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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 the Material Tracking phases can only display their full functional scope if they are used in the sequence of **Identify material**, **Produce material**, **Account material**.

The following phases are available:

- Identify Material (page [3](#))
- Produce Material (page [15](#))
- Account Material (page [23](#))

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.

TIP

Instructions in this manual are based on Windows 7. Select the appropriate commands if you are using a different operating system.

Identify Material

The **Identify material** phase allows an operator to identify material on subplot 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.

TIP

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

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.

When the operator has registered the materials available for identification, he can unlock the **Confirm** button and 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.

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.

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.

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

- batch and/or subplot identifiers
- planned quantity
- identified quantity.

The Navigator displays the ratio between identified quantity and planned quantity in percent 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. \$SL00000456BX140					
Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Identified quantity
D003-04	Ethanol 96 %	BX140	SL00000456	10.0 g	10.0 g
					10.0 g
D130-01	Sonolin 100 mg premix			1,000.0 g	0 g
D005-04	Talc			20.0 g	0 g

Figure 1: Identify material during execution

Identify the materials for Tableting. \$SL00000473BX142					
Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Identified quantity
D005-04	Talc	BX141	SL00000467	20.0 g	400.0 g
					200.0 g
		BX141	SL00000466		200.0 g
D003-04	Ethanol 96 %	BX140	SL00000457	10.0 g	20.0 g
					10.0 g
		BX140	SL00000456		10.0 g
D130-01	Sonolin 100 mg premix			1,000.0 g	4,000.0 g
		BX142	SL00000473		2,000.0 g
					2,000.0 g
		BX142	SL00000471		2,000.0 g

D005-04: Re-identify 10.0 g.
D003-04: Re-identify 10.0 g.
D130-01: Re-identify 505.0 g.

Figure 2: Reactivated Identify material during execution with Comment to execution

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

Confirm

To identify manually, enter the subplot identifier.

Confirm

Figure 3: User-triggered exceptions of Identify material

Identify the materials for Tableting.

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Identified quantity
D003-04	Ethanol 96 %			10.0 g	10.0 g
		BX140	SL00000456		10.0 g
D130-01	Sonolin 100 mg premix			1,000.0 g	2,000.0 g
		BX142	SL00000471		2,000.0 g
D005-04	Talc			20.0 g	200.0 g
		BX141	SL00000466		200.0 g

Confirm

Figure 4: Identify material after phase completion

Identify the materials for Tableting.

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Identified quantity
D005-04	Talc			20.0 g	400.0 g
		BX141	SL00000467		200.0 g
		BX141	SL00000466		200.0 g
D003-04	Ethanol 96 %			10.0 g	20.0 g
		BX140	SL00000457		10.0 g
		BX140	SL00000456		10.0 g
D130-01	Sonolin 100 mg premix			1,000.0 g	4,000.0 g
		BX142	SL00000473		2,000.0 g
		BX142	SL00000471		2,000.0 g

D005-04: Re-identify 10.0 g.
 D003-04: Re-identify 10.0 g.
 D130-01: Re-identify 505.0 g.

Confirm

Figure 5: Reactivated Identify material after phase completion with Comment to execution

Identification
 Identify Tableting Inputs

100%

Identify

Undo

Figure 6: Identify material in the Navigator

To identify an additional subplot, enter the subplot identifier.

Confirm

Figure 7: Post-completion exception of Identify material (Identify)

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

Confirm

Figure 8: 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. 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 in the bottom row provides the **Unlock** button, while the right column holds the **Confirm** 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.

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 10) 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.

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 10) 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 .

Attribute	Type	Comment
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 8) and expiry date (page 8) 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.

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.

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 the calculated result of several phase outputs as value into a parameter attribute. When you reference phase outputs in this manner you need to be aware of the following restrictions:

- Only if a phase has been processed does it provide an output that can be fed into another phase as attribute value. For this reason, you can never reference an output of a phase that is a strict successor of the phase 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 phase to 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:

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.
- **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 lists all materials that have been available for processing in the preceding phases. An operator can indicate and register the number and quantities of the produced material sublots.

When the operator has registered the produced material sublots, he can unlock the **Confirm** button and complete the production. For each of the produced sublots the system prints a subplot label.

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.

As long as the phase is active, it provides a user-triggered exception to reprint a subplot label, by typing the identifier of the produced subplot.

After phase completion, it provides a post-completion exception to reprint a subplot label, 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 and/or subplot identifiers
- planned quantity
- produced quantity.

The Navigator displays the overall produced quantity and provides access to the post-completion exception.

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.

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot

g

kg

Produce

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity
D130-01	Sonolin 100 mg premix	BX143		1,010.0 g	1,010.0 g
		BX143	SL00000476		505.0 g
		BX143	SL00000477		505.0 g


Confirm

Figure 9: Produce material during execution

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity
D130-01	Sonolin 100 mg premix	BX143		1,010.0 g	1,515.0 g
		BX143	SL00000476		505.0 g
		BX143	SL00000477		505.0 g
		BX143	SL00000478		505.0 g

D130-01: SL00000476 contaminated, re-produce 505.0 g.




