HTML tags).

Batch definition

When the produced material represents a new batch, this setting determines its initial status (**Blocked**, **Quarantined**, **Released**).

When the produced material adds sublots to an existing batch, the setting does **not** overwrite its existing batch status.

Attribute	Type	Comment
Batch status	Choice list	Defines the batch status of the newly created batch. Default setting: Quarantined .

Overwrite target subplot status

Defines the status of the produced sublots if it needs to differ from the target subplot status set with the material output parameter of the phase.

Attribute	Type	Comment
Enabled	Flag	Controls if the defined target subplot status of the material output parameters will be overwritten by the subplot status selected with the Sublot status attribute. Default setting: No .

Attribute	Type	Comment
Sublot status	Choice list	Defines the target sublot status. Available settings: ---, Blocked , Quality Inspection , Unrestricted . Default setting: ---. Can be defined by information flow. The meaning, not the localized value, of the choice element value needs to be provided. For keeping the sublot status empty, set “null”.

Allow loop exit with Stop

Defines if the phase allows to exit its loop without performing the checks that are triggered by the **Done** button.

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Limit quantity to single sublot

Defines whether the system only allows the production of exactly one sublot per phase run.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Limit quantity to single logistic unit

Defines whether the system only allows the production of exactly one logistic unit per phase run.

Unless there are packaging levels defined for the produced material one of the packaging levels has **Logistic unit** as its inventory level, the parameter is not relevant and you can skip its configuration.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Check planned quantity

Represents a system-triggered exception that is displayed in the Exception Window to resolve incidents when the planned and produced quantities do not match. It addresses the following cases:

- If the phase was completed with **Continue** and the produced quantity already corresponds to or exceeds the planned quantity.
- If the phase was completed with **Done** and the produced quantity is less than the planned quantity.

TIP

When a produced subplot is rendered unusable, for example due to contamination during transport and the phase is reactivated to re-produce the subplot, the system also raises the exception. The reason for this is that the sum of all produced subplot quantities, which also includes the subplot that is no longer usable, exceeds the planned quantity.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Reprint

Represents a post-completion exception that is accessible from the Navigator.
The exception allows an operator to reprint a subplot label for a produced subplot.
It covers incidents when a subplot label is illegible or damaged so that it cannot be attached to the produced subplot.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Cancel subplot

Represents a post-completion exception that is accessible from the Navigator.
The exception allows an operator to cancel one of the produced subplots.
It covers incidents when an entire subplot is damaged or contaminated after production so that it needs to be destroyed.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Warehouse error

TIP

Please note that warehouse-related errors can only occur if PharmaSuite is configured to communicate with Warehouse Management. If not, the **Warehouse error** process parameter is not relevant and you can skip its configuration.

Represents a user-triggered exception that is accessible from the Exception Window. It allows an operator to record a warehouse-related error that has occurred during phase processing.
It must be registered before the phase can be confirmed.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Instruction links

In addition to the permanent process parameters that are always present, the **Produce material** phase provides instruction links as optional process parameters, which you can insert if required.

You can add up to ten instruction link parameters.

TIP

Instruction links are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.



ADDING INSTRUCTION LINKS

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
2. Select the **Instruction Link** type.
The system opens the **Add Instruction Link** dialog to define the instruction link's identifier.
3. Type an identifier and click the **OK** button.
The system adds the instruction link parameter and the first link definition row to the list of parameters.
Instruction link parameters are generally inserted below all other parameters. Where within the block of instruction link parameters the system adds a new link parameter depends on the current selection in the Parameter Panel:
 - If no parameter is selected, the system adds the new instruction link parameter as last parameter.
 - If an instruction link parameter is selected, the system adds the new instruction link parameter below the selected one.
 - If any other parameter is selected, the system adds the new instruction link parameter as first parameter of the instruction link parameter block.

TIPS

Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa. The identifier of the instruction link parameter is shown as **Identifier** of the link's instruction text parameter.

