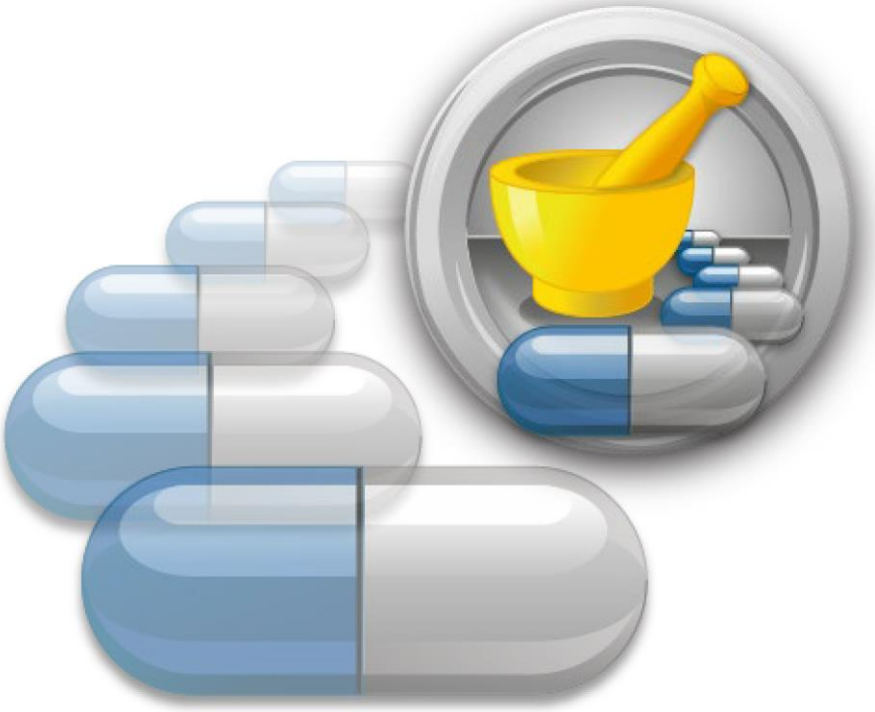
PharmaSuite®



NON-FUNCTIONAL REQUIREMENTS

RELEASE 10.02.00

FUNCTIONAL REQUIREMENT SPECIFICATION

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Chapter 1

Introduction

This document details the non-functional requirements of PharmaSuite.

Each requirement is composed of a name and a unique identifier (e.g., Performance of Master Recipe Import 1 (SR1095.10.4.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g., Master Recipe - Performance (SR1095.10.4+)).

In some cases, additional context information is available, indicated in the document by a frame and a gray background color. This context information is related to the respective requirement, but not part of the formal requirement description.

The revision history (page 49) lists the changes made to the document with PharmaSuite 10.01.00 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g., status).

Chapter 2

Performance Requirements (SR1095.10+)

The detailed list of the PharmaSuite performance requirements is structured in the following sections:

For performance requirements of phase building blocks, please refer to

- **Show historical data chart** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (page 47).
- **Set OPC values** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (page 47).
- **Get OPC values** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (page 47).

Master Recipe - Performance (SR1095.10.4+)

For details about recipe management, see "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 47).

Reference scenario 1

The reference recipe holds a total of:

- 3 unit procedures,
- 5 operations,
- 20 phases, and

- 100 process parameters.

Boundary scenario 1

The boundary recipe holds a total of:

- up to 30 unit procedures,
- up to 35 operations,
- up to 3,000 phases, and
- up to 12,000 process parameters.

Its procedural structure includes various branches and loops.

Performance of Master Recipe Import 1 (SR1095.10.4.1)

Based on the Boundary scenario 1 (page 4), the import of the boundary recipe does not take longer than 10 minutes.

Performance of Master Recipe Export 1 (SR1095.10.4.2)

Based on the Boundary scenario 1 (page 4), the export of the boundary recipe does not take longer than 10 minutes.

Performance of Master Recipe Saving 1 (SR1095.10.4.3)

Based on the Boundary scenario 1 (page 4), saving the boundary recipe does not take longer than 10 seconds.

Performance of Prepare for Status Change 1 (SR1095.10.4.6)

Based on the Boundary scenario 1 (page 4), the preparation of a status transition from **Draft** to **Verification** of a master recipe or master workflow does not take longer than 20 seconds.

Performance of Master Recipe Report 1 (SR1095.10.4.5)

Based on the Reference scenario 1 (page 3), the response time for printing the Master Recipe Report of the reference recipe in the **Verification** status (time between "trigger the print function" and "display of the preview") does not take longer than 1 minute.

Performance of Order Explosion 1 (SR1095.10.4.4)

Based on the Boundary scenario 1 (page 4), the order explosion of a boundary recipe-related order does not take longer than 1 minute.

Change Request - Performance (SR1095.10.1+)

For details about change requests, see "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 47).

Reference scenario 1

For the performance test of the change request, the scope of the reference scenario is defined by replacing a **ShowSOP** custom phase within a total of 100 affected reference recipes.
The reference recipe is built with a total of 10 unit procedures, 22 operations, and 192 phases.

The recipe structure is as follows:

- 4 parallel Dispense unit procedures
  - Each with 1 Dispense operation
    - Each with 9 phases
    - Incl. 1 phase based on the **ShowSOP** custom phase
- 6 subsequent processing unit procedures
  - Each with 3 subsequent operations
    - 2 operations
      Each with 3 subsequent phases
      Incl. 1 phase based on the **ShowSOP** custom phase
    - 1 operation
      20 subsequent phases
      Incl. 4 phases based on the **ShowSOP** custom phase

Each procedure, unit procedure, and operation of the master recipe is built based on a custom building block in the **Approved** status. In total, 2 custom unit procedures, 4 custom operations, and 14 custom phases are used.

Boundary scenario 1

For the boundary test of the change request, the scope of the boundary scenario is defined by replacing a **ShowSOP** custom phase within a total of 1000 affected reference recipes.

Performance of Change Request Execution 1 (SR1095.10.1.1)

Based on the Reference scenario 1 (page 5), the execution of the change request does not take longer than 40 minutes.

Performance of Change Request Execution 2 (SR1095.10.1.2)

Based on the Boundary scenario 1 (page 5), the execution of the change request is completed without any system errors.

Performance of Usage List Creation 1 (SR1095.10.1.3)

Based on the Boundary scenario 1 (page 5), the initial creation of the usage list within the change request is completed within 80 seconds.