Figure 10: Reactivated Produce material during execution with Comment to execution

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




Figure 11: User-triggered exception of Produce material

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity
D130-01	Sonolin 100 mg premix	BX143		1,010.0 g	1,010.0 g
		BX143	SL00000476		505.0 g
		BX143	SL00000477		505.0 g





Figure 12: Produce material after phase completion

Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity
D130-01	Sonolin 100 mg premix	BX143		1,010.0 g	1,515.0 g
		BX143	SL00000476		505.0 g
		BX143	SL00000477		505.0 g
		BX143	SL00000478		505.0 g

D130-01: SL00000476 contaminated, re-produce 505.0 g.




Figure 13: Reactivated Produce material after phase completion with Comment to execution



Figure 14: Produce material in the Navigator



Figure 15: Post-completion exception of Produce material

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. The center column holds text boxes to type the number and quantity of the sublots produced. The right column of the row with the quantity text box provides the **Toggle unit of measure** button and, in the next row, the **Produce** button to register the entries the operator has typed in the text boxes.

In the next rows, the phase displays the list of materials available for production, spanning all columns. Once a material has been registered as produced, its sublots and their data appear as new rows of the table. The center column in the bottom row provides the **Unlock** button, while the right column holds the **Confirm** button.

When the phase is completed it shows the same three-column, three-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
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.

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 .

Reprint

Represents a user-triggered exception that is accessible from the Exception Window. 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 2000 characters.

Post - 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 2000 characters.

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 the calculated result of several phase outputs as value into a parameter attribute. When you reference phase outputs in this manner you need to be aware of the following restrictions:

- Only if a phase has been processed does it provide an output that can be fed into another phase as attribute value. For this reason, you can never reference an output of a phase that is a strict successor of the phase 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 phase to 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:

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".

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, 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 28) 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).

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.

When the operator has accounted the material sublots, he can unlock the **Confirm** button and complete 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.

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
- waster quantity
- sampled quantity
- returned quantity.

The Navigator displays the ratio between accounted quantity and the identified quantity in percent.

Account the tableted materials.

Refresh  Account 

Material ID	Material short description	Batch ID	Sublot ID	Identified	Consumed	Wasted	Sampled	Returned
D003-04	Ethanol 96 %			10.0 g	10.0 g	0 g	0 g	0.0 g
		BX10						
			SL00000381	10.0 g	10.0 g	0 g	0 g	0.0 g
D005-04	Talc			100.0 g				
		BX34						
			SL00000393	100.0 g				
D130-01	Sonolin 100 mg premix			2,020.0 g				
		BX30						
			SL00000399	2,020.0 g				



 Confirm 

Figure 16: Account material during execution

Identified

t
g
kg

Consumed

t
g
kg

Wasted

t
g
kg

Sampled

t
g
kg

Returned

t
g
kg

Account

Cancel

Figure 17: Provide quantities for Account material

Account the tableted materials.

Refresh

Account

Material ID	Material short description	Batch ID	Sublot ID	Identified	Consumed	Wasted	Sampled	Returned
D003-04	Ethanol 96 %			10.0 g	10.0 g	0 g	0 g	0.0 g
		BX10		10.0 g	10.0 g	0 g	0 g	0.0 g
			SL00000381	100.0 g	20.0 g	0 g	0 g	80.0 g
D005-04	Talc			100.0 g	20.0 g	0 g	0 g	80.0 g
		BX34		100.0 g	20.0 g	0 g	0 g	80.0 g
			SL00000393	2,020.0 g	1,000.0 g	0 g	10.0 g	1,010.0 g
D130-01	Sonolin 100 mg premix			2,020.0 g	1,000.0 g	0 g	10.0 g	1,010.0 g
		BX30		2,020.0 g	1,000.0 g	0 g	10.0 g	1,010.0 g
			SL00000399	2,020.0 g	1,000.0 g	0 g	10.0 g	1,010.0 g

Confirm

Figure 18: Account material after phase completion

Tableting

Account Tableting Inputs

100 %

Figure 19: Account material in the Navigator

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. 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 in the bottom row provides the **Unlock** button, while the right column holds the **Confirm** 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.

Accounting 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.

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 .

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 the calculated result of several phase outputs as value into a parameter attribute. When you reference phase outputs in this manner you need to be aware of the following restrictions:

- Only if a phase has been processed does it provide an output that can be fed into another phase as attribute value. For this reason, you can never reference an output of a phase that is a strict successor of the phase 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 phase to 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:

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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 - Process parameter • 27
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Instance count (output)

Account material • 29

Identify material • 13

Produce material • 21

Instruction (parameter)

Account material • 27

Identify material • 7

Produce material • 19

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Output variable

Account material • 29

Completion time (Account material) • 30

Completion time (Identify material) • 14

Completion time (Produce material) • 22

Identifier (Account material) • 29

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Instance count (Account material) • 29

Instance count (Identify material) • 13

Instance count (Produce material) • 21

Produce material • 21

Start time (Account material) • 30

Start time (Identify material) • 14

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Expiry date check configuration (Identify material) • 8
Identify manually (Identify material) • 11
Identify material • 7
Instruction (Account material) • 27
Instruction (Identify material) • 7
Instruction (Produce material) • 19
Post - Identify additionally (Identify material) • 12
Post - Reprint (Produce material) • 20
Post - Undo identification (Identify material) • 12
Produce material • 19
Reprint (Produce material) • 19
Undo identification (Identify material) • 11
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Output variable • 21
Process parameter • 19

R

Reprint (Produce material, parameter) • 19

S

Start time (output)
Account material • 30
Identify material • 14
Produce material • 22

U

Undo identification (Identify material, parameter) • 11