4. Specify the instruction text to be displayed and mark the link texts by enclosing them in curly brackets.

5. Specify the list of link definitions. Each row of the list defines one hyperlink. The button bar above the list provides the following functions:



adds a new row to the list. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.



deletes the currently selected rows.



moves the currently selected row one row up.



moves the currently selected row one row down.



REMOVING INSTRUCTION LINKS

1. In the list of parameters, select the instruction link parameter you wish to remove.
2. Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction link parameter.

The following process parameters are available to configure the phase's behavior during execution:

Instruction text with links

Defines the text of the optional instruction link that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (page 50).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

Instruction link definition

Defines all links to be available within the instruction text defined with the **Instruction text with links** process parameter (page 49). You can either access a file on the web, such as your intranet, by using the web access syntax or a file on your file system, by using the file access syntax.

Examples:

`https://rockwellautomation.com`

`file:///c:/SOP/SOP1492.pdf`

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

Instruction tables

In addition to the permanent process parameters that are always present, the **Produce material** phase provides instruction tables as optional process parameters, which you can insert if required.

You can add up to ten instruction tables with up to 50 table rows.

TIP

Instruction tables are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.



ADDING INSTRUCTION TABLES

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
2. Select the **Instruction Table** type.
The system opens the **Add Instruction Table** dialog to define the instruction table's identifier.
3. Type an identifier and click the **OK** button.
The system adds the parameter definition and the first table row to the list of parameters.
Instruction table parameters are generally inserted below all other parameters. Where within the block of instruction table parameters the system adds a new table depends on the current selection in the Parameter Panel:
 - If no parameter is selected, the system adds the new instruction table as last parameter.
 - If an instruction table parameter is selected, the system adds the new instruction table below the selected one.
 - If any other parameter is selected, the system adds the new instruction table as first parameter of the instruction table parameter block.

TIPS

Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa.

The identifier of the instruction table is shown as **Identifier** of the table's definition parameter. The identifiers of the individual table rows (**Row-1**, **Row-2**, etc.) are system-defined and not editable.

4. Specify the overall appearance of the table:
 - Select the number of columns to define the layout.
 - Set the width of the first column. If you do not set it to narrow, all columns have equal widths. If you set the first column to narrow, the remaining columns will have equal widths.
 - Define if your table needs to have borders. You can either show all borders of the table and its cells or none.

- Specify the table rows and their content. The button bar above the rows table provides the following functions:



adds a new row to the table. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.



deletes the currently selected rows.



moves the currently selected row one row up.



moves the currently selected row one row down.

TIP

Please note that the system always retains the consecutive numbering of the rows. If you reorder the table rows or delete rows, the row identifiers are updated accordingly.



REMOVING INSTRUCTION TABLES

- In the list of parameters, select the instruction table parameter you wish to remove.
- Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction table with its definition and rows.

The following process parameters are available to configure the phase's behavior during execution:

Instruction table definition

Defines the appearance of the optional instruction table that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns. Default setting: 1 column.

Attribute	Type	Comment
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text

Specifies the instruction texts to be displayed in the individual cells of the instruction table.

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

Output Variables

Instead of specifying a fixed value to be displayed or used during execution, you can also use an expression created in the Expression editor to draw the output of another phase or operation or the calculated result of several outputs as value into a parameter attribute. When you reference outputs in this manner you need to be aware of the following restrictions:

- Only when a component has been processed does it provide an output that can be fed into another component as attribute value. For this reason, you can never reference an output of a component that is a strict successor of the component in which you try to use the output.
- Branches and loops, however, require special notice in this context, since they are only potentially passed through and/or completed during processing, so their outputs are not reliably available. Thus, you can reference any such potentially available outputs, but need to be aware of the fact that the provided value may be **Undefined** so that the component into which you are feeding the output must be able to deal with such an **Undefined** input value.

The **Produce material** phase provides the following output variables:

LU quantity

- Data type: MeasuredValue, used for displaying numeric values qualified by a unit of measure.
- Usage: The output variable provides the produced quantity for a maximum logistic unit load as a **MeasuredValue** object.