The expected response time is based on the following assumptions:

- All recipes that already existed in the database before the reference scenario was created (100 new recipes), are already indexed.
- Along with the creation of the usage list, new indexes are created only for the new recipes of the reference scenario.

Equipment - Performance (SR1095.10.2+)

For details about equipment management, see "Functional Requirement Specification Data Management" [A2] (page 47).

Reference scenario 1

For the performance test of the equipment management functionality, a reference equipment model is considered with a total of 230 classes, 5,000 entities, and 4,225 property types.

The model is structured as follows:

- Units, each with 67 properties
- Filters, hoses, instruments, each with 15 properties
- Number of class-entity-assignments and used property types (assumption: re-usage of property types between same type of classes of 50 %):
  - 100 unit classes, each with 10 entities
    - Based on 3,250 property types
  - 10 filter classes, each with 100 entities
    - Based on 75 property types
  - 20 hose classes, each with 50 entities
    - Based on 150 property types
  - 100 instrument classes, each with 20 entities
    - Based on 750 property types

Boundary scenario 1

For the boundary test of the equipment management functionality, the reference scenario is scaled up completely by a factor of 10, which means 2,300 classes, 50,000 entities, 42,250 property types.

Update scenario 1

Based on Reference scenario 1 (page 6), an update rate per day of 1 % is assumed, which means that, e.g. 50 entities are updated per day with 1 runtime property being updated per entity.
This results in:

- 18,250 change history entries per year,
- 36,500 change history entries after 2 years, and
- an average of 7-8 update-related change history entries per entity after 2 years.

Update scenario 2

Based on Reference scenario 1 (page 6), an update rate per day of 10 % is assumed, which means that, e.g. 100 entities are updated per day with 5 runtime properties being updated per entity.
This results in:

- 182,500 equipment logbook entries per year,
- 365,000 equipment logbook entries after 2 years, and
- an average of 73 update-related equipment logbook entries per entity after 2 years.

Performance of Unit Class Export 1 (SR1095.10.2.1)

Based on Reference scenario 1 (page 6), the export of 1 unit class does not take longer than 5 seconds.

Performance of Unit Class Import 1 (SR1095.10.2.2)

Based on Reference scenario 1 (page 6), the import of 1 unit class does not take longer than 5 seconds for an initial import.

Performance of Filter Class Export 1 (SR1095.10.2.5)

Based on Reference scenario 1 (page 6), the export of 1 filter class does not take longer than 15 seconds.

Performance of Filter Class Import 1 (SR1095.10.2.6)

Based on Reference scenario 1 (page 6), the import of 1 filter class does not take longer than 15 seconds for an initial import.

Recipe Execution - Performance (SR1095.10.7+)

For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (page 47).

Reference scenario 1

The reference recipe holds a total of:

- 1 Dispense unit procedure,
- 1 Dispense operation
- All Dispense-related phases (D Identify material, D Select scale, D Tare, D Weigh, D Release scale, D Print report)
- 10 materials to be dispensed

Boundary scenario 1

The boundary recipe holds a total of:

- up to 30 unit procedures,
- up to 35 operations,
- up to 3,000 phases, and
- up to 12,000 process parameters.

Its procedural structure includes various branches and loops.

Performance of Recipe Execution 1 (SR1095.10.7.1)

Based on the Boundary scenario 1 (page 8) and phase completion through automated test, the related control recipe is executable within 60 minutes.

Printing of Barcode Label and Dispensing Report - Performance

For details about the barcode labels, see "Functional Requirement Specification Runtime Data Management" [A7] (page 47), "Functional Requirement Specification Dispense and Inline Weighing" [A8] (page 47), and "Functional Requirement Specification Output Weighing" [A9] (page 47).

For details about the dispensing report, see "Functional Requirement Specification Dispense and Inline Weighing" [A8] (page 47).

Performance of Printing (SR1090.4.6)

Printing a barcode label does not take longer than 3 seconds (on average) and less than 5 sec (in 80% of the cases).

A reference Dispensing report contains of four pages and the reference printer prints at least 15 pages per minute.
Based on the reference report, printing the Dispensing report does not take longer than 30 seconds (in the average) and less than 60 seconds (in 80% of the cases).

EBR Server - Performance (SR1095.10.3+)

For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (page 47).

Reference scenario 1

For the performance test of the EBR server, the reference scenario is as follows:

- Size of recipe:
  - 4 unit procedures (2 parallel)
  - Each with 4 operations (2 parallel)
- Order explosion and order execution take place in parallel
- 50 Production Execution Clients
- 500 orders (10 sequential orders per client)

The focus of the performance test is on the behavior of the EBR server. Therefore, the execution of operations is performed as a virtual execution on a virtual client, which results in a zero second response time from a client.

Performance of Order Processing 1 (SR1095.10.3.1)

Based on Reference scenario 1 (page 9), the EBR server is capable to process 500 orders in less than 50 minutes (10 orders or 160 operations per minute).

TOM Server - Performance (SR1095.10.5+)

For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (page 47).

Reference scenario 1

For the performance test of the TOM server, the reference scenario is as follows:

- Test case includes:
  - 3 times start and removal of ETO templates
  - 10 times start and completion of ETO runs
  - 10 times escalation and expiration of ETO runs
- Scale-up consists of:
  - 50 Production Execution Clients running in parallel, all connected to the same TOM server
  - 10 consecutive runs of the test case on each client

The reference scenario results in a total of

- 1,500 ETO templates,
- 5,000 completed ETO runs, and
- 5,000 expired ETO runs,

that are managed by the TOM server.

The focus of the performance test is on the behavior of the TOM server. Therefore, the execution of operations is performed as a virtual execution on a virtual client, which results in a zero second response time from a client.

Performance of ETO Processing 1 (SR1095.10.5.1)

Based on Reference scenario 1 (page 10), the TOM server is capable to process ETO templates and runs in less than 30 minutes (50 templates per minute, 330 completed and expired runs per minute).

Exception Dashboard - Performance (SR1095.10.8+)

For details about the Exception Dashboard, see "Functional Requirement Specification Review and Approval" [A4] (page 47).

Reference scenario 1

The reference recipe holds a total of:

- 3 unit procedures,
- 5 operations,
- 20 phases, and
- 100 process parameters.

Performance of Review by Exception 1 (SR1095.10.8.1)

Based on the Reference scenario 1 (page 11) and a finished order, opening a unit procedure with 50 exceptions within the Details panel does not take longer than 50 seconds.

Performance of Batch Report Printing 1 (SR1095.10.8.2)

Based on the Reference scenario 1 (page 11), the response time for printing the Batch Report of a finished order (time between "trigger the print function" and "display of the preview") does not take longer than 1 minute.

