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GLOSSARY

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Allen-Bradley • Rockwell Software

Rockwell Automation

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Contents

Chapter 1

Terms

This section provides a glossary of terms.

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21 CFR Part 11
Code of Federal Regulations, Title 21 - Food And Drugs, Part 11 Electronic Records; Electronic Signatures
Regulations for audit trail, electronic records, and electronic signatures.
[reference: 21 CFR Part 11 (Electronic Records; Electronic Signatures; Department of Health and Human Services); FDA [2] (page 39)]

A

Active pharmaceutical ingredient / drug substance
Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product (API). Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
[source: Guidance for Industry, Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients [13] (page 39)]

Agility
The agility concept of PharmaSuite allows flexible order and workflow execution by:

- Parallel execution of one unit procedure at multiple stations.
- Unprepared assignment of non-stationary devices to stations.
- Continuation of an operation on a different station.

AI server
See: Automation Integration server (page 2)

API
See: Active pharmaceutical ingredient (page 1)

Approved custom building block
See: Custom building block (page 6)

Archiving
During the lifetime of an MES a large amount of orders and their related data is created. For long-term archiving, orders and workflows can be exported into record-specific containers.

See also: Purging (page 26)

Audit trail
Audit trail means preparation of data in a logical structure that images the sequence of events and thus guarantees that all procedures may be traced back. This also includes the chronological recording of system activities that permits reconstruction, verification, and examination of a sequence of activities and their environment conditions.
[reference: 21 CFR Part 11, Subpart B, 11.10(e) (Electronic Records; Electronic Signatures; Department of Health and Human Services;) FDA [16] (page 39)]

Whenever data objects that are under audit trail are created or modified, an audit trail data set is written automatically by the system. The audit trail data contains several attributes, which have the purpose to identify the circumstances and the context of the performed actions.
The system does not write an explicit data set at deletion of a data object that is under audit trail. In this case the period of validity (which is different from the period of validity in the context of version control) is shortened. That means that the timestamp of the period of validity changes from "not limited" (e.g. 9999-12-31 23:59:59) to the exact time of deletion (e.g. 2008-10-30 09:48:56).

Automation Integration server
A PharmaSuite server component that controls the communication with automation-related systems (e.g. FactoryTalk Live Data).

Auxiliary packaging material
Auxiliary packaging materials are materials that are required for additional packaging of trade packs, such as wrapping film, adhesive tape etc.

See also: Material (page 19), Packaging material (page 23)

Auxiliary substance
An auxiliary substance is a component of a drug. Auxiliary substances do not have a therapeutical effect but are used as flavor or to improve a product's stability.

See also: Material (page 19)

B

Barcode
An automatic identification technology that encodes information into an array of adjacent varying-width parallel rectangular bars and spaces that are commonly referred to as 1D barcodes. Barcodes consisting of patterns of squares, dots, hexagons, and other geometric patterns are called 2D barcodes or matrix codes. 2D barcodes have more data representation capability than 1D barcodes.

Batch
A batch is a quantity of substance, packaging materials, or product manufactured during one step or in a series of steps that is expected to be homogeneous.
In the pharmaceutical industry it refers to pharmaceuticals that are produced and packaged during the same production sequence with identical raw materials.

Batches are used to control material flow, starting at goods receipt, in the production process. To ensure the proper quality of materials, batches typically go through several statuses, such as **Blocked** or **Quarantined**, before they are **Released** and can be used for production.

See also: Material (page 19), Order (page 22), Sublot (page 31)

Batch production record
According to S88, a batch production record (short: batch record) is a subset of the execution and business information that is retained based upon business requirements identified by the batch production record specification.
[source: ANSI/ISA-88.00.04-2006; Batch Control Part 4: Batch Production Records; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-978-2 [11] (page 39)]

For the definition of a **batch record** according to 21 CFR Part 211, Subpart J, 211.188 (Current Good Manufacturing Practice for Finished Pharmaceuticals; Department of Health and Human Services); FDA [17] (page 39), see batch production record report (page 3).

Batch production record report
According to S88, a batch production record report (short: batch report) is an extraction of information from one or more batch production records that is formatted for printing, displaying, or sending to a collaborating system.
[source: ANSI/ISA-88.00.04-2006; Batch Control Part 4: Batch Production Records; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-978-2 [11] (page 39)]

In 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals; Department of Health and Human Services); FDA [4] (page 39), a **batch report** is called **batch record**: Batch records should be prepared for each intermediate, Active Pharmaceutical Ingredient (API), and bulk product and should include complete

information relating to the production and control of each batch. The batch record should be checked before issuance to assure that it is the correct version and a legible accurate reproduction of the appropriate master recipe.
[reference: 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals; Department of Health and Human Services); FDA [4] (page 39)]
A batch report should include a reference to the approved master recipe that it is based on.

If Dispensing was executed, the batch report includes a Dispensing Report.

Batch record
See: Batch production record (page 3)

Batch report
See: Batch production record report (page 3)

Building block
An individual structural component on any level of a master recipe or master workflow that can be used in building a recipe or workflow structure: procedure, unit procedure, operation, or phase.

A **closed** building block hides its internal structure from the recipe or workflow author, an **open** building block reveals its internal structure.

A **system** building block is a building block that is provided along with the PharmaSuite application. A **custom** building block is a building block that has been saved by a recipe or workflow author from within the application.

See also: Custom building block (page 6), Operation (page 22), Phase (page 24), Procedure (page 25), Unit procedure (page 33)

Building block element
A building block becomes a building block element when it is used within another building block. Saving element-specific properties and parameters does not affect the original building block that was used as a template.

See also: Building block (page 4), Recipe element (page 27), Workflow element (page 36)

Building block library
The library of building blocks available for use in Recipe and Workflow Designer.

See also: Building block (page 4), Recipe and Workflow Designer (page 27)

Bulk material
A bulk material is defined as the finished but not yet packaged pharmaceutical product, such as loose, uncounted tablets, that is used in producing finished goods, e.g. blistered

and packaged tablets. In this sense, a bulk material is a specific case of a semi-finished good.

See also: Finished good (page 13), Material (page 19)

C

Campaign weighing
In campaign weighing (material processing) it is possible to select several Dispense order steps with common materials for processing. This allows a material-optimized weighing sequence over the selected order steps.

