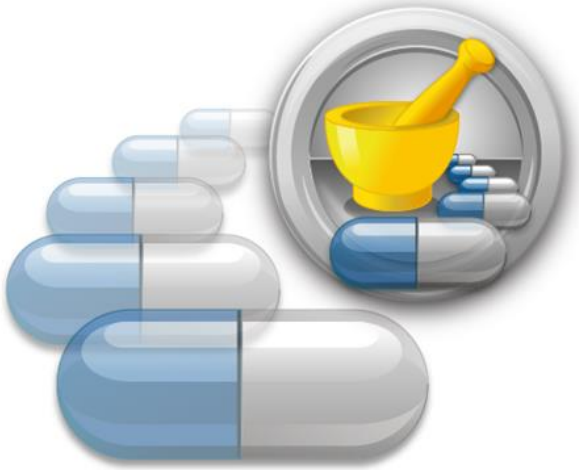
# FT PharmaSuite 10.02.00

## Quality Document



*This document contains information which is confidential and proprietary.*

# Contents

# Introduction

This document summarizes the quality-related planning activities and results for FT PharmaSuite 10.02.00 to support further customer-related qualification and validation activities. Other planning activities and results are not covered within this document.

Development of PharmaSuite® followed

- Good Engineering Practices
- Good Testing Practices
- Good Documentation Practices
- Supplier Good Practices

Regarding quality assurance and verification, PharmaSuite® has been developed following a scalable science-based verification process that is fully compliant with the Quality Risk Management as described in ICH Q9 [1] and the risk-based test approach as described in GAMP® 5 [2].

A 2-step approach was used to analyze the system impact and assess the risk of any system change.

The basic development and verification approach as well as the product life-cycle are mainly defined in two internal documents, the Project Plan [18] and the Testing Guideline [15] (with project-specific aspects described in the Test Plan [20]).

Note: Internal documents are confidential and will only be shown to external parties in case a Non-Disclosure Agreement is in place.

The underlying processes are defined in a mature Quality Management System [4] and complemented by various guidelines specific to PharmaSuite®.

Note: Specific terms and abbreviations are explained in chapter *Glossary & Abbreviations*.

# Life-Cycle Methodology

## General Development Model

FT PharmaSuite 10.02.00 has been developed using an iterative development approach based on (i) iterations (typically lasting three weeks each), (ii) a prioritized product backlog, and (iii) review, retrospective, and planning meetings per iteration, see *Figure 1*. As a result, each iteration produces a potentially shippable product. The last four iterations were reserved for final verification and clean-up activities.


*Figure 1: Iterative development approach*

## Requirements Engineering

The specification artifacts are described in detail in a separate chapter *Specification Artifacts* on page 5.

## Roles and Responsibilities

A list of stakeholders and all personnel involved in designing, coding, testing, and documenting FT PharmaSuite 10.02.00 is provided in section 3.1 of the Project Plan [18].

## Development: Design and Coding

Procedural aspects regarding design reviews, code reviews, the development environment, and tools are documented in the Architecture Specification [26]. Furthermore, the underlying processes for design and code review and their project-specific adaptations are described in sections 5.6.6 and 5.6.7, respectively, of the Development Guideline [14].

## Test Strategy

The test strategy is described in detail in a separate chapter *Test Strategy* on page 6.

## Validation Activities

These activities are described in detail in a separate chapter *Validation Activities* on page 9.

## User and Technical Documentation

For a list of user and technical manuals, please refer to chapter *References* on page 18.

User and technical manuals are also available as WebHelp, for most user manuals with context-sensitive access from the PharmaSuite® application. All reviews have been conducted by subject matter experts. Reviews are informal, whereas all approvals are documented via DMS [6].

## Risk Management

Risk management followed the risk management process as described in section 5.10 of the Development Guideline [14].

## Configuration Management

Configuration management is described in section 5.11 of the Development Guideline [14] and in the Configuration Management Plan [19].

## Traceability

Traceability is described in detail in a separate chapter *Traceability* on page 10.

## Quality Management

Quality Management is described in detail in a separate chapter *Quality Management* on page 11.