Chapter 3

Scalability Requirements (SR1095.30+)

EBR Server - Scalability (SR1095.30.1)

The system shall provide the ability to distribute the workload to one or several EBR Servers.

Chapter 4

Compliance Requirements (SR1095.50+)

The detailed list of the PharmaSuite compliance requirements is structured in the following sections:

- **Audit Trail (SR1095.50.1)** requirements (page 15)
- **Electronic Signatures (SR1095.50.2)** requirements (page 16)
- **Access Control (SR1095.50.3)** requirements (page 19)

Audit Trail (SR1095.50.1)

The system shall provide functionality for audit trail.

The following data shall be included as part of any human-readable form of an audit trail record:

- Transaction type (insert, update, delete).
- Timestamp.
- Logged-in user (login name, first and last name).
- Link to electronic signature(s), if applicable
- Transaction type-specific data (shall be defined for each transaction type)

Audit trail data is available for:

- Users, **Audit Trail (SR1095.50.3.2.1)** requirement (page 21)
- User groups, **Audit Trail (SR1095.50.3.3.1)** requirement (page 23)
- Access privileges, **Audit Trail (SR1095.50.3.4.1)** requirement (page 24)
- Lists, **Audit Trail (SR1095.9.1.1)** requirement (page 27)
- Applications, **Audit Trail (SR1095.9.2.1)** requirement (page 28)
- Materials, **Audit Trail (SR3146.1.1.5)** requirement in "Functional Requirement Specification Data Management" [A2] (page 47)

Electronic Signatures (SR1095.50.2)

The system shall support electronic signatures.
For electronics signature in the context of EBR and the Production Execution Client, see **Signatures for Exceptions and Comments (SR1079.2.1)** and **Signature for Phase Completion (SR1089.4+)** in "Functional Requirement Specification Execution Framework" [A3] (page 47).

Single and Double Electronic Signatures (SR1095.50.2.1)

The system shall support single and double electronic signatures. Double electronic signatures support the witness role.
When an electronic signature is required, the system shall request the user to authenticate with his user name and password. In case of a double electronic signature, two consecutive electronic signatures are required from two different users.

Whether a single or a double electronic signature is required shall be defined in the system configuration or during recipe or workflow definition.

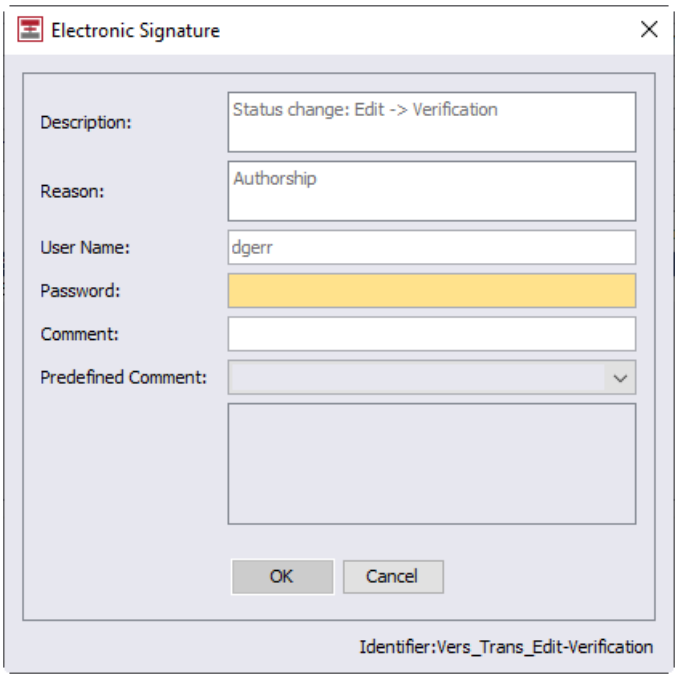

Figure 1: Example of a single electronic signature with pre-defined comment

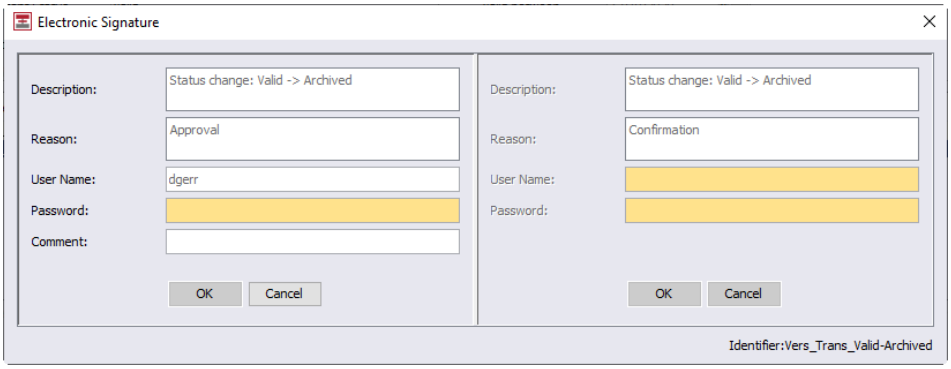

Figure 2: Example of a double electronic signature to support witness role

For electronic signatures, the authentication requires the login name and password of a user as used for system login.

COMMENTS (SR1095.50.2.1.1)

The system shall allow to enter a comment along with an electronic signature and to extend a comment by a pre-defined text.
This does not apply to phase completion signatures during execution in the Production Execution Client.

Whether a comment is mandatory, optional, or not supported shall be defined in the system configuration or during recipe or workflow definition.
Whether a comment is extendable by a pre-defined text shall be defined in the signature definition.

For signature comments of signatures that automatically trigger the creation of an exception, the system shall add a signature-related comment as an exception-related comment to the exception. The exception-related comment of a single (or first) signature is prepended with "Signature comment: ", the exception-related comment of the second signature of a double signature is prepended with "2nd signature comment: ".

LINKAGE TO ELECTRONIC RECORD (SR1095.50.2.1.2)

The system shall ensure that the linkage of an executed electronic signature to the electronic records for which the signature was given is unambiguous and incorruptible.