See also: Dispense (page 7)

Capability
Capability parameters define if certain behaviors or capabilities are available during recipe and workflow execution.

cGMP
The term cGMP or "current" GMP refers to processes performed according to industry standards.

See: Good Manufacturing Practice (page 15)

cGxP
Current Good X Practice (FDA compliance; X can mean: Clinical, Laboratory, Manufacturing, Pharmaceutical).

See: GxP (page 15)

Change request for mass changes
Recipe and Workflow Designer provides the **Change request** function to support the controlled and documented update of recipes and workflows in terms of replacing a custom building block that is re-used in all of the affected recipes and workflows.

Closed building block
See: Building block (page 4)

Cockpit
The Cockpit represents an operator's entry point to the execution process. Specific to each station and user, the Cockpit provides a list of all startable, resumable, and running processes, from which the operator can select unit procedures and operations to start or switch to. The running processes also include those operations of the same unit procedure that are running at another station.

Consumed quantity
The quantity of an input material that is used for production or wasted.

Container
See: Equipment (page 10)

Control recipe
The control recipe starts as a copy of a specific version of a master recipe and is then modified as necessary with scheduling and operational information to be specific to a single batch. It contains product-specific process information necessary to manufacture a particular batch of product. It provides the level of detail necessary to initiate and monitor equipment procedural entities in a process cell. It may have been modified to account for actual raw material qualities and actual equipment to be utilized. The selection of units and appropriate sizing can be done any time before that information is needed.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

See also: Master recipe (page 19)

Custom building block
A building block that was created from an existing building block by a recipe or workflow author. A custom building block is available for reuse.

The following characteristics apply to a custom building block, its properties, parameters, and transitions during the recipe or workflow authoring process:

- An **approved** custom building block has been verified. Once an **approved** custom building block is used (e.g. in a master recipe, master workflow), only parameters and transitions that are **not locked** can be modified.
- A **locked** parameter or transition cannot be modified. **Locked** parameters and transitions cannot be **unlocked** once a custom building block has been **approved**.
- A **frozen** parameter or transition has passed through the following process: the parameter or transition was **locked**, the related building block was **approved**, and the **approved** building block is being used as element of a building block, recipe, or workflow.

See also: Building block (page 4), Recipe element (page 27), Workflow element (page 36)

D

Data Manager
Data Manager is a graphical workbench for creating and maintaining master data (e.g. equipment data, work center data). It is available in two modes: as Data Manager - Equipment and as Data Manager - Work Center.

DCS
See: DCS Adapter (page 7)

DCS Adapter
An adapter provided by Rockwell Automation to establish the connection between Manufacturing Execution Systems (MES) and Distributed Control Systems (DCS).

Device
A device is a distinct item that results from discrete manufacturing, such as a tablet computer (electronic device) or a pacemaker (medical device).
In PharmaSuite, a device is the produced material of a device order and belongs to a sublot and thus to a batch. Each device has a serial number, which is unique per material, so that the unique identifier of a device consists of its serial number and the identifier of its material.
A device can assume various statuses, such as **Pending** or **Produced**.

Device history record
A device history record contains all information related to the manufacturing of a device (e.g. master recipe and order data, serial number, production dates).

See also: 21 CFR Part 820, Subpart M, 820.184 (Quality System Regulation; Department of Health and Human Services); FDA [21] (page 39)

DHR report
See: Device history record (page 7)

Dispense
The Dispense phases are the PharmaSuite framework for processing a complete dispensing process. The phases are executed within a Dispense operation in the Production Execution Client for EBR.

A typical Dispense operation comprises Dispense-specific phase building blocks and transitions between them.

- The **Identify material** phase (D Identify Material) allows an operator to identify material on sublot or batch level.
- The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
  The usage of the **Show GHS data** phase during Dispense is optional.
- The **Select scale** phase (D Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.
- The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be dispensed and to bind this

entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.
The usage of the **Identify container** phase during Dispense is optional.

- The **Tare** phase (D Tare) allows an operator to record the actual tare of a target container.
- The **Weigh** phase (D Weigh) allows an operator to record the actual weight of a target container.
- The **Release scale** phase (D Release Scale) checks whether the scale value returns back to zero after unloading.
- The **Print report** phase (D Print Report) prints a batch report related to the current unit procedure when the phase becomes active.

The behavior of the phases can be affected by exceptions and the applied weighing method.

See also: Inline Weighing (page 16), Output Weighing (page 23), Shop floor-defined order workflow (page 30), Weighing method (page 34)

E

EBR
See: Electronic batch recording (page 10)

EBR server
A PharmaSuite server that executes activity sets of S88 procedures and unit procedures related to the execution of PharmaSuite control recipes.
See: Electronic batch recording (page 10)

Editor
There are several editors for special purposes available in PharmaSuite:

- **BigDecimal editor** to enter a number or a range between two numbers. It allows to define a unit of measure for the value or range.
  BigDecimal editor for Historian to retrieve numeric values from a historical data archive. It allows to define a unit of measure for the values.
- **Boolean editor** to handle boolean values.
- **Change Action Selection editor** to
  - select a FlexibleStateModel property with its bundle of possible change actions and
  - define which of the possible change actions are available to an operator during execution.

- **CleaningRules editor** to define which of the available cleaning rules are to apply to an entity and which cleaning demand they involve.
- **Date/Time Picker editor** to enter a date with or without a time.
- **Duration editor** to enter a duration with days as largest and milliseconds as smallest unit.
- **Expression editor** in Recipe and Workflow Designer to define
  - expressions that provide inputs to process parameter attributes,
  - transition conditions, which are required if a graph contains selection branches or loops, and
  - expressions that define complex rules for equipment requirements.
- **Expression editor** in Data Manager to define
  - conditions of graph transitions, which determine if the expected circumstances are met so that the transition can be executed,
  - actions of graph transitions, which are performed along with the transition.
- **FlexibleAttributeDefinition editor** to create and configure a bundle of runtime attributes.
- **FlexibleStateModel editor** to
  - define a status graph to govern an equipment entity and
  - to set the required status the equipment entity must have to be suitable for use.
- **FlexibleTagDefinition editor** to create and configure a bundle of automation properties mapped to individual tags of an equipment entity.
- **GraphStatusChange editor** to change the current status of an entity along with the expiry date of the status, if it can expire.
- **Label Layout Selection** editor to select the layout for the labels of equipment entities.
- **List editor** to define the items of a list.
- **Measured Value editor** to provide a value with a unit of measure.
- **Multi-line text editor** to write text that is too long for a simple input box.
- **Option List editor** to define the key and display text pairs of option lists.
- **Packaging Level Data editor** to define the attributes of packaging levels.
- **Property Selection editor** to select a property type to be added as property to a process parameter.