## Project Monitoring and Control

More details on Project Monitoring and Control, based upon the approach described in chapter *Life-Cycle Methodology*, can be found in section 5.13 of the Development Guideline [14].

## Project Closure

The formal approval of the Project Closure Report [25] officially closed the project.

## Further Development of the System

The remaining anomalies will be evaluated for resolution in future versions of PharmaSuite®.

## Quality Risks

Known issues relevant for end users have been documented in the project's Release Notes [24].

Note: The qualification of FT PharmaSuite 10.02.00 has been completed following a risk-based test approach focusing on all changes made to the PharmaSuite® system since the previous release. All changes have been analyzed and tested with regard to their risk and impact on the system.

# Specification Artifacts

Requirements for FT PharmaSuite 10.02.00 have been developed in a 2-step approach.

In a first step, certain artifacts, using various tools (e.g. mind maps, graphics, drawings, text documents), have been created as supporting documents for items on the Product Backlog (PBL). This has been done in order to support the required effort estimation and knowledge dissemination.

As soon as a certain backlog item had been committed for implementation within an iteration, more specific details were provided. During iterations, a spreadsheet has been used to hold the entire set of requirements. Finally, all of the relevant specification details, including use cases and requirements, have been compiled within the Supported Platforms Guide [27] and the Functional Requirement Specification (FRS) documents ([28] -[36]).

Requirements are subject to version control and base-lined per approved document. Baseline requirements are modified using change control per relevant QMS procedures. Changes have been tracked through the change control mechanism of the respective documents.

As a result, the Supported Platforms Guide and all FRS documents of FT PharmaSuite 10.02.00 include all requirements and list all changes that apply to this release (compared to previous releases).

All specification documents have been posted on the Document Management Systems [6] for formal approval.

# Test Strategy

The software test process is generally described in the Software Testing Procedure [9]. The document outlines the testing process as well as the entry and exit criteria of the different test types.

This chapter describes the framework requirements and methods of test planning. The detailed planning of test activities and their execution have been described in a Risk-Based Testing Guideline [15], with project-specific deviations defined in the Test Plan [20].

## Principles of Test Execution

The objective of testing is the verification of the correspondence between the system and its specification. In order to achieve this objective, testing tried to reveal any deviation in the implemented functionality against requirements, use cases, and other specification artifacts. Anomalies found in the scope of testing have been recorded and analyzed. The majority has been resolved and verified according to the change control procedures and guidelines ([16] and [17]) until a high level of confidence had been assured that the system meets the specified requirements.

## Structure of Test Documentation

The highest level document is the Project Plan [18]. It lays out the general framework of requirements for test execution and for the structure of test plans and individual testing phases as well as the general test scope.

The Risk-based Testing Guideline [15] in combination with the project-specific Test Plan [20] constitutes the second level. It describes all activities of the testing phase. The testing phase reflects important milestones in the product development. A Test Summary Report was generated at the end of the testing phase [21]. The Test Summary Report corresponds to the Test Plan and gives a summary of all test activities and their results for that test phase.

Third level items are the System Impact Analyses, Risk Assessments, as well as Test Cases. The System Impact Analysis along with the Risk Assessment identifies and assesses the risk of changes related to the system. Based on the results, the required test scope has been derived. Details are defined in the Risk-Based Testing Guideline [15].

Prior to test execution, all test documents were reviewed and approved.

## Document Management System

All quality-relevant documents and project documentation are subject to the organization's Document Management Systems (either [5] or [6]). Each document is numbered and version-controlled.

All documentation of FT PharmaSuite 10.02.00 is generally stored following Rockwell Automation's Record Retention Procedure [13].

## Evaluation of Test Results

A combination of the type and frequency of anomalies is applied as metrics for the software quality during the testing phase. This requires a suitable classification of anomalies.

The triage team is responsible for conducting an initial analysis on the anomaly submitted to determine the appropriate FMEA value following the FMEA guidelines as described in the Defect Management Guideline [16].