Result

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Usage: The output variable provides the result of the phase processing:
 - The value is `CONTINUE` if the phase was completed with **Continue**.
 - The value is `STOP` if the phase was completed with **Stop**.
 - The value is `DONE` if the phase was completed with **Done**.

Sublot identifiers

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Usage: The output variable provides a comma-separated list of identifiers of the created sublots.

Identifier

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Usage: The output variable provides the identifier of the phase.

Instance count

- Data type: Long, used for integral numbers:
12345
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

Start time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the start time of the phase.

Completion time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the completion time of the phase.

TIP

To calculate a duration from two timestamps and display it in a specific format, you need to use two conversion functions on the calculation:

- **Convert to Unitless Number (convertTo)** takes the calculated duration and converts it into the duration's value for one of its units (e.g., minutes or seconds).
- **Convert to String for Display (convertToDisplayString)** takes the converted value and displays it as string to which you can add the unit, also as string.

Example:

Sample Phase with Start time = 14-Nov-2014@10:15

Sample Phase with Completion time = 14-Nov-2014@11:47

The duration is to be displayed in minutes.

```
convertToDisplayString
  (convertTo
    ({Sample Phase}.{Completion time}-{Sample Phase}.{Start time},
    "min")
  )
  + " min"
```

As result of the expression, the system displays "92 min".

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Account Material

The **Account material** phase allows an operator to account identified sublots in terms of consumed, wasted, sampled, and returned quantities.

TIP

Please note that the **Account material** phase is only available for use in master recipes, not in workflows.

It can be used for processing requirements, such as:

- **Consume partial sublots**
For sublots that were not completely used up during processing, the actual amount of material that has been utilized can be declared as consumed and the remainder can be declared as to be returned.
- **Consume sublots completely**
If several sublots of one material have been identified and consumed completely, the consumption can be declared per material at once.
- **Account samples**
A processing step requires to create samples. The quantity that was used for sampling purposes can be declared separately.
- **Account unused sublots**
One of the identified sublots was not used at all during processing. The entire subplot can be returned.

Execution

The **Account material** phase lists all materials that have been available for identification in the preceding phases or phase runs, along with the sublots and quantities that have actually been identified.

TIP

Please note that 10 is the maximum number of materials you can assign as parameters to the phase.

In a dedicated input dialog, an operator can indicate and register per subplot how much of its identified quantity has been used up during execution. From the indicated quantities, the system calculates the remaining quantity. Depending on the calculation mode (page 66) configured for the phase, the system declares the calculated remaining quantity either as return quantity or as waste.

The following quantities enter into the calculation:

- Identified (drawn from a preceding **Identify material** phase)
- Consumed (operator input)
- Wasted (operator input or calculated remaining quantity)
- Sampled (operator input)
- Returned (operator input or calculated remaining quantity).

TIP

Please note that you can add a phase action signature to request a signature each time the accounting dialog is completed.

If the quantities relevant to accounting the sublots change while the **Account material** phase is active, due to additionally identified material, an operator can tap the **Refresh** button to update the calculation quantities.

If the phase is configured to run without a loop and the operator has accounted the material sublots, he can unlock the **Confirm** button and complete the accounting.

If the phase is configured to run in a loop, the operator has registered the materials required for the current phase run, and there will be further phase runs to account further materials, he selects the **Continue** option and can **Confirm** the partial accounting.

If the phase is configured to run in a loop or an event-triggered-operation, the operator has registered the materials required for the moment, but there will be additional sublots accounted elsewhere for the same position, he selects the **Stop** option, and can **Confirm** the partial accounting.

If the operator has registered the materials required for the final phase run, he selects the **Done** option, and can **Confirm** and thus complete the accounting.