- **Ranges editor** to define up to three ranges per equipment by specifying the high and low limits, the resolution, and the unit of measure of each range.
- **ScaleConfiguration editor** to enter scale driver and scale connection data.
- **ScaleTestAndCalibration editor** to define test weights and additional test and calibration information.
- **Searchable Option List editor** to select options from option lists with a large number of selectable items.
- **String editor** to handle any sequence of characters.
- **Trigger Selection editor** to select triggers available for a specific purpose.

Electronic batch recording
Electronic batch recording (EBR) is a way of providing electronic work instructions to operators on the shop floor and compiling production data electronically, unique for each batch produced. This includes on-time validity checks of operator input and allows automatic data interfacing to equipment. EBR complies with 21 CFR Part 11. Running EBR enables a rigid control of processes, supports operators, and helps to eliminate documentation errors. In addition, review-by-exception principles can be applied to EBR.

See also: 21 CFR Part 11 (page 1)

Electronic signature
A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: Food and Drug Administration (page 13)

Equipment
Devices required to execute the production of a semi-finished or finished product. Such devices can be for example containers, sieves, shovels, filters, mixer, ropes, rooms, scales, and other.

The following model applies to Equipment Management within PharmaSuite:

- An **equipment class** provides a means to bundle and address equipment entities that share a common set of properties and capabilities.
  Example: Mixer, vessel
- A **property** describes a characteristic of an equipment entity.
  Example: Maximum speed, temperature range, size
- A **property type** specifies equipment properties and equipment property requirements.
  Example: Mixer speed, vessel temperature range, vessel size

- An **equipment capability** describes the procedural aspect of an equipment entity.
  Example: Provides cleaning status
- An **equipment requirement** specifies the needs an equipment entity must provide for a specific process step.
  Equipment requirements are used to prevent identification of equipment entities not satisfying the process requirements.
  Example: Is member of a specified equipment class.
- An **equipment entity** is the data representation of a physical piece of equipment and its properties. Equipment entities can be derived from an equipment class, a template equipment entity, or from another equipment entity. They can be assigned to all classes whose properties they share.
  Additionally, equipment entities can be collected in groups to facilitate scenarios such as a common treatment of otherwise unconnected entities, e.g. sterilization, or a complex piece of equipment that consists of a base entity and several other attached entities, e.g. an assembled machine. A group of entities consists of a parent entity and one or more child entities, which themselves can also be parent to an entity group.
  The following types of equipment entities require a specific set of properties to be fully configured and suitable for use with the Weighing and Dispense phases of PharmaSuite:
  - **Container** is a generic term to cover the various types of equipment for holding materials between processing steps. Typical containers used in pharmaceutical production environments are bins or IBCs.
  - A **room** is a physical location, at which a step of an order execution is performed, such as dispensing, mixing, packaging, etc.
  - A **scale** is a type of equipment used to measure the weight of a material or an object.
- A **template equipment entity** is the data representation of a piece of equipment that is used during processing as a master to generate new equipment entities and required for pieces of equipment such as filter liners, hoses, or plastic bags, which are used as equipment during processing and thus need to be tracked. The template entity can be assigned to a material in order to specify the properties that generated equipment entities of the material will have. Template entities without a material reference can be used for components that are not inventoried.
- An **equipment graph** specifies the statuses an equipment entity can assume while it is used in execution, the triggers that affect the entity's status, as well as the transitions between the statuses, their conditions, and actions.

See also: ANSI/ISA-88.00.02-2001; Batch Control Part 2: Data Structures and Guidelines for Languages; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-745-3 [9] (page 39)

Equipment mass change
Data Manager provides the equipment mass change process to propagate changes performed on an equipment class in an automated way to the equipment entities that share this class.

ETO
See: Event-triggered operation (page 12)

Event-triggered operation
An operation that only exists as non-executable template until an external trigger or an operator action creates executable runs of the template during execution.

Exception
Exceptions need to be recorded to document irregular circumstances that have occurred during processing. They are an important element of the processing report (batch, device, workflow).

- A **user-defined exception** can be recorded by a user at any time for an active or a completed phase. Exceptions of this category are free-text exceptions and cover unexpected exceptions (e.g. someone enters a production facility without GxP-conforming clothing).
- A **user-triggered exception** can be recorded by a user for an active phase. Exceptions of this category cover expected, pre-defined exception options that are provided by the phase (e.g. the "Identify material" phase could provide the "manual identification" exception to cover an incident when a scanner is out of order or a label is illegible).
- A **system-triggered exception** is based on the data recorded during phase execution. The phase will prompt the user to record the exception. Exceptions of this category cover expected, pre-defined exceptions that are provided by the phase (e.g. a limit violation of a requested value entry during execution).
- A **post-completion exception** can be recorded by a user for a completed phase. Exceptions of this category cover expected, pre-defined exceptions that are provided by the phase (e.g. label reprint).

Exception Dashboard
A dashboard that is part of the Production Response Client. It enables QC personnel to review and process exceptions of running and completed orders.

See also: Production Response Client (page 26)

F

FDA
See: Food and Drug Administration (page 13)

Finished good
Finished goods (also known as finished products) are products that are ready for shipping. A variety of different starting materials and/or semi-finished goods is typically involved in the production of finished goods.

See also: Material (page 19), Semi-finished good (page 30)

Finished product
See: Finished good (page 13)

Food and Drug Administration
An agency within the Department of Health and Human Services (...).
The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
[source: U.S. Food and Drug Administration [14] (page 39)]

It publishes warning letters, which are also an important source of cGMP interpretation.

See also: Good Manufacturing Practice (page 15)

Formula
A category of recipe (or workflow) information that includes process inputs, process parameters, and process outputs.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

See also: Master recipe (page 19), Master workflow (page 19), Process input (page 25), Process output (page 26), Process parameter (page 26)

Frozen parameter
See: Custom building block (page 6)

Frozen transition
See: Custom building block (page 6)

FTPC
Abbreviation of FactoryTalk® ProductionCentre.