## Repetition of Tests

The repetition of a testing phase after a correction cycle followed the principle of regression testing (for details see Software Testing Procedure [9]). The tests to be executed during the repeated execution of a testing phase usually represent a subset of the original test cases. The selection process was geared by the System Impact Analysis and Risk Assessment, as described in detail in the Risk-Based Testing Guideline [15].

Implementation of corrective actions and regression testing was repeated until all anomalies violating the acceptance criteria (see [16] for details) were corrected and verified.

## Testing Phases

The testing of FT PharmaSuite 10.02.00 was conducted in phases. The typical course of testing was as follows:

- Creation of the Test Plan [20] (incl. review and approval)
- Creation or update of Test Cases [22] (incl. review and approval)
- Test execution and recording of results
- Classification of detected anomalies and definition of corrective actions
- Creation of a report summarizing the test results of the testing phase
- Review and approval of the Test Summary Report [21]

Prior to testing, an installation qualification for the software has been carried out with the objective to document the proper installation of software for all work stations and servers used for the tests. This was executed based on the guidelines defined in the Risk-Based Testing Guideline [15].

## Release Criteria

The test phase was accepted when all defined test cases had been completed (incl. review and approval) and the results of the execution of all tests were accepted and thereby no CRs violating the project's release criteria (as defined per [16]) were left.

Note: FT PharmaSuite 10.02.00 provides add-on functionality to ProductionCentre and thus uses existing functionality of ProductionCentre.

During verification and qualification of FT PharmaSuite 10.02.00, testing has been focused on FT PharmaSuite 10.02.00 requirements. ProductionCentre was considered to be a qualified baseline for FT PharmaSuite 10.02.00.

## Test Environment and Tools

The list of hardware and software used for testing is captured in the Test Summary Report [21] and included in this document in *Appendix B: Test Equipment*.

## Test Plan

A project-specific Test Plan [20] has been created, reviewed, and approved before start of test. See chapter *Test Planning* for more details.

## Test Reports

After finalization of the system test, a report summarizing the test results of the testing phase has been created, reviewed, and approved [21].

In addition, all test cases have been listed in the Final Test Status Report [22].

# Validation Activities

Note: The term validation refers to the definition of the Validation Procedure [10], based upon the CMMI definition [3]. It does neither refer to the definition of GAMP [2] (Computer System Validation: Achieving and maintaining compliance with applicable GxP regulations and fitness for intended use (…)) nor to regulations like 21 CFR 820.70(i), as a supplier can obviously not fulfill these requirements. However, FT PharmaSuite 10.02.00 was launched in a qualified status, thereby allowing customers to leverage both, Rockwell Automation's verification and validation activities.

All validation activities for FT PharmaSuite 10.02.00 followed the Validation Procedure [10]. In general, validation has been performed by extended peer reviews while creating new and revising existing requirements. The peer reviews have been performed

- by relevant stakeholders of all disciplines (Requirements Engineering, Product Management, Development, and Testing) involved in the project;
- on detailed requirements (or other comparable specification artifacts like Use Cases etc.) level;
- according to the Peer Review Procedure [11].

Furthermore, newly developed features have been presented to the engineering team, to the product owners, and to integrators after completion of each iteration. This review-per-demonstration process ensured to receive feedback on new features as soon as possible. Also, intermediate product builds including new features have been shown to prospective customers as well.

# Traceability

Traceability is maintained partially within a traceability matrix document, and partially within the different types of documents:

- SRs reference to MRs.[1]
- Work items reference to related SRs implemented and anomalies fixed.
- Code and design review protocols are documented at work items (and defects, as needed) in the defect management tool.
- Each work item references in which build it was integrated.[2]
- Work items and / or anomaly CRs list the changes to the system.
- Test cases reference to the SRs they are going to verify.

The traceability matrix document [23] is maintained per iteration as part of the "Done" state, and finally uploaded to the Document Management System [6] for approval (prior to project completion). This document shows the mapping of SRs to test cases, thereby helping to assure that all requirements have been verified.

[1] For releases 1.0 and 1.1 only, i.e. no new market requirements have been developed for FT PharmaSuite 10.02.00 and traceability from SRs to MRs has not been maintained anymore for FT PharmaSuite 10.02.00. Rationale: By using the iterative life-cycle methodology and the product backlog, a different method is applied to gear the prioritization of feature implementation. Furthermore, MRs have not been used for formal tracking and have not been part of the formal testing approach, but were used for documentation and project control purposes only.