TIP

Please note that the **Unlock** button that enables phase confirmation is not present when the phase has been configured to request a phase completion signature. When the phase is configured for looping, it provides the **Continue** and **Done** options instead of an **Unlock** button. The **Continue** button is marked with an asterisk (*) as soon material has been accounted with the current phase run.

If PharmaSuite is configured to communicate with Warehouse Management, the phase provides a user-triggered exception to record warehouse-related errors. If a warehouse-related error occurs, the operator cannot confirm the phase unless he records the exception. Once he has recorded the exception, the subplot whose processing caused the exception is completed automatically. The operator can continue to account the remaining sublots.

After completion the phase displays the accounted material with the following data in the Execution Window:



- batch and/or subplot identifiers
- identified quantity
- consumed quantity
- wasted quantity
- sampled quantity
- returned quantity
- accounting status.

The Navigator displays the processing result.

Account the tableted materials.								
Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	
		BX194						
		SL00008697		10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	
20	D005-04 / Talc		(20.0 g)	100.0 g				
		BX196						
		SL00008706		100.0 g				
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g				
		BX197						
		SL00008716		400.0 g				
		BX201						
		SL00008725		200.0 g				
		BX219						
		SL00008750		505.0 g				

Figure 36: Account material during execution (sequential processing)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	900.0 g	680 g	0 g 20 g	0.0 g	
		BX176						
		SL00008679		200.0 g				
		SL00008670		300.0 g	290 g	0 g 10 g	0.0 g	
		SL00008683		400.0 g	390 g	0 g 10 g	0.0 g	




Continue Done Confirm 

Figure 37: Account material during execution (simultaneous processing)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,000.00 g)	500.0 g	500.0 g	0.0 g 0.0 g	0.0 g	
		BX386						
		SL00000252		500.0 g	500.0 g	0.0 g 0.0 g	0.0 g	




Continue (*) Done Confirm 

Figure 38: Account material during execution (simultaneous processing with marker)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600.0 g	300.0 g	0.0 g 0.0 g	0.0 g	
		BX10						
		SL00000007		300.0 g	300.0 g	0.0 g 0.0 g	0.0 g	
		SL00000010		300.0 g				


Continue (*) Stop Confirm 

Figure 39: Account material during execution (simultaneous processing with marker and Stop)

Confirm to record the warehouse error.

Confirm 

Figure 40: User-triggered warehouse error exception

Identified	<input type="text" value="200.0"/>	<div><div>t</div><div>g</div><div>kg</div></div>
Consumed	<input type="text" value="105.0"/>	<div><div>t</div><div>g</div><div>kg</div></div>
Wasted	<input type="text" value="0.0"/>	<div><div>t</div><div>g</div><div>kg</div></div>
Sampled	<input type="text" value="5.0"/>	<div><div>t</div><div>g</div><div>kg</div></div>
Returned	<input type="text" value="90.0"/>	<div><div>t</div><div>g</div><div>kg</div></div>

Account


Cancel 

Figure 41: Provide quantities for Account material


Identified t g kg

Consumed t g kg

Wasted t g kg



Sampled t g kg

Returned t g kg



Tester

Figure 42: Provide quantities for Account material with phase action signature

Account the tableted materials.  

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	Accounted
		BX194						
		SL00008697		10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	
20	D005-04 / Talc		(20.0 g)	100.0 g	20.0 g	0.0 g 0.0 g	80.0 g	Accounted
		BX196						
		SL00008706		100.0 g	20.0 g	0.0 g 0.0 g	80.0 g	
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g	1,000.0 g	0.0 g 15.0 g	90.0 g	Accounted
		BX197						
		SL00008716		400.0 g	395.0 g	0.0 g 5.0 g	0.0 g	
		BX201						
		SL00008725		200.0 g	105.0 g	0.0 g 5.0 g	90.0 g	
		BX219						
		SL00008750		505.0 g	500.0 g	0.0 g 5.0 g	0.0 g	



 

Figure 43: Account material after phase completion (sequential processing)

Account the packaged material.