G

GCP
See: Good Clinical Practice (page 14)

GDP
See: Good Distribution Practice (page 14)

GHS
See: Globally Harmonized System of Classification and Labelling of Chemicals (page 14)

Globally Harmonized System of Classification and Labelling of Chemicals
The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) addresses classification and labelling of chemicals by types of hazards.
[source: United Nations Publications]

GLP
See: Good Laboratory Practice (page 14)

GMP
See: Good Manufacturing Practice (page 15)

Good Clinical Practice
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: GxP (page 15)

Good Distribution Practice
Guidelines for the proper distribution of medicinal products for human use. Good Distribution Practice (GDP) is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs, intended for human consumption.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: GxP (page 15)

Good Laboratory Practice
Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. GLP helps assure regulatory authorities that the

data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: GxP (page 15)

Good Manufacturing Practice
Regulations of the FDA and comparable non-US agencies that describe the minimum standards for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packaging, or holding a drug, to assure that such drugs meet the requirements of the Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to posses.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: GxP (page 15), [reference: 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Department of Health and Human Services); FDA [3] (page 39)], [reference:21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals; Department of Health and Human Services); FDA [4] (page 39), [reference: 21 CFR Part 11 (Electronic Records; Electronic Signatures; Department of Health and Human Services); FDA [2] (page 39)]

GxP
One or a combination of GCP, GMP, GLP, GDP - often used for everything of interest for the Regulatory Bodies. ‘x’, one of: Clinical, Manufacturing, Laboratory, Distribution.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: Good Clinical Practice (page 14), Good Distribution Practice (page 14), Good Manufacturing Practice (page 15), Good Laboratory Practice (page 14)

H

Hidden Phase
A **Hidden Phase** is a structural phase that is required to build adjacent branches or loops in valid SFC syntax. Thus it is only visible in Recipe and Workflow Designer and does not appear as executable phase during order or workflow processing.

See also: Sequential function chart (page 30)

I

I18N
See: Internationalization (page 17)

Inline Weighing
The Inline Weighing (Dispense) phases are the PharmaSuite framework for processing Inline Weighing before charging. The phases are executed within an Inline Weighing unit procedure and several operations in the Production Execution Client for EBR.

The structure of an Inline Weighing operation comprises Inline Weighing-specific phase building blocks and transitions between them.

- The **Identify material** phase (D Identify Material) allows an operator to identify material on sublot or batch level.
- The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
  The usage of the **Show GHS data** phase during Inline Weighing is optional.
- The **Select scale** phase (D Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.
- The **Tare** phase (D Tare) allows an operator to record the actual tare of a charging vessel.
- The **Weigh** phase (D Weigh) allows an operator to record the actual weight of a charging vessel.
- The **Release scale** phase (D Release Scale) checks whether the scale value returns back to zero after unloading.

The behavior of the phases can be affected by exceptions and the applied weighing method.

See also: Dispense (page 7), Output Weighing (page 23), Weighing method (page 34)

Input material
The materials that have to be used in the manufacturing process to get the planned output.

See also: Material flow control (page 19), Process input (page 25), Process output (page 26)

Intermediate good
Intermediate goods are partially processed materials that must go through additional production stages before they become semi-finished goods, such as tablet bodies prior to coating.

See also: Material (page 19), Semi-finished good (page 30)

Internationalization
Internationalization (I18N) is the process of planning and implementing products and services so that they can easily be adapted to specific local languages and cultures, a process called localization. The internationalization process is sometimes called translation or localization enablement. Enablement can include:

- Allowing space in user interfaces (for example, hardware labels, help pages, and online menus) for translation into languages that require more characters
- Developing with products (such as Web editors or authoring tools) that can support international character sets (Unicode)
- Creating print or Web site graphic images so that their text labels can be translated inexpensively
- Using written examples that have global meaning
- For software, ensuring data space so that messages can be translated from languages with single-byte character codes (such as English) into languages requiring multiple-byte character codes (such as Japanese Kanji)

[source: Whatis.com IT Encyclopedia [18] (page 39)]

See also: Localization (page 18)

Intra material
Intra materials are materials that occur only temporarily between two processing steps. They are related to MFC transfer items.

See also: Material (page 19), Material flow control (page 19)

Inventory
Inventory is a repository that serves for storing and managing goods and materials. In PharmaSuite for Production Management it has a hierarchical structure and consists of the following three components:

- warehouse
- storage area, and
- storage location.

The inventory is managed on the batch, sublot, and device level.

See also: Batch (page 3), Device (page 7), Inventory correction (page 17), Storage area (page 31), Storage location (page 31), Sublot (page 31), Warehouse (page 34)

Inventory correction
An inventory correction becomes necessary if, during an inventory check for example, it turns out that a sublot contains more or less material than registered in the system. In

these cases the sublot quantity can be changed to the actual quantity of material contained in the sublot.

See also: Inventory (page 17)

Inventory level
An inventory level defines the object that is represented by the level when handled in a warehouse.

See also: Packaging level (page 23)

J

There is no term available.

K

There is no term available.

L

L10N
See: Localization (page 18)

Localization
Localization (L10N) is a process of adapting a product or service to a particular language, culture, and desired local "look-and-feel". Ideally, a product or service is developed so that localization is relatively easy to achieve - for example, by creating technical illustrations for manuals, in which the text can easily be changed to another language and allowing some expansion room for this purpose. This enabling process is termed **I18N**. An internationalized product or service is therefore easier to localize. In localizing a product, in addition to idiomatic language translation, such details as time zones, money, national holidays, local color sensitivities, product or service names, gender roles, and geographic examples must all be considered. A successfully localized service or product is one that appears to have been developed within the local culture.
[source: Whatis.com IT Encyclopedia [19] (page 39)]

See also: Internationalization (page 17)

Locked parameter
See: Custom building block (page 6)

M

Master recipe
The master recipe is that level of recipe that is targeted to a process cell or a subset of the process cell equipment. A master recipe can be derived from a general recipe or a site recipe. It can also be created as a stand-alone entity if the recipe creator has the necessary process and product knowledge. Recipes contain the following categories of information: header, formula, equipment requirements, procedure, and other information.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

In its role as container for both the what (to manufacture) and the how (to manufacture), the master recipe is the place where the flow of the materials through the production process is specified. Thus a master recipe typically contains all pharmaceutically-relevant data required to support GxP-compliant production. Master recipes are under version and status control.