Configuring Electronic Signatures (SR1095.50.2.2)

The system shall allow the system administrator and system integrator to configure the following parameters of an electronic signature:

- Signature type (single, double)
- Meaning of the signature (description)
- Required user role of the user who signs (reason)

- Comment (no comment, optional, mandatory)
  This does not apply to phase building blocks that are executed in the Production Execution Client.
- Pre-defined comment list
  Definition of the list of pre-defined texts to be appended to the comment when an electronic signature is given.
  By default, no list is defined.
  This does not apply to phase building blocks that are executed in the Production Execution Client.
- Entitled user group
- Signature level (disabled, implicit w/o warning, explicit, warning w/ implicit, error (= no way to proceed))
  This does not apply to phase building blocks that are executed in the Production Execution Client.
  - With the **implicit w/o warning** level, the system supports silent electronic signatures.
    If configured, instead of requesting an electronic signature, the system shall record the logged-in user automatically.

Performing Electronic Signatures (SR1095.50.2.3)

When the system requests an electronic signature it shall unambiguously provide the signer with the following information:

- Meaning of the signature
- Required user role (e.g. Confirmation, Approval)
- Scope of the signature
- Comment (as defined for the signature):
  1. no comment
  2. optional comment
  3. mandatory comment
- Pre-defined comment
  The signature dialog allows to select a pre-defined text from the list configured for the signature (only if a list has been defined).
  - If a list has been defined, the selection of a text is mandatory.
  - If a list contains only one entry, this entry is pre-selected.
- In case the user is the second signer of a double signature, the data entered by the first signer must be visible for the second signer.

Data of an Electronic Signature (SR1095.50.2.4)

The system shall add the following data of a given electronic signature (single or double) to any human-readable form of the affected electronic record (e.g. printout, electronic display):

- Meaning of the signature
- Role of the user who signed
- Scope of the signature as seen by the signer (context data related to the signature)
- Signer, timestamp, and comment (if mandatory or provided by the user)

Access Control (SR1095.50.3)

The system shall provide functionality for access control.

For access control requirements of specific system parts (e.g. access rights for editing or viewing data in Data Manager), please refer to

- "Functional Requirement Specification Execution Framework" [A3] (page 47)
- "Functional Requirement Specification Runtime Data Management" [A7] (page 47)
- "Functional Requirement Specification Review and Approval" [A4] (page 47)
- "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 47)
- "Functional Requirement Specification Data Management" [A2] (page 47)

Authentication for System Login and Electronic Signature (SR1095.50.3.1)

The system shall ensure that only users with sufficient privileges have access to the system and are allowed to perform an electronic signature.

Verification During Authentication (SR1095.50.3.1.1)

The system shall perform the following verification checks:

- Login name belongs to a valid user account.
- Password is correct.
- Password has not expired.
- User account is activated.
- Maximum number of invalid authentication attempts is not exceeded.
- User has sufficient access privileges to access the application or perform the electronic signature.

Invalid Authentication Attempt (SR1095.50.3.1.2)

In case of an invalid authentication attempt, the system shall display system messages to the user that do not give any hints to a possible intruder.

Logging Unsuccessful Authentication Attempts (SR1095.50.3.1.3)

The system shall log unsuccessful authentication (login and electronic signature) attempts.
It shall be possible to notify a dedicated responsible person (or persons) of the event. The configurable notification shall include the following information:

- Used login name (identification code).
- Change of user account status (when the number of invalid login attempts is reached).
- Description of unsuccessful authentication.
  Example: Attempt to authenticate with a locked account.

The used medium for notifications shall be e-mail.

Number of Invalid Authentication Attempts Exceeded (SR1095.50.3.1.4)

In case the number of invalid authentication attempts of a user account is exceeded, any further authentication request shall be blocked by the system. The user must contact the system administrator to reset the number of invalid authentication attempts.

Multiple Logins per User (SR1095.50.3.1.5)

The system shall allow that one user is logged in in more than one session at the same moment.

Viewing System Access History (SR1095.50.3.1.6)

The system shall track system access of users.
It allows a user to view the users with the login (successful, invalid) and logout information. The information includes (but is not limited to) the following properties:

- Timestamp
- Login name
- Transaction type (login, logout, failed login)
- Database name

Management of Users (SR1095.50.3.2)

The system allows the system administrator to define and manage users and their access privileges. This includes the assignment of a user-specific start form.

Separation of Access Privileges for Creating and Editing Users (SR1095.50.3.2.11)

The system shall provide separate access privileges for creating and editing users.

The access privileges are only available in PS Administration.

Audit Trail (SR1095.50.3.2.1)

The system allows a user to view audit trail data recorded for users.

Default User Account Settings (SR1095.50.3.2.2)

The system shall allow the system administrator to define default settings for user accounts:

- Maximum number of invalid authentication attempts: [No limit, 1..10]
  Default: No limit.
- Password strength:
  - Minimum length: [No limit, 1..10]
    Default: No limit.
  - Minimum number of lowercase characters: [0..10]
    Default: 0
  - Minimum number of uppercase characters: [0..10]
    Default: 0
  - Minimum number of numeric characters: [0..10]
    Default: 0
  - Minimum number of special characters: [0..10]
    Default: 0

The system shall use the following setting if the password is changed:

- Minimum number of previous passwords before reuse: 3
- Maximum length of new password: 32

The system shall use the following setting for password expiration notifications:

- Notification of password expiration at login: 7 days

The system shall use the following default settings if a new user account is created:

- Validity timeframe for user accounts: December 31, 9999
- Expiration for passwords: December 31, 9999

MANDATORY ATTRIBUTES (SR1095.50.3.2.12)

The system shall force the system administrator to define a login name (user name), first name, last name, and password when creating a user account.

First and last name are only mandatory in PS Administration.

UNIQUE LOGIN NAME (SR1095.50.3.2.3)

The system shall force the system administrator to define a unique login name when creating a user account.

With a unique login name (identification code), the combination of it and a password is always unique.

IMMUTABLE LOGIN NAME (SR1095.50.3.2.4)

The system shall prevent that a login name of a user account can be changed after the account has been created.

VALIDITY TIMEFRAME (USER ACCOUNT) (SR1095.50.3.2.5)

The system shall allow the system administrator to define the date when a user account becomes invalid.
The system shall use default values for the end date of the validity timeframe as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

ACTIVITY STATUS (USER ACCOUNT) (SR1095.50.3.2.6)

The system shall allow the system administrator to activate and deactivate a user account.

NUMBER OF INVALID AUTHENTICATION ATTEMPTS (SR1095.50.3.2.7)

The system shall allow the system administrator to define how many false authentication attempts are allowed for user accounts before they are locked.
The system shall use default values for the maximum number of invalid authentication attempts as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

PASSWORD STRENGTH (SR1095.50.3.2.8)

The system shall allow the system administrator to define the required password strength.
The system shall use the default values as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

Expiry Date (Password) (SR1095.50.3.2.9)

The system shall allow the system administrator to define an expiry date for the password of a user account.
The system shall use the rules for generating the password expiry date as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

Import/Export of Users (SR1095.50.3.2.13)

The system shall provide the capability to transfer users between systems. For this purpose, it is possible to export and import users.