[2] Build numbers are increasing over time. Beware: Work items may reference to a build that did not match acceptance criteria. However, the next number of a build meeting acceptance criteria also contains that work item.

# Quality Management

## Product and Process Quality

Product and process quality is assured through regular assessments.

## Anomaly Management

Anomaly tracking has been done within Jira per the Defect Management Guideline [16]. The triage team reviewed and evaluated anomalies in regular meetings (frequency as needed) according to the Defect Management Guideline [16]. The triage team was led by the Test Manager. In this role, the Test Manager had the final decision in case of disagreement of the triage team. Further members of the triage team can be found in section 3.1 of the Project Plan [18].

# Test Planning

This chapter discloses important information from the Risk-based Testing Guideline [15]. Parts that have not been transferred to this document may be reviewed during audits, as needed.

## Test Approach

Testing was conducted to verify the stability of the product and the functionality based on the specification artifacts (e.g. requirements, use cases, etc.). The following sub-sections describe the types of testing that have been conducted on FT PharmaSuite 10.02.00. The definitions for each testing type are defined in the Software Testing Procedure [9] and the Software Process Document Glossary [8].

For the verification of FT PharmaSuite 10.02.00, a risk-based testing approach has been applied (see [15]). In general the approach is defined as follows:

- Each new feature and functionality had to be analyzed through a risk assessment to determine the risk priority.
- All system changes (i.e. the corresponding Change Requests) needed to be analyzed within a System Impact Analysis (SIA) and a risk assessment had to be conducted to determine the necessity and rigor of testing.
- The risk-based approach was not applied to installation tests, installation qualification, unit tests, performance tests, and the final acceptance tests, as a variation of the test depth (level of detail) was not foreseen for these types of test cases.

Based on the various risk assessments, test cases have been created or revised to define the individual test scope. Sometimes, several features or functionalities have been combined into one test scenario.

### Risk Evaluation

The risk-based approach is considered to establish a scalable science-based verification process and to ensure that the work and testing effort spent focuses on risky areas. Therefore, the risk evaluation was divided in two interrelated processes:

1. The first step of the risk evaluation is to identify all system areas affected with potential risk within the System Impact Analysis (SIA).
2. The second step is to rate the potential risk to get the risk priority as an indicator for the resulting testing or mitigation strategy.