See also: Formula (page 13), Order (page 22), Procedure (page 25)

Master workflow
A master workflow defines the processing data of workflows, which are often intended for multiple executions and have a non-production purpose, such as cleaning processes. It is structurally similar to a master recipe but only allows one element on the unit procedure level.

See also: Formula (page 13), Procedure (page 25), Workflow (page 36)

Material
Materials are defined as all substances that are directly or indirectly related to or utilized in the manufacturing process, that are relevant to the pharmaceutical production process, and must thus be taken into consideration for all planning purposes. Materials can be classified by their types.

See also: Auxiliary packaging material (page 2), Auxiliary substance (page 2), Bulk material (page 4), Finished good (page 13), Input material (page 16), Intermediate good (page 16), Intra material (page 17), Material flow control (page 19), Output material (page 22), Packaging material (page 23), Raw material (page 27), Secondary packaging material (page 30), Semi-finished good (page 30)

Material flow control
Material flow control (MFC) defines the material flow between the unit procedures of a master recipe, master workflow, or procedure building block. MFC uses the material input and output parameters defined with the phases to specify during which unit procedures the materials enter the production process and how they are moved and transformed during processing until their flow ends with the produced material.

The flow of materials is represented by three types of MFC items:

- An input item represents a material that enters into a process step, such as a raw material.
- A transfer item represents a material that moves from one process step to the next, such as an intra material.
- An output item represents the final product that leaves the last process step. There can only be one output per master recipe.
  Only Dispense stand-alone master recipes can have more than one output item.

In Recipe Designer - Batch all three types of MFC items (input, transfer, output) are used, while in Recipe Designer - Device and Workflow Designer there are only input items.

See also: Input material (page 16), Material (page 19), Output material (page 22)

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

See also: Inventory (page 17)

Material receipt
Material receipt is the pre-defined workflow for introducing materials into small storage areas in a shop-floor environment, such as buffer or line warehouses. It can be used for adding materials to existing batches or to generate new batches. At the end of a successful material receipt the fully identified and labeled material sublots are available for further processing on the shop floor. The material receives a batch identifier, the target storage location is specified, its sublots are registered individually, and one or more labels are printed for sublot identification.

See also: Inventory (page 17)

MFC
See: Material flow control (page 19)

MFC input
See: Material flow control (page 19)

MFC output
See: Material flow control (page 19)

MFC transfer
See: Material flow control (page 19)

N

National Fire Protection Association
The National Fire Protection Association (NFPA) is an international nonprofit organization that was established in 1896. The company’s mission is to reduce the worldwide burden of fire and other hazards on the quality of life by providing and advocating consensus codes and standards, research, training, and education.

NFPA 704 presents a system to simplify determining the degree of health, flammability and instability hazards of chemicals. The system also provides for the recognition of unusual water reactivity and oxidizers. The NFPA 704 ratings are displayed in markings that are commonly referred to as the "NFPA hazard diamond".

[source: National Fire Protection Association [15] (page 39)]

Navigator
The Navigator represents an operator's information and service point during the execution process. Specific to each unit procedure, the Navigator provides a historical view of the executed process steps. For each step, the operator can access basic and detail information as well as additional actions.

NFPA
See: National Fire Protection Association (page 21)

O

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

OES
See: Operation Execution server (page 22)

Open building block
See: Building block (page 4)

Operation
An operation is an ordered set of phases that defines a major processing sequence that takes the material being processed from one state to another, usually involving a chemical or physical change. It is often desirable to locate operation boundaries at points in the procedure where normal processing can safely be suspended. Examples of operations include the following:

- Preparation: Pull a vacuum on the reactor and coat the walls with antifoulant.
- Charge: Add demineralized water and surfactants.
- React: Add VCM and catalyst, heat, and wait for the reactor pressure to drop.

[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

For example, in a pharmaceutical environment, "Prepare", "Run tableting", and "Yield calculation" would be operations of a "Tableting" unit procedure.

See also: Master recipe (page 19), Master workflow (page 19), Phase (page 24), Procedure (page 25), Unit procedure (page 33)

Operation Execution server
A PharmaSuite server component that supports the execution of phases that are related to a server-run operation.

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

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

On the basis of its assigned master recipe, material, and quantity, the order is exploded to generate all order-related objects that are necessary for executing the order.

See also: Control recipe (page 6), Master recipe (page 19), Material (page 19), Order step (page 22)

Order step
Order steps are generated during order explosion. They represent the activities that will be processed at the specified work centers.

See also: Order (page 22)

Output material
The materials that result from the manufacturing process, either as a finished product or any kind of intra material or semi-finished product.

See also: Material flow control (page 19), Process input (page 25), Process output (page 26)

Output Weighing
The Output Weighing phases are the PharmaSuite framework for weighing of produced material. The phases are executed within an Output Weighing operation in the Production Execution Client for EBR.

The typical structure of an Output Weighing operation comprises Output Weighing-specific phase building blocks and transitions between them.

- The **Manage produced material** phase (O Manage Produced Material) allows an operator to manage produced material on container and/or sublot level.
- The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
  The usage of the **Show GHS data** phase during Output Weighing is optional.
- The **Select scale** phase (O Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.
- The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be produced and to bind this entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.
  The usage of the **Identify container** phase during Output Weighing is optional.
- The **Tare** phase (O Tare) allows an operator to record the actual tare of a target container.
- The **Weigh** phase (O Weigh) allows an operator to record the actual weight of a target container or sublot and to print a label for it.
- The **Release scale** phase (O Release Scale) checks whether the scale value returns back to zero after unloading.

The behavior of the phases can be affected by exceptions and the applied weighing method.

See also: Dispense (page 7), Inline Weighing (page 16), Weighing method (page 34)

P

Packaging level
Packaging levels define the packaging structure of a material.

See also: Inventory level (page 18)

Packaging material
Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as

primary or secondary according to whether or not they are intended to be in direct contact with the product (e.g. blisters vs. folding cartons).
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

See also: Material (page 19)

Parameter
Process inputs (material-related and equipment-related), process outputs (material-related and equipment-related), and process parameters (such as temperature, pressure) are represented as configurable parameters when used in a master recipe or master workflow.