Refresh ✓ Account ✓

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	900.0 g	870 g	0 g 30 g	0.0 g	
		BX176						
		SL00008670		300.0 g	290 g	0 g 10 g	0.0 g	
		SL00008679		200.0 g	190 g	0 g 10 g	0.0 g	
		SL00008683		400.0 g	390 g	0 g 10 g	0.0 g	

Continue Done Confirm ✓

Figure 44: Account material after phase completion (simultaneous processing)

Account the packaged material.

Refresh ✓ Account ✓

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600.0 g	300.0 g	0.0 g 0.0 g	0.0 g	
		BX10						
		SL00000007		300.0 g	300.0 g	0.0 g 0.0 g	0.0 g	
		SL00000010		300.0 g				

Continue Stop Confirm ✓

Figure 45: Account material after phase completion (simultaneous processing with Stop)

Tableting
Account Tableting Inputs

Done

Figure 46: Account material in the Navigator (sequential processing)

Accounting
Account Material

Continue

Figure 47: Account material in the Navigator (simultaneous processing - Continue)

Accounting
Account Material [2]

Stop

Figure 48: Account material in the Navigator (simultaneous processing - Stop)

Accounting
Account Material [4]

Done

Figure 49: Account material in the Navigator (simultaneous processing - Done)

Phase Design

The characteristics of the **Account material** phase are defined via process parameters and their attributes.

TIP

To have a material listed in the table for accounting, you need to assign it as material input parameter to the phase. The accounting inputs, however, are **not** MFC-relevant.

Its user interface is designed in three columns that span several rows. When the phase is active, the merged columns of the first row provide space for textual instructions. that span several rows. The center column holds the **Refresh** button to update the **Identified** quantities. The right column provides the **Account** button to open the dialog for entering the quantities required for accounting.

In the next rows, the phase displays the list of material sublots available for accounting, spanning all columns. Once a material subplot has been accounted, its quantities appear in the respective columns of the table. The center column of the bottom row provides the **Unlock** button, while the right column holds the **Confirm** button. If the phase is configured for looping, the phase shows the **Continue** and the **Stop** or **Done** options instead of the **Unlock** button.

When the phase is completed it shows the same three-column, three-row layout with the data of the accounted material sublots listed in the table.

Exception handling during execution is controlled by a risk assessment classification and an exception message that are both defined by the recipe author in the exception's process parameter.

Process Parameters

The following process parameters are available to configure the phase's behavior during execution:

Instruction

Represents the instruction text that is visible on the preview, the active, and the completed view of the phase.

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	Not used.

Enable loop

Defines if the phase is intended for a single run or to allow looping with several phase runs.

Attribute	Type	Comment
Enabled	Flag	Defines if the Continue/Done buttons will be available and the phase can be looped without accounting checks. Default setting: No .

Allow loop exit with Stop

Defines if the phase allows to exit its loop without performing the checks that are triggered by the **Done** button. To enable the looping behavior of the phase, make sure the **Enable loop** process parameter (page 65) is set to **Yes**.

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Include sample and waste quantities

Defines the scope of the tolerance check for the accounted quantity.

Attribute	Type	Comment
Enabled	Flag	Defines if the Quantity out of tolerance check against the planned quantity for the accounted quantity shall include besides the consumed quantity also the sampled and wasted quantities. Default setting: No .

Calculation configuration

Defines the calculation mode used for the phase. It determines if it calculates the return or the waste quantity as result. This setting also controls if an operator needs to enter a **Wasted** quantity (required for calculating the return quantity) or a **Returned** quantity (required for calculating the waste quantity).

Attribute	Type	Comment
Result	Choice list	Defines whether the returned quantity or the wasted quantity is calculated. Return(ed) qty = Identified qty - Consumed qty - Sampled qty - Wasted qty Waste(d) qty = Identified qty - Consumed qty - Sampled qty - Returned qty Default setting: Return .