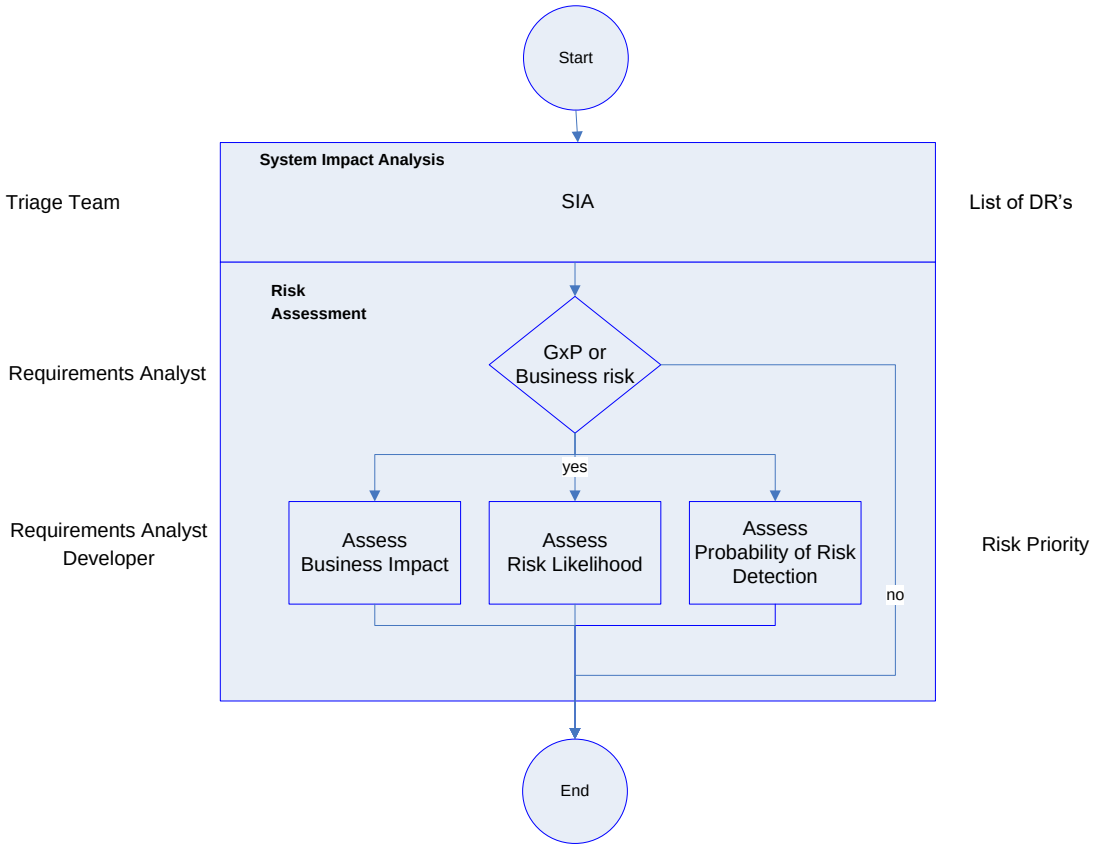



*Figure 2: Risk Evaluation Process*

### System Impact Analysis (SIA)

All changes made to the system have to be listed and analyzed within the System Impact Analysis. This means every change (e.g. bug fixes, new functionalities) needs to be analyzed to identify all system areas with potential risk (e.g. by side effects) caused by the changes. The System Impact Analysis identifies affected system areas as a first indication of the appropriate scope of testing.

### Risk Assessment (RA) Process

The risk assessment aims to classify the risk to the different functionalities of FT PharmaSuite 10.02.00 using pre-defined assessment criteria.

Adapted from this, a Subject Matter Expert derived the appropriate risk priority for each function. The risk assessment was performed based on specification artifacts identified during the System Impact Analysis process.

The assessment of the GxP and Business Risk as well as the Business Impact are artifact-specific attributes and therefore independent of the change. These classifications have been documented per specification artifact in the System Impact Analysis (SIA) & Risk Assessment (RA).

Guidelines for risk assessment are described in detail in the Testing Guideline [15].

## Testing Scope

### Unit Tests

JUnit has been used for unit testing where applicable (up to and including the service layer). Therefore, the public interfaces of MES components as described in the Architecture Specification [26] have been tested. Unit testing followed the Unit Testing Guideline [12]. The tests were managed within Subversion like ordinary source code.

More details regarding Unit Tests can be found in the Risk-based Testing Guideline [15].

### Installation Test

The installation test was aimed to check the correct implementation and description of the FT PharmaSuite 10.02.00 installation process including the configuration for all components.

The installation process was based on the description of FT PharmaSuite 10.02.00's Installation Manual [37].

### Feature Tests

All feature tests were based on the specification artifacts, refer to chapter *Specification Artifacts*, page 5.

Note: Parts of the feature tests have been realized as automated tests. However, independent of the used technique, there is no difference to the claim of the tests. Both, automated as well as manual tests have been treated as equally qualified test methods.

### Performance Tests

Performance tests (as well as stress tests, boundary tests, limit tests, and response tests) are implicitly covered within the feature tests. The performance test scope was covered within the System Impact Analysis [38] and [39].

### Reliability Tests

The objective of reliability testing was to show the system running 12+ hours, performing operations like insertions and deletions of master data. Therefore, special scripts have been run to verify the reliability as described. Reliability tests have been performed in the qualified test environment..

### Integration Tests

Integration tests for new features or functionalities as well as CRs have been covered within the feature or regression tests. The integration test scope was covered within the System Impact Analysis [38] and [39].

### System Tests

System tests as described in the Software Testing Procedure [9] have been covered within the corresponding risk evaluation and the resulting regression tests. Therefore, no additional system tests were required.

### Customer Acceptance Testing

Customer acceptance tests were not planned for FT PharmaSuite 10.02.00.

### Regression Tests

Regression testing of FT PharmaSuite 10.02.00 was based on a risk assessment, which results in the potential risks and impact of any code change (defect resolution or feature). The impact is evaluated with regard to existing functions.

Regression testing was executed by re-running feature tests that had been executed in previous releases against the current system. The objective was to ensure that the functionality of the system continues to work as expected after all features have been implemented and defects have been resolved. The scope has been derived by and described in the respective risk evaluation of the System Impact Analysis ([38] and [39]).

Note: Parts of the regression tests have been realized as automated tests. However, independent of the used technique, there is no difference to the claim of the tests. Both, automated as well as manual tests have been treated as equally qualified test methods.

### CR verification

Change requests (CRs) integrated in the system were objects of this test, as long as they were not covered by other tests. The verification of CRs ensures that anomalies have been resolved satisfactorily.

Anomalies violating the defined system acceptance criteria had to be verified on a controlled test environment.

### Final Acceptance Tests (FAT)

The final acceptance test represented a high-level, overarching test scenario in the course of FT PharmaSuite 10.02.00 qualification. It examined the functional capability of the system installed based on the final build[3]. The objective of the final acceptance test was to examine the system applicability in the operational area and to confirm the product satisfies the criteria for the customer.

### Integrated Solutions Testing

Within this project, no integrated solution tests were planned.

## Requirements Traceability

A traceability matrix [23] has been generated to trace the test cases to the appropriate detailed requirement(s) and other specification artifacts. The matrix has been developed throughout the testing activities as new test cases were created and executed or as specifications changed.

## Test Team and Responsibilities

The test team members and responsibilities are called out in the Project Plan [18].

[3] "Final" in the sense that this is the final build of the current release, the build that is going to be shipped.

## Test Environment

For the execution of tests, dedicated test hardware (clients and servers) available in the test lab of Rockwell Automation campus Karlsruhe has been used. The test lab provides a segregated network managed by the test team. All test hardware used for official tests has been installed according to the definitions in the detailed requirement specifications.

For more details, refer to *Appendix B: Test Equipment*.

### Installation Qualification

The objective of the installation qualification was to check the suitability of client and server hardware as far as dedicated to FT PharmaSuite 10.02.00, as well as software components related to FT PharmaSuite 10.02.00 installation. The installation qualification was performed on the test environment before start of formal testing.

For this specific test, no acceptance criteria were defined. The software installed on the clients and servers must correspond to the definitions in the Supported Platforms Guide [27]. Otherwise, the work station or server must not be used within the official test. The software installation qualification refers to all clients and servers mentioned in the Supported Platforms Guide [27].

# Glossary & Abbreviations

| Term | Definition |
|---|---|
| *CMMI* | Capability Maturity Model Integration<br>A process improvement approach that provides organizations with the essential elements for effective process improvement. |
| *CR* | Change Request<br>A record that describes a request to change the system and may be an anomaly, an enhancement, etc. |
| *Done state* | Final state of a product backlog item indicating that all related tasks (e.g. specification, implementation, test, documentation) have been completed. |
| *DRS* | Detailed Requirements Specification<br>Collection of detailed software requirements (SRs) |
| *FRS* | Functional Requirements Specification<br>Includes detailed software requirements (SRs) |
| *IDS, IDSs* | Integrated Design Specification(s) |
| *Jira* | Anomaly management system used by Rockwell Automation |
| *MES* | Manufacturing Execution System |
| *MR, MRs* | Market Requirement(s) (high level) |
| *PBL* | Product Backlog<br>Prioritized list of items to be realized in PharmaSuite |
| *SR, SRs* | Software Requirement(s) |
| *Triage* | Process of deciding upon further processing of CRs (resolving, deferring, etc.). |
| *Triage team* | Team of subject matter experts, led by the Test Manager, performing the triage process. |

# References

[1] ICH Q9 Quality Risk Management; International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use; Step 4, version 09-Nov-2005

[2] GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems; ISPE; Feb 2008

[3] CMMI Guidelines for Process Integration and Product Improvement, Mary Beth Chrissis, Mike Konrad, Sandy Shrum, SEI

[4] Rockwell Software Quality Management System (QMS), https://rockwellautomation.sharepoint.com/teams/AS/ISPB/PMO/MES/pharmasuite/LSQMS/

[5] Rockwell Software Document Management System (DMS), http://softwaredms.na.home.ra-int.com

[6] Rockwell Automation Document Management System (DMS), basic functionality included in central SAP

[7] Rockwell Automation Testing Environment, https://ra.qtestnet.com/

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[8] Software Development Process Glossary, Doc No. 102295, Rev. 2.1

[9] Software Testing Procedure, Doc No. 102378, Rev. 3.4

[10] Validation Procedure, Doc No. 102634, Rev. 2.1

[11] Peer Review Guideline, Doc No. 102556, Rev. 1.5

[12] Unit Testing Guideline, Doc No. 101890, Rev. 1.2

[13] Record Retention Procedure, Doc. No. 103837, Rev. 2.2

[14] LS Release Development Guideline, Doc No. 105112, Rev. 3.0

[15] LS Risk-Based Testing Guideline, Doc No. 104706, Rev. 2.0

[16] LS Defect Management Guideline, Doc No. 105543, Rev. 2.0

[17] LS Work Item Management Guideline, Doc No. 105547, Rev. 2.0

[18] PS 10.02.00 – Project Plan

[19] PS 10.02.00 – Configuration Management Plan

[20] PS 10.02.00 – Test Plan

[21] PS 10.02.00 – Test Summary Report

[22] PS 10.02.00 – Final Test Status Report

[23] PS 10.02.00 – Traceability Matrix

[24] PS 10.02.00 – Release Notes

[25] PS 10.02.00 – Project Closure Report
[26] PS 10.02.00 – Architecture Specification
[27] PS 10.02.00 – Supported Platforms Guide
[28] PS 10.02.00 – FRS Data Management
[29] PS 10.02.00 – FRS Execution Framework
[30] PS 10.02.00 – FRS Execution Viewer
[31] PS 10.02.00 – FRS Non-functional Requirements
[32] PS 10.02.00 – FRS Recipe and Workflow Management
[33] PS 10.02.00 – FRS Review and Approval
[34] PS 10.02.00 – FRS DCS Phases
[35] PS 10.02.00 – FRS EBR Phases
[36] PS 10.02.00 – FRS IPC Phases
[37] PS 10.02.00 – TM Installation
[38] PS 10.02.00 – Artifact Specific Risk Assessment
[39] PS 10.02.00 – System Impact Analysis (SIA) & Risk Assessment (RA)
[40] Implementation of 21 CFR Part 11 – FT PharmaSuite 10.02.00
[41] PS 10.02.00 – TM Administration
[42] PS 10.02.00 – TM Configuration and Extension, Volume 1 – 5
[43] PS 10.02.00 – TM Installation - Building Blocks
[44] PS 10.02.00 – TM Installation - Upgrade
[45] PS 10.02.00 – IG PS Administration
[46] PS 10.02.00 – UM Data Manager
[47] PS 10.02.00 – UM Production Management
[48] PS 10.02.00 – UM Production Execution
[49] PS 10.02.00 – UM Production Execution Viewer
[50] PS 10.02.00 – UM Production Responses
[51] PS 10.02.00 – UM Recipe and Workflow Management, Volume 1- 3
[52] PS 10.02.00 – UM DCS Phases
[53] PS 10.02.00 – UM Dispense and Weighing Phases
[54] PS 10.02.00 – UM EBR Phases
[55] PS 10.02.00 – UM Equipment Phases
[56] PS 10.02.00 – UM IPC Phases
[57] PS 10.02.00 – UM Material Tracking Phases

Note: For the DIR numbers and latest revisions of the PharmaSuite 10.02-specific documents, refer to “PS 10.02.00 - Documents and Approvals”, DIR 10005692395 /REV.

# Approvals