See also: Formula (page 13), Master recipe (page 19), Master workflow (page 19), Process input (page 25), Process output (page 26), Process parameter (page 26)

Parameter class
Represents the collection of properties of a process parameter. Examples of parameter classes for phases are

- "Get value" with two properties: "Lower limit" and "Upper limit"
- "Get mixing speed" with the property "UoM" already set to "rpm"

The generic parameter classes become specific process parameters when used in a master recipe or master workflow.

See also: Building block (page 4), Phase (page 24), Process parameter (page 26)

PEC
See: Production Execution Client (page 26)

Phase
The smallest element of procedural control that can accomplish a process-oriented task is a phase. (...) Examples of phases include the following:

- Add VCM.
- Add catalyst.
- Heat.

[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

For example, in a pharmaceutical environment, "Identify" and "Read signature" would be phases of a "Prepare" operation.

See also: Dispense (page 7), Master recipe (page 19), Master workflow (page 19), Operation (page 22), Procedure (page 25), Unit procedure (page 33)

PMC
See: Production Management Client (page 26)

Potency
The therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).
[source: 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Department of Health and Human Services); FDA [3] (page 39)]

PRC
See: Production Response Client (page 26)

Primary packaging material
See: Packaging material (page 23)

Procedure
The procedure is the highest level in the (recipe) hierarchy and defines the strategy for carrying out a major processing action such as making a batch. It is defined in terms of an ordered set of unit procedures. An example of a procedure is "Make PVC".
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

For example, in a pharmaceutical environment, "Manufacture tablets" would be a procedure.

See also: Master recipe (page 19), Master workflow (page 19), Operation (page 22), Phase (page 24), Unit procedure (page 33)

Process Designer
Process Designer is the user interface of FactoryTalk ProductionCentre. It provides objects to model your process and build your application.

The Process Designer interface provides an environment for developing a custom application with minimal scripting by combining graphical user interface (GUI) functions, such as drag and drop and point and click, with built-in object selectors and text fields. The form and subroutine interfaces provide scripting and test tools that enable you to create, custom-script, and test your application.

Process input
The identification and quantity of a raw material or other resource required to make a product. (...) Process inputs consist of both the name of the resource and the amount required to make a specific quantity of finished product. Quantities may be specified as absolute values or as equations based upon other formula parameters or the batch or equipment size. Process inputs may specify allowable substitutions, expressed in the same basic form.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The

Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]
In the current version of PharmaSuite, materials are process inputs.

See also: Formula (page 13), Input material (page 16), Output material (page 22)

Process output
A process output is the identification and quantity of a material and/or energy expected to result from one execution of the recipe. This data may detail environmental impact and may also contain other information such as specification of the intended outputs in terms of quantity, labeling, and yield.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]
In the current version of PharmaSuite, materials are process outputs.

See also: Formula (page 13), Input material (page 16), Output material (page 22)

Process parameter
Information that is needed to manufacture a material but does not fall into the classification of process input or process output.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

See also: Building block (page 4), Formula (page 13), Parameter class (page 24)

Production Execution Client
The PharmaSuite framework for the shop-floor front-end used during the execution of a manufacturing process on the shop floor.

Production Management Client
The PharmaSuite framework for the front-end used by system administrators, recipe authors, workflow authors, managers, and supervisors to maintain master data and orders.

Production quantity
The final result of a processing, but without waste, scrap, and samples that have been removed from the overall produced quantity.

Production Response Client
The PharmaSuite framework for the front-end used by production managers or QC personnel to monitor and process production response-related data.

Purging
During the lifetime of an MES a large amount of orders, recipes, and equipment items is created. Purging of runtime data (e.g. order data) that is no longer used helps to offload the system and keep it responsive.

See also: Archiving (page 2)

Q

There is no term available.

R

R/S phrases
See: Risk and safety phrases (page 28)

Raw material
A raw material is defined as each substance used during the manufacturing of a drug that is not a packaging material.

See also: Material (page 19), Packaging material (page 23)

Recipe and Workflow Designer
Recipe and Workflow Designer is a graphical workbench for building and maintaining master recipes, master workflows, and their component building blocks. It is available in several modes: as Recipe Designer - Batch, Recipe Designer - Device, and Workflow Designer.

See also: Sequential function chart (page 30)

Recipe Designer, Recipe Designer - Batch, Recipe Designer - Device
See: Recipe and Workflow Designer (page 27)

Recipe element
A building block becomes a recipe element when it is used within a recipe. Saving element-specific properties and parameters does not affect the original building block that was used as a template.

See also: Building block (page 4), Building block element (page 4)

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

Resolution
A scale has a resolution for each scale range. It is the maximal level of uncertainty for the defined scale range. The uncertainty can be measured by performing the following tests: linearity, repeatability and eccentricity.

Retest date
The date after which samples of the drug substance should be examined to ensure that the material is still in compliance with the specification and thus suitable for use in the

manufacture of a given drug product.
[source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

Review by exception
See: Exception Dashboard (page 12)

Revision management
Revision management applies to custom building blocks and supports a recipe or workflow author in the creation and management of various revisions of a custom building block.
Multiple revisions of one custom building block can be in the **Approved** status at the same time.

See also: Custom building block (page 6)

Risk and safety phrases
Risk and safety phrases is a system of hazard codes and phrases for labeling dangerous chemicals and compounds.

Risk phrases specify hazards arising from dangerous properties of a material. Safety phrases give advice on necessary precautions that need to be taken during handling of the material, such as indicating the required protective gear.

See also: Material (page 19)

Room
See: Equipment (page 10)

Room cleaning
Room cleaning is a weighing support workflow for adjusting the cleaning status of a room equipment entity, such as a weighing booth, which has a room cleaning graph assigned to it and is thus under cleaning status control. The room status is set to its new value.

See also: Equipment (page 10)

S

S88

- ANSI/ISA-88.01-1995 Batch Control Part 1: Models and Terminology (Formerly ANSI/ISA-S88.01-1995).
  [reference: [8] (page 39)]
- ANSI/ISA-88.00.02-2001 Batch Control Part 2: Data Structures and Guidelines for Languages.
  [reference: [9] (page 39)]

- ANSI/ISA-88.00.03-2003, Batch Control Part 3: General and Site Recipe Models and Representation.
  [reference: [10] (page 39)]
- ANSI/ISA-88.00.04-2006 Batch Control Part 4: Batch Production Records.
  [reference: [11] (page 39)]

The standard defines reference models for batch control as used in the process industries and terminology that helps explain the relationships between those models and terms.