Accounting check configuration

Represents a system-triggered exception that is displayed in the Exception Window to indicate that not all of the sublots available for accounting have been accounted.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

Quantity out of tolerance

Represents a system-triggered exception that is displayed in the Exception Window to prevent the use of accounted quantities that violate the quantity range defined for a material. It is only relevant to material positions defined in the **Identify material** phase (page 9) with the **As produced** or **As defined** planned quantity modes.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Warehouse error

TIP

Please note that warehouse-related errors can only occur if PharmaSuite is configured to communicate with Warehouse Management. If not, the **Warehouse error** process parameter is not relevant and you can skip its configuration.

Represents a user-triggered exception that is accessible from the Exception Window. It allows an operator to record a warehouse-related error that has occurred during phase processing.
It must be registered before the phase can be confirmed.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Instruction links

In addition to the permanent process parameters that are always present, the **Account material** phase provides instruction links as optional process parameters, which you can insert if required.

You can add up to ten instruction link parameters.

TIP

Instruction links are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.



ADDING INSTRUCTION LINKS

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
2. Select the **Instruction Link** type.
The system opens the **Add Instruction Link** dialog to define the instruction link's identifier.
3. Type an identifier and click the **OK** button.
The system adds the instruction link parameter and the first link definition row to the list of parameters.
Instruction link parameters are generally inserted below all other parameters. Where within the block of instruction link parameters the system adds a new link parameter depends on the current selection in the Parameter Panel:
 - If no parameter is selected, the system adds the new instruction link parameter as last parameter.
 - If an instruction link parameter is selected, the system adds the new instruction link parameter below the selected one.
 - If any other parameter is selected, the system adds the new instruction link parameter as first parameter of the instruction link parameter block.

TIPS

Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa. The identifier of the instruction link parameter is shown as **Identifier** of the link's instruction text parameter.

4. Specify the instruction text to be displayed and mark the link texts by enclosing them in curly brackets.

5. Specify the list of link definitions. Each row of the list defines one hyperlink. The button bar above the list provides the following functions:



adds a new row to the list. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.



deletes the currently selected rows.



moves the currently selected row one row up.



moves the currently selected row one row down.



REMOVING INSTRUCTION LINKS

1. In the list of parameters, select the instruction link parameter you wish to remove.
2. Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction link parameter.

The following process parameters are available to configure the phase's behavior during execution:

Instruction text with links

Defines the text of the optional instruction link that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (page 70).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

Instruction link definition

Defines all links to be available within the instruction text defined with the **Instruction text with links** process parameter (page 69). You can either access a file on the web, such as your intranet, by using the web access syntax or a file on your file system, by using the file access syntax.

Examples:

`https://rockwellautomation.com`

`file:///c:/SOP/SOP1492.pdf`

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

Instruction tables

In addition to the permanent process parameters that are always present, the **Account material** phase provides instruction tables as optional process parameters, which you can insert if required.

You can add up to ten instruction tables with up to 50 table rows.

TIP

Instruction tables are visible in the Phase Preview window in Recipe and Workflow Designer. During execution, however, they are not displayed in the preview mode, but only when the phase becomes active and after its completion.



ADDING INSTRUCTION TABLES

1. Click the **Add parameter** button.
The system opens an option list that holds all optional parameter types available for the phase.
 2. Select the **Instruction Table** type.
The system opens the **Add Instruction Table** dialog to define the instruction table's identifier.
 3. Type an identifier and click the **OK** button.
The system adds the parameter definition and the first table row to the list of parameters.
Instruction table parameters are generally inserted below all other parameters. Where within the block of instruction table parameters the system adds a new table depends on the current selection in the Parameter Panel:
 - If no parameter is selected, the system adds the new instruction table as last parameter.
 - If an instruction table parameter is selected, the system adds the new instruction table below the selected one.
 - If any other parameter is selected, the system adds the new instruction table as first parameter of the instruction table parameter block.
- TIPS**

Please note that you can mix the sequence of instruction link and instruction table parameters. This means you can add an instruction link parameter anywhere within a list of instruction table parameters and vice versa.