Assigning User Groups to Users (SR1095.50.3.2.10)

The system shall allow the system administrator to assign a user to one or multiple user groups and to revoke the assignment.
The system shall not limit the number of user groups to which a user can be assigned.
A user shall inherit the access privileges of the user group to which the user is assigned.

Management of User Groups (SR1095.50.3.3)

The system allows the system administrator to define and manage user groups and their access privileges, This includes the assignment of users to a user group.

Separation of Access Privileges for Creating and Editing User Groups (SR1095.50.3.3.2)

The system shall provide separate access privileges for creating and editing user groups.

The access privileges are only available in PS Administration.

Audit Trail (SR1095.50.3.3.1)

The system allows a user to view audit trail data recorded for user groups.

Import/Export of User Groups (SR1095.50.3.3.3)

The system shall provide the capability to transfer user groups between systems. For this purpose, it is possible to export and import user groups.

Separation of User and Functional System Administration (SR1095.50.3.7)

The system allows the separation of the user and user group administration from the functional system administration (configuring access privileges and their assignment to user groups, configuring lists and applications). This is a configurable option per system installation.

Management of Access Privileges (SR1095.50.3.4)

The system allows the system administrator to define and manage access privileges (access rights and electronic signatures including their signature definition). This includes the assignment of privileges to user groups.

Separation of Access Privileges for Creating and Editing Access Privileges (SR1095.50.3.4.6)

The system shall provide separate access privileges for creating and editing access privileges.

The access privileges are only available in PS Administration.

Audit Trail (SR1095.50.3.4.1)

The system allows a user to view audit trail data recorded for access privileges.

Access Privileges for Pre-defined Set of Functions (SR1095.50.3.4.2)

The system shall provide access privileges for a set of pre-defined functions.
This set of functions shall be extendable by a system integrator.

Pre-defined Roles and Profiles (SR1095.50.3.4.3)

The system shall provide a set of pre-defined roles, mapped to user groups, with pre-defined access privileges according their assigned profiles.
This set of user groups and access privileges shall be changeable and extendable by a system integrator.

Import/Export of Access Privileges (SR1095.50.3.4.7)

The system shall provide the capability to transfer access privileges between systems. For this purpose, it is possible to export and import access privileges.

Viewing Access Privileges of Users or User Groups (SR1095.50.3.4.4)

The system allows a user to view the access privileges of a user or user group at any defined moment.

This moment can be in the past until the present time.

Viewing Users or User Groups of Access Privileges (SR1095.50.3.4.5)

The system allows a user to view the users or user groups of an access privilege at any defined moment.

This moment can be in the past until the present time.

Password Security (SR1095.50.3.5)

The system shall ensure confidentiality of passwords that are managed in the system. Only the related person shall know his personal password.

An exception is the initial password.

Password Encryption (SR1095.50.3.5.1)

The system shall fulfill the following items related to password encryption:

- Passwords are always stored encrypted.
- The system must not provide a function to decrypt an encrypted password. The encryption is a one-way encryption.
- The system encrypts passwords that need to be sent over a network that can be accessed by other users.

Password Must Not Be Displayed (SR1095.50.3.5.2)

The system shall never display a password in plain text on any kind of user interface including printouts.

Password Change (SR1095.50.3.6)

The system shall support that the password can be changed.

Password Change - User-initiated (SR1095.50.3.6.1)

The system shall provide functionality for the user to change his password. The system requests the user to enter his old password and the new password twice. The new password shall fulfill the password requirements as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

Password Change - After Login (SR1095.50.3.6.2)

The system shall allow a user to change the password directly after a successful login. This is important in case the password is going to expire within the next n days and the user needs to have the system available immediately.

PASSWORD CHANGE – SYSTEM-FORCED (SR1095.50.3.6.3)

In case the password has expired, the system shall force the user to change his password at login. There shall be no possibility to access the system without changing the expired password.
The system requests the user to enter his old password and the new password twice. The new password shall fulfill the password requirements as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (page 21).

Chapter 5

Functional System Administration (SR1095.9+)

The functional system administration includes:

Management of Lists (SR1095.9.1)

The system allows the system administrator to define and manage lists.

Audit Trail (SR1095.9.1.1)

The system allows a user to view audit trail data recorded for lists.

Pre-defined Lists (SR1095.9.1.2)

The system shall provide pre-defined lists to be used in, for example, application objects. This set of lists shall be extendable by a system integrator.

Import/Export of Lists (SR1095.9.1.3)

The system shall provide the capability to transfer lists between systems. For this purpose, it is possible to export and import lists.

Duplicate List Elements (SR1095.9.1.4)

The system shall provide a configuration option to define whether duplicate elements are allowed in a list or not.

List Element Types (SR1095.9.1.5)

The system supports the following list element types:

- string,
- report design.

Sorting of List Elements (SR1095.9.1.6)

The system allows to sort list elements in ascending or descending order.

Management of Applications (SR1095.9.2)

The system allows the system administrator to define and manage application objects. This includes the assignment of users, user groups, and stations.

The system supports the assignment of **String**, **Long**, **Decimal**, **Boolean**, and **Object** property types to an application object.

An application object consists of configuration keys with a non-system default setting per site, user, user group, or station.

Separation of Access Privileges for Creating and Editing Application Objects (SR1095.9.2.4)

The system shall provide separate access privileges for creating and editing application objects.

The access privileges are only available in PS Administration.

Audit Trail (SR1095.9.2.1)

The system allows a user to view audit trail data recorded for application objects.

Import/Export of Application Objects (SR1095.9.2.2)

The system shall provide the capability to transfer application objects between systems. For this purpose, it is possible to export and import the application objects.

Inheritance of an Application Object as Default (SR1095.9.2.3)

Application objects shall be able to reference other application objects.

In this case, the settings of the referenced application object are inherited as default settings. Thus, only additional configuration keys or changed configuration keys must be maintained, thereby minimizing the configuration effort.

Chapter 6

Internationalization and Localization (SR1095.1+)

PharmaSuite is marketed globally. This requires the software to support internationalization (I18N) and localization (L10N).

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.

Localization (L10N) is a process of adapting a product or service to a particular language, culture, and desired local "look-and-feel".

The requirements specific to internationalization and localization are structured in the following sections:

- **Skills for Localization (SR1095.1.1)** requirements (page 29)
- **Locale-related** requirements (page 30)

Skills for Localization (SR1095.1.1)

The system shall be localizable into a specific language or terminology by a system integrator.

It shall be possible that a person used to work with office software without knowledge of the system or specific IT knowledge is able to modify choice lists contents and text labels of the user interface and reports. It shall be possible for a system integrator to export this information from the system. The result of the modification must be in a format that it can be integrated to the system by a system integrator.

Tool Support (SR1095.2.4)

The system shall provide tools that allow a system integrator to localize the user interface, reports, barcode labels, system messages, etc. for a particular language or terminology.

Internationalized Output Media (SR1095.2)

The system shall provide internationalization for those parts of the system that are presented to common users of the system, so that it is possible to localize them into a particular language or terminology. The user roles do not include system integrators, project engineers, etc.

The internationalized parts include the user interface, online help, reports, barcode labels, system messages, installation software, and user manuals. Internationalization is not limited to text but also includes data formats like date, time, and number formats.

Locale-related Requirements

A locale defines the regional settings with specific parameters. For example language of the user interface, keyboard layout, number format, date and time format, paper size.

Supported Locales (SR1095.1.2)

The system shall support localization into the following locales (sequence not related to priority):

- English (United States) - Default
- German (Germany)
- Spanish (Spain-Modern Sort)
- Italian (Italy)
- French (France)
- Chinese (PRC)
- Korean
- Japanese
- Russian (Russia)
- Hebrew
- Hindi

Provided Locales (SR1095.2.3+)

English (United States) (SR1095.2.3.1)

The default locale of the system shall be English (United States):

- Default date format: mm/dd/yyyy
- Default digit grouping symbol: , (comma)
- Default decimal separator: . (dot)
- Default time format: hh:mm:ss (AM/PM)

Locales within One Installation (SR1095.2.1)

The system shall support multiple locales within one installation.

Choice of Locale (SR1095.2.2)

The system shall allow the user to choose the locale to be used at when logging on to the system.

Configurable Locale-specific Settings (SR1095.1.3)

The system shall allow the configuration of the following locale-specific settings:

- Date format
- Number format (digit grouping symbol and decimal separator)
- Time format

Chapter 7

Installation, Backup, and Upgrade (SR1095.4+)

Installation of PharmaSuite (SR1095.4.1)

The system shall allow to be installed by system administrators.

Existing Database (SR1095.4.1.7)

The installation shall support installation into an existing database installation (other instances already installed on the database).

Installation Result (SR1095.4.1.8)

The installation shall inform the user if the installation was successful or not.

Logging of Installation (SR1095.4.1.8.1)

The installation shall write all installation steps into a log file including the status of each step and, if applicable, the reason for failure.

Installation Manual (SR1095.4.1.4)

The system shall provide an installation manual that supports a system administrator when installing the system.

Backup (SR1075.6)

The system shall allow to backup data and system.

Backup of a Running System (SR1075.6.1)

The system shall allow to backup the data stored in the database during production time with an appropriate third-party backup tool. The backup does not include data in the local client's cache.

Backup and Restoring (SR1075.6.3)

It shall be possible to completely backup and restore both, system and data, with a third-party tool. The configuration and execution of the backup and restore environment is done by IT subject matter experts.

Upgrade Tool (SR1075.8+)

The system shall provide an upgrade tool to update the system and to migrate the data.

Basic Upgrade Engine (SR1075.8.1)

The basic upgrade engine allows the upgrade of a PharmaSuite releases in five stages:

- Stage 1 verifies the completeness of the upgrade package.
- Stage 2 determines the planned changes required to upgrade from the base to the new version.
- Stage 3 checks the planned changes against the target system and reports non-resolvable conflicts as well as potential conflicts (based on project extensions).
- Stage 4 performs the system update and the data migration on the target system based on the results of stage 3.
- Stage 5 verifies the results of the upgrade process.

Upgrade - Continue execution (SR1075.8.3.5)

Along with the upgrade of the system to a following new software version, the system shall allow to execute and finish orders with the new release that originally have been started with the previous release.

System Update Tasks (SR1075.8.2+)

The upgrade tool shall provide the following system update tasks:

Update task for DSX objects (generic DSX) (SR1075.8.2.1)

The upgrade tool shall support an update task for objects that are part of FactoryTalk ProductionCentre DSX format (generic DSX).

Update task for Message objects (SR1075.8.2.2)

The upgrade tool shall support an update task for message packs. The conflict handling shall be done on message ID level.

Update task for EAR files (SR1075.8.2.3)

The upgrade tool shall support an update task for EAR artifacts.

Update task for ATRow objects (SR1075.8.2.4)

The upgrade tool shall support an update task for ATRow artifacts.

Update task for Library objects (SR1075.8.2.5)

The upgrade tool shall support an update task for library artifacts.

Update task for Image objects (SR1075.8.2.6)

The upgrade tool shall support an update task for image artifacts.

Update task for FSM (Flexible State Model) objects (SR1075.8.2.7)

The upgrade tool shall support an update task for FSM artifacts.

Update task for AT Definition objects (SR1075.8.2.8)

The upgrade tool shall support an update task for AT Definition artifacts.

Update task for UDA Definition objects (SR1075.8.2.9)

The upgrade tool shall support an update task for UDA Definition artifacts.

Update task to report customer notifications (SR1075.8.2.11)

The upgrade tool shall support an update task to report customer modifications.
This task shall only be applicable to **Stage 3** (Checking Target System for Conflicts) and create a report with the list of objects that have been added to, modified in, or deleted from the customer system.

Update task for Application objects (SR1075.8.2.12)

The upgrade tool shall support an update task for Application artifacts.

Update task for Versioning Configuration objects (SR1075.8.2.13)

The upgrade tool shall support an update task for Versioning Configuration artifacts.

Update task for Report Design objects (SR1075.8.2.14)

The upgrade tool shall support an update task for Report Design artifacts.

Update task for Access Privilege objects (SR1075.8.2.15)

The upgrade tool shall support an update task for Access Privilege artifacts.

System Update and Data Migration Packages (SR1075.8.3+)

The upgrade tool shall provide system update and data migration packages specific to a PharmaSuite version.

System update from the previous software version (SR1075.8.3.25)

The system update package shall allow to update a PharmaSuite system from the previous software version to the subsequent software version by applying functional and structural changes and adding new functions.

For an overview of the default system update tasks, please refer to the **System Update Tasks (SR1075.8.2+)** requirement (page 34).

For a system update from PharmaSuite 10.01.00 to PharmaSuite 10.02.00, the following specific system update task is available:

- Artifacts related to GHS statements are not migrated and warnings about unhandled files are suppressed.

Data migration from the previous software version (SR1075.8.3.26)

The data migration package shall allow to migrate specific data that already resided in a previous software version of PharmaSuite to be suitable for use with the new or changed system functions of the subsequent software version.

For a data migration from PharmaSuite 10.01.00 to PharmaSuite 10.02.00, no specific data migration tasks are available.

Extensibility (SR1075.8.5+)

Upgrade packages (SR1075.8.5.1)

The system upgrade tool shall allow a system integrator to adapt system update and data migration packages, so that customized releases of PharmaSuite can be upgraded with the extended upgrade packages.

This extension use case shall be documented and informally tested.

Pre-install Configuration (SR3146.7)

The system shall support specific pre-install configurations by a system integrator.

General Client Framework (SR3071.1)

The system shall support general client framework capabilities.

System Login (SR3071.1.1)

The system shall enforce user login.

System Exit (SR3071.1.3)

The system shall provide a function to exit the system in a controlled manner. The system shall check if there is any unsaved data and shall warn the user if that is the case.
Before shutting down the system it shall warn the user that it is going to shut down and shall ask for confirmation.

Exiting the system means shutting down and ending all relevant system processes.

Unique Device (SR3071.1.5)

The system shall be able to identify the unique physical device that is used for accessing PharmaSuite. This applies to PharmaSuite running directly on a physical device or PharmaSuite running via remote access.

Unique Session of the Production Execution Client (SR3071.1.6)

For any given device, the system shall not allow to start another Production Execution Client (PEC)session of PharmaSuite.

About Dialog (SR3071.1.7)

The system shall provide an About dialog for each client, which provides general information (e.g. version, logged-in user) and installation details (e.g. application server, application configuration).

The About dialog of PS Administration shall provide version and database information.

Online Help (SR3071.1.8)

If a client-specific help system is available, the system shall provide access to the client-specific help system.

User Experience (SR1095.5+)

Messages (SR1095.5.1.1)

The system shall display only meaningful system and error messages to the user. Pure technical messages shall be avoided.

Example: The operator is generally not interested that a unique constraint in a database table is violated, but that the batch identifier is not unique.

Device-specific Usability (SR1095.5.1.4+)

Touch Screen (SR1095.5.1.4.2)

The system shall provide a user interface for the Production Execution Client that allows to operate the system via touch screen.

Virtual Keyboard (SR1095.5.1.4.2.1)

As an EBR operator I need to be able to enter data via a virtual keyboard ("soft keyboard"), so that I can operate the system via touch screen only.

Look and Feel (SR1095.5.7)

The Look and Feel of the system shall be state-of-the-art.

GUI Design (SR1095.5.7.3)

The GUI shall be designed in a way that supports easy readability of key information, in support of the special needs of the operator. This includes structure, design and sizing of forms and panels.

GUI Adaptation (SR1095.5.7.1)

The user interface of PharmaSuite shall be adaptable by simple means, allowing to adjust colors, fonts, and font sizes.

Dialog Boxes (SR1095.5.7.2)

The dialog boxes used within PharmaSuite shall all have a common appearance in terms of colors, fonts, and button style.

Grid Components (SR1095.5.7.4)

The system shall support state-of-the-art grid components. When functionally suitable, this includes:

- sorting by rows,
- manual adjustment of sequence of columns, and
- support of multi-selection (per configuration).

Reset User-specific Layout (SR1095.5.7.5)

The system shall allow the system administrator to reset a user-specific layout to the default layout of the respective client.

Extensibility (SR1095.5.1.2+)

System - Customization (SR1095.5.1.2.1)

The system shall be customizable in a way that a system integrator is able to:

- add or modify workflows,
- add, remove, or modify data object attributes,
- add, remove, or modify fields and labels of the user interface,
- rename labels of the user interface, and
- add, remove, or modify reports and barcode labels.

It must be possible to perform the modifications "offline" in a development system and to integrate them into an existing customer system. The respective guidelines shall be documented in Technical Manuals.

System - View Model-related Objects (SR1095.5.1.2.3)

The system shall allow a system integrator to add attributes to a view model-related object without the need of Java coding.
This extension use case shall be documented and tested.

System - Material Attribute (SR1095.5.1.2.9)

The system shall allow a system integrator to add a material/batch attribute across the system and to implement business logic that makes use of this attribute.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Second potency** attribute.

System - ERP BOM Attribute (SR1095.5.1.2.11)

The system shall allow a system integrator to add a new attribute to the ERP BOM, which is automatically populated into the related new attribute of the material parameter.
In case the same attribute also exists as material master data, the default value for the material parameter will be taken from the material master data in case no value exists in the ERP BOM.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Second potency** attribute.

System - Batch Status (SR1095.5.1.2.10)

The system shall allow a system integrator to add a batch status to the flexible state model (FSM) and to implement business logic that makes use of the new status.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Conditionally released** status of a batch.

Master Recipe - Approval Workflow (SR1095.5.1.2.13)

The system shall allow a system integrator to adapt the approval workflow of a master recipe according to project needs. This includes the ability to

- add a new status that has the same semantic meaning as one of the given **Edit** and **Verification** statuses,
- adjust status transitions accordingly, and
- rename statuses and status transitions (actions).

This extension use case shall be documented and informally tested.

Expression Editor - Context Data (SR1095.5.1.2.14)

The system shall allow a system integrator to enhance the context data-related capability of the Expression editor. This includes the ability to

- add a new attribute to the list of available attributes for a given object-related function and
- add a new function to access the context data of a new object.

This extension use case shall be documented and informally tested.

Building Block - Name Spaces (SR1095.5.1.2.4)

The system shall support the deployment of building blocks from different system integrators by definition of name spaces.
This extension use case shall be documented and tested.

Building Block - Mainstream GUI Programming (SR1095.5.1.2.6)

For the implementation of a GUI of a System Building Block, the system shall support mainstream Java GUI programming mechanisms, rather than being dependent on proprietary components.

Master Recipes, Master Workflows, and Custom Building Blocks - Comparison (SR1095.5.1.2.17)

The system shall allow a system integrator to extend the comparison functionality (see chapter "**Comparing Master Recipes, Master Workflows, and Custom Building Blocks (SR3146.15+)**" in the "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 47)) in regards of customized data structures referencing the master recipe. (Directly extended master recipe data structures such as process parameters are not included here).

For details, see chapter "Extending Comparison in Recipe and Workflow Designer" in Volume 3 of the "Technical Manual Configuration and Extension" [A6] (page 47).

Execution - Autostart (SR1095.5.1.2.2)

For a system integrator, the system shall allow to configure specific activity sets that are started automatically upon start of the Production Execution Client. One activity set can be started multiple times in case multiple instances are allowed for this activity set (configurable).

Execution - Select Order Grid (SR1095.5.1.2.5)

For the **Select order** grid of the Batch or Workflow Processing actions of the Cockpit, the system shall allow a system integrator to add project-specific fields/columns to the grid and to adjust the pre-defined filter criteria, according to project-specific business rules. This extension use case shall be documented and tested.

Execution - EBR Header Bar (SR1095.5.1.2.8)

The system shall allow a system integrator to change the content of the EBR header bar of the Production Execution Client.

Reporting (SR1095.5.1.2.16+)

Master Recipe Report Variants (SR1095.5.1.2.16.1)

The system shall allow a system integrator to create and print a master recipe report variant from Recipe Designer in addition to the standard master recipe report.
This extension use case shall be documented and informally tested.

MASTER WORKFLOW REPORT VARIANTS (SR1095.5.1.2.16.2)

The system shall allow a system integrator to create and print a master workflow report variant from Workflow Designer in addition to the standard master workflow report.
This extension use case shall be documented and informally tested.

BATCH REPORT VARIANTS (SR1095.5.1.2.16.3)

The system shall allow a system integrator to create and print a batch report variant from the Production Management Client and the Production Response Client in addition to the standard batch report.
This extension use case shall be documented and informally tested.

WORKFLOW REPORT VARIANTS (SR1095.5.1.2.16.4)

The system shall allow a system integrator to create and print a workflow report variant from the Production Management Client in addition to the standard workflow report.
This extension use case shall be documented and informally tested.

Receive Material Data - Key Tags for Barcoded Information (SR1076.22)

The system shall allow a system integrator to define the key tags that serve to distinguish barcodes for different data objects.

CONCATENATED INFORMATION (SR1076.23)

The system shall allow a system integrator to configure at least three different barcode definitions that concatenate batch, material sublot, material number, and sublot quantity information.

SUBLOT (SR1076.24)

The system shall allow a system integrator to configure at least one barcode format that contains a sublot identifier.

BATCH (SR1076.25)

The system shall allow a system integrator to configure at least one barcode format that contains a batch identifier.

Precision of Numerical Data (SR1095.5.1.3+)

Fixed Point Numbers (SR1095.5.1.3.1)

The system shall support decimal fixed-point numbers for the definition of input and output parameters to support the control of scaling of decimal values.

Floating Point Arithmetic (SR1095.5.1.3.2)

For calculations, the system shall use decimal floating point arithmetic that is compliant to the IEEE 754R standard.

Errors at Calculation (SR1095.5.1.3.3)

Errors at calculation (division by zero, overflow, underflow, inexact, invalid operation), as defined in the IEEE 754R standard, shall be reported by the system.

Input Data Errors (SR1095.5.1.3.4)

The system shall not consider input data errors at calculation, i.e. the scale of a calculation result is not adapted by the system. The correct setting of the scale of a calculation result lies within the responsibility of the system user.

Rounding (SR1095.5.1.3.5)

At rounding, the following method shall apply (round-half-up): if the discarded digits are greater than or equal to a half (0.5) of a one in the next left position then the result coefficient shall be incremented by 1 (rounded up) - otherwise the discarded digits are ignored.

Input Length Limitations (SR1095.5.1.8+)

Depending on the used character encoding, string input fields allow different numbers of characters. A maximum length definition of a string field always refers to single-byte encoding.

Concurrent Data Access - Pessimistic Locking (SR1095.5.1.5)

Concurrent data access shall not lead to data inconsistency.
The system shall support pessimistic locking mechanisms.

Example:
Record 1 is locked by user 1; user 1 has read and write rights.
For user 2, who comes later than user 1, the system assures that user 2 cannot modify or delete the locked record.

In the Production Management Client and Recipe and Workflow Designer, the system still allows user 2 to read the record while it is locked by user 1.

Restart and Recovery (SR1095.8)

The system shall support "save points".
At a save point, the system generates consistent data in the system accessible by other users and functions.

The default save points are defined in the application. They are not configured nor shall be configurable. The locations of the save points are defined in the requirements of the respective pre-defined workflows. In case of a system breakdown, all modifications done up to there are rolled back if no save point has been reached in the respective workflow.

Client Data Consistency after Database Server Reconnect (SR1095.8.1)

In case a client loses its database server connection, after reestablishing the connection, the system shall ensure that the client operates with the same data as available in the database.

Reference Documents

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

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM010C-EN-E
A2	PharmaSuite Functional Requirement Specification Data Management	PSFRSDM-RM006C-EN-E
A3	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM006C-EN-E
A4	PharmaSuite Functional Requirement Specification Review and Approval	PSFRSRA-RM006C-EN-E
A5	PharmaSuite Functional Requirement Specification Equipment Automation Phases	PSFRSEA-RM006A-EN-E
A6	PharmaSuite Technical Manual Configuration & Extension - Volume 3	PSCEV3-GR010C-EN-E
A7	PharmaSuite Functional Requirement Specification Runtime Data Management	PSFRSRT-RM006C-EN-E
A8	PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM008B-EN-E
A9	PharmaSuite Functional Requirement Specification Output Weighing	PSFRSOW-RM004B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

Appendix A

Document Information

The document information covers various data related to the document.

Approval

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

Name	Role
Norbert Ern	Product Owner
Wolfgang Schmitt	Technical Lead
Ignaz Wangler	Test Lead

Version Information

Object	Version
PharmaSuite	10.02.00
Functional Requirement Specification	1.0

Revision History

The following tables describe the history of this document.

Changes related to the document:

Object	Description	Document
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Changes related to "Performance Requirements" (page 3):

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

Changes related to "Scalability Requirements (page 13)":

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

Changes related to "Compliance Requirements" (page 15):

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

Changes related to "Functional System Administration" (page 27):

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

Changes related to "Internationalization and Localization" (page 29):

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

Changes related to "Installation, Backup, and Upgrade" (page 33):

Object	Description	Document
System Update from the Previous Software Version (SR1075.8.3.25) (page 36)	Update System update task added: Treatment of GHS statement artifacts.	1.0
Data Migration from the Previous Software Version (SR1075.8.3.26) (page 36)	Update No specific data migration tasks are available.	1.0

Changes related to "General Client Framework" (page 37):

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

Changes related to "User Experience" (page 39):

Object	Description	Document
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