S95
ISA-95.00.01-2000 Enterprise-Control System Integration Part 1: Models and Terminology.
[reference: [12] (page 39)]

This standard defines the interface content between manufacturing control functions and other enterprise functions.
It describes the relevant functions in the enterprise and the control domain and which objects are normally exchanged between these domains. This includes how these objects can be exchanged in a robust, secure, and cost-effective manner preserving the integrity of the complete system.

Scale
See: Equipment (page 10)

Scale calibration
Scale calibration is a weighing support workflow for guiding an operator through the regular calibration activities on a scale equipment entity that is connected to a weighing work station. A scale calibration graph is assigned to the scale equipment entity. The workflow ensures that the scale functions correctly. The result of the scale calibration is documented in the workflow report.

See also: Equipment (page 10), Scale test (page 29)

Scale test
Scale test is a weighing support workflow for performing regular tests on a scale equipment entity that is connected to a weighing work station. A scale test graph and pre-defined test weights are assigned to the scale equipment entity. The workflow can run for one or more pre-defined test weights. In a pharmaceutical environment, a scale test is due typically once a day. The result of the scale test is documented in the workflow report.

See also: Equipment (page 10), Scale calibration (page 29)

Scrap
Loss of material during manufacturing that is immanent to the process, therefore process-specific. An analysis concerning scrap quantities might lead to an optimization of the process.

In PharmaSuite, relative and absolute scrap quantities are used as input parameters during order explosion and added to the planned quantity.
The relative scrap is used as a scrap factor, whereas the absolute scrap is used as a scrap offset.

Secondary packaging material
See: Packaging material (page 23)

Semi-finished good
Semi-finished goods are materials that are yet unfit for sale or shipment. They can either be produced internally or purchased externally and are usually utilized in further production phases for manufacturing other products - typically finished goods.

See also: Finished good (page 13), Material (page 19)

Sequential function chart
Sequential function chart (SFC) programming offers a graphical method of organizing the program. The three main components of an SFC are steps, actions, and transitions. Steps are merely chunks of logic, i.e., a unit of programming logic that accomplishes a particular control task. Actions are the individual aspects of that task. Transitions are the mechanisms used to move from one task to another. (..)
[source: Rockwell Automation [20] (page 39)]

In PharmaSuite, steps are represented as building blocks.

See also: Building block (page 4)

SFC
See: Sequential function chart (page 30)

Shop floor-defined order workflow
The shop floor-defined order workflow is designed to support shop floor-defined dispensing. It allows to create dispensing orders that are executed in the Production Execution Client for EBR.

A typical shop floor-defined order workflow comprises the following phase building blocks.

- The **Define order** phase (D Define Order) allows an operator to create an order based on a pre-defined master recipe.
- The **Edit BOM** phase (D Edit BOM) allows an operator to manage the BOM items of a shop floor-defined order.

- The **Dispatch order** phase (D Dispatch Order) allows an operator to dispatch the order to one or more work centers out of a pre-defined set of work centers in the master recipe. If no work center is assigned, the order can be processed at all work centers.
- The **Release order** phase (D Release Order) allows an operator to change the order's status to **Released** and thereby make it available for processing.

See also: Dispense (page 7)

SOP
See: Standard operating procedure (page 31)

Standard operating procedure
Written procedures (prescribing and describing the steps to be taken in normal and defined conditions) which are necessary to assure control of production and processes. [source: ISPE Glossary of Pharmaceutical Terms; ISPE [1] (page 39)]

Station
A station represents an operator's access point to execution activities with PharmaSuite at a work center. To actually perform execution activities, an operator uses a stationary or mobile device registered at the station. It is possible to register more than one device at a station. If a work center is of the **Dispense** type, only one device can be registered at a station at a time.
For processing, stations need to be assigned to operations.

See also: Operation (page 22), Unit (page 33), Work center (page 36)

Storage area
A storage area defines a physical area in a warehouse and is relevant to goods receipt and goods issue transactions. It occupies the middle level in the physical hierarchy of a PharmaSuite-controlled inventory.
Each storage area consists of a specified number of storage locations. This number depends on the warehouse type (e.g. high-rack warehouse).

See also: Storage location (page 31), Warehouse (page 34)

Storage location
A storage location is identified by topological data, which defines the exact spatial position of the storage location in the warehouse. It occupies the lowest level of the physical hierarchy in a PharmaSuite-controlled inventory.

See also: Storage area (page 31), Warehouse (page 34)

Sublot
A sublot is the smallest material unit in a PharmaSuite-controlled warehouse. It can assume various statuses, such as **Blocked**, **Released**, or **Quarantined**, which are

inherited from the batch to which the sublot belongs. It can be necessary to update the quantity of a sublot. One reason for a quantity update, for example, can be that material was lost during transport or was damaged.

See also: Batch (page 3), Material (page 19), Sublot split (page 32)

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

See also: Sublot (page 31)

System building block
See: Building block (page 4)

T

Tolerance
During execution, the tolerance defines the permitted difference between an actual, measured value and the required value as defined in the specification.

TOM server
See: Triggered Operation Management server (page 33)

Transaction history
Transaction history stores data on any events that result in modifying the properties of batches, sublots, and devices in their life cycles. It helps to trace material-related activities on the batch and sublot level, such as the batch creation, change of potency, change of batch status, generation and consumption of sublots, goods issue, etc.
In PharmaSuite, all inventory transactions are recorded in the transaction history.

See also: Batch (page 3), Device (page 7), Sublot (page 31)

Transition
A transition consists of a condition that defines which step is the next to be executed when there is more than one potential successor step. Thus a transition predetermines which step to choose in a selection branch during execution or whether a loop needs to be executed.

See also: Editor (page 8), Sequential function chart (page 30)

Triggered Operation Management server
A PharmaSuite server component that communicates with the OE server and manages the states of ETOs.

See also: Event-triggered operation (page 12), Operation Execution server (page 22)

U

Unit
A collection of associated control modules and/or equipment modules and other process equipment in which one or more major processing activities can be conducted.
[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

For example, in a pharmaceutical environment, a unit represents equipment on the unit procedure level (e.g. mixer, granulator). Units are stationary or mobile.