The identifier of the instruction table is shown as **Identifier** of the table's definition parameter. The identifiers of the individual table rows (**Row-1**, **Row-2**, etc.) are system-defined and not editable.
4. Specify the overall appearance of the table:
 - Select the number of columns to define the layout.
 - Set the width of the first column. If you do not set it to narrow, all columns have equal widths. If you set the first column to narrow, the remaining columns will have equal widths.
 - Define if your table needs to have borders. You can either show all borders of the table and its cells or none.

- Specify the table rows and their content. The button bar above the rows table provides the following functions:



adds a new row to the table. The row is inserted after the currently selected row. If there is no row selected, the system inserts the new row below the last row.



deletes the currently selected rows.



moves the currently selected row one row up.



moves the currently selected row one row down.

TIP

Please note that the system always retains the consecutive numbering of the rows. If you reorder the table rows or delete rows, the row identifiers are updated accordingly.



REMOVING INSTRUCTION TABLES

- In the list of parameters, select the instruction table parameter you wish to remove.
- Click the **Remove parameter** button.
The system asks you to confirm the action and then removes the instruction table with its definition and rows.

The following process parameters are available to configure the phase's behavior during execution:

Instruction table definition

Defines the appearance of the optional instruction table that is visible in the preview in Recipe and Workflow Designer, and in the active and completed views during execution.

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns. Default setting: 1 column.

Attribute	Type	Comment
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text

Specifies the instruction texts to be displayed in the individual cells of the instruction table.

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

Output Variables

Instead of specifying a fixed value to be displayed or used during execution, you can also use an expression created in the Expression editor to draw the output of another phase or operation or the calculated result of several outputs as value into a parameter attribute. When you reference outputs in this manner you need to be aware of the following restrictions:

- Only when a component has been processed does it provide an output that can be fed into another component as attribute value. For this reason, you can never reference an output of a component that is a strict successor of the component in which you try to use the output.
- Branches and loops, however, require special notice in this context, since they are only potentially passed through and/or completed during processing, so their outputs are not reliably available. Thus, you can reference any such potentially available outputs, but need to be aware of the fact that the provided value may be **Undefined** so that the component into which you are feeding the output must be able to deal with such an **Undefined** input value.

The **Produce material** phase provides the following output variables:

Result

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Values: CONTINUE, DONE, STOP
- Usage: The output variable provides the result of the phase processing:
 - The value is CONTINUE if the phase was completed with **Continue**.
 - The value is STOP if the phase was completed with **Stop**.
 - The value is DONE if the phase was completed with **Done** or the **Enable loop** process parameter (page 65) is set to **No**.

Identifier

- Data type: String, used for displaying a pre-defined sequence of characters, such as "**Read Instruction**".
- Usage: The output variable provides the identifier of the phase.

Instance count

- Data type: Long, used for integral numbers:
12345
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

Start time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the start time of the phase.

Completion time

- Data type: Timestamp, used for displaying dates and times and for time-related calculations.
To use a timestamp in a phase attribute, you have to make sure it has a matching data type, so to display it in an instruction text, you have to convert it into a string.
- Usage: The output variable provides the completion time of the phase.

TIP

To calculate a duration from two timestamps and display it in a specific format, you need to use two conversion functions on the calculation:

- **Convert to Unitless Number (convertTo)** takes the calculated duration and converts it into the duration's value for one of its units (e.g., minutes or seconds).
- **Convert to String for Display (convertToDisplayString)** takes the converted value and displays it as string to which you can add the unit, also as string.

Example:

Sample Phase with Start time = 14-Nov-2014@10:15

Sample Phase with Completion time = 14-Nov-2014@11:47

The duration is to be displayed in minutes.

```
convertToDisplayString
(
  convertTo
    ({Sample Phase}.{Completion time}-{Sample Phase}.{Start time},
    "min")
)
+ " min"
```

As result of the expression, the system displays "92 min".

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