See also: Station (page 31)

Unit procedure
According to S88, a unit procedure consists of an ordered set of operations that causes a contiguous production sequence to take place within a unit. Only one operation is presumed to be active in a unit at any time. An operation is carried to completion in a single unit. However, multiple unit procedures of one procedure may run concurrently, each in different units.
However, PharmaSuite allows modeling and execution of parallel operations in compliance with general SFC rules.

Examples of unit procedures include the following:

- Polymerize VCM
- Recover residual VCM
- Dry PVC

[source: ANSI/ISA-88.01-1995; Batch Control Part 1: Models and Terminology; ISA The Instrumentation, Systems, and Automation Society; ISBN: 1-55617-562-0 [8] (page 39)]

For example, in a pharmaceutical environment, "Tableting" would be a unit procedure of the "Manufacture tablets" procedure.

See also: Master recipe (page 19), Master workflow (page 19), Phase (page 24), Procedure (page 25), Operation (page 22), Sequential function chart (page 30)

V

Version control
Version control provides a frame for the life cycle of a data object and helps achieving compliance. Its design enables the modeling of individual operational processes and conventions.

The statuses and status changes of the version-controlled data object (master recipes) also involve version management. The execution of status changes can be linked to user rights, which are automatically checked by the system. A change of the version number can also be caused by status changes.
Additionally, the system checks each status change for compliance with defined consistency conditions. All changes are logged in the status history so that the entire life cycle of a data object including the operators involved in their changes can be traced.

W

Warehouse
A warehouse is a physical location, in which materials and goods used in the production process are stored and managed. It is the highest level in the inventory structure.

See also: Storage area (page 31), Storage location (page 31)

Weighing method
Weighing methods provide pre-defined steps for common Dispense, Inline Weighing, Output Weighing, and weighing support scenarios:

- In **Net weighing**, first the tare weight of the target container (or charging vessel for Inline Weighing) is weighed. Then, for Dispense and Inline Weighing, the input material is filled into the target container and weighed. For Output Weighing, the produced material is filled into the target vessel and weighed.
  This weighing method is not supported for all operation modes of the **Get weight** (weighing support) phase.
- In **Net removal weighing**, first the source container is placed on the scale. Then, material is removed to the target container (or charging vessel for Inline Weighing) and the remaining material in the source container is weighed. Since material was removed, the weight is displayed as a negative value.
  This weighing method is not supported for Output Weighing.
  This weighing method is not supported for all operation modes of the **Get weight** (weighing support) phase.
- In **Gross weighing**, first the filled source vessel is placed on the scale. Then, the tare of the source vessel is entered manually and the source vessel is weighed.
  This weighing method is not supported for Output Weighing.
  This weighing method is not supported for all operation modes of the **Get weight** (weighing support) phase.

- In **Gross removal weighing**, first the source container is placed on the scale. Then, the tare of the source container is entered manually, material is removed to another container, and the remaining material in the source container is weighed.
  This weighing method is not supported for Output Weighing.
  This weighing method is not supported for all operation modes of the **Get weight** (weighing support) phase.
- In **Pallet weighing**, first the loaded pallet is placed on the scale. Then, the tare of the pallet and of one of the vessels it holds are entered manually, along with the number of vessels. Finally, the loaded pallet is weighed.
  This weighing method is not supported for Inline Weighing.
  This weighing method is not supported for Output Weighing.
  This weighing method is not supported for the **Get weight** (weighing support) phase.
- In **Only identification**, no weighing takes place at all. Sublots that hold a pre-defined material quantity are identified and their known weight is recorded.
  This weighing method is not supported for Output Weighing.
  This weighing method is not supported for the **Get weight** (weighing support) phase.
- In **Quantity entry**, no physical scale is used at all. The quantity provided by external means has to be entered manually.
  The **Tare** and **Release scale** phases are skipped in this weighing method.
  This weighing method is not supported for all operation modes of the **Get weight** (weighing support) phase.

See also: Dispense (page 7), Inline Weighing (page 16), Output Weighing (page 23), Weighing support (page 35)

Weighing support

Dispense and weighing processes require the use of specific equipment, primarily scales and weighing rooms to support their full functional scope. To make sure the equipment involved in the process is qualified and suitable for use, there are weighing support workflows required to test and calibrate scales and to clean weighing rooms.

An operation of a weighing support workflow comprises the following phase building block and the transitions between the phase building block and other PharmaSuite phase building blocks.

- The **Get weight** phase allows an operator to record an actual weight. It supports multiple use cases: recording of an actual weight (**Get gross weight** operation mode) or weighing material against a planned quantity and within pre-defined limits (**Get net weight** operation mode). The phase covers the three weighing-related features zeroing, taring, and weighing.

The behavior of the phases can be affected by exceptions and the applied weighing method.

See also: Dispense (page 7), Inline Weighing (page 16), Output Weighing (page 23), Room cleaning (page 28), Scale calibration (page 29), Scale test (page 29), Weighing without order (page 36), Weighing method (page 34)

Weighing without order
Weighing without order is a weighing support workflow for simple weighing of any item that is not related to an order, cost center, or specific material. Simple weighing can, for example, be used for inventory checks to verify the weight of inventoried sublots.

Work center
A work center can be characterized as a suitably equipped location or area within the operational system where personnel utilizes machines, tools, and devices. A work center can comprise one or more stations. If a work center is of the **Dispense** type, only one station can be assigned.
For processing, work centers need to be assigned to unit procedures.

See also: Station (page 31), Unit procedure (page 33)

Workflow
A workflow is typically intended for multiple executions and has a non-production purpose such as cleaning.

See also: Master workflow (page 19)

Workflow Designer
See: Recipe and Workflow Designer (page 27)

Workflow element
A building block becomes a workflow element when it is used within a workflow. Saving element-specific properties and parameters does not affect the original building block that was used as a template.

See also: Building block (page 4), Building block element (page 4)

Workflow record
A workflow record contains all information related to the execution of a specific workflow (e.g. master workflow, execution dates).

Workflow report
See: Workflow record (page 36)

Workflow step
Workflow steps are generated during workflow explosion. They represent the activities that will be processed at the specified work centers.

See also: Master workflow (page 19), Workflow (page 36)

X

There is no term available.

Y

There is no term available.

Z

There is no term available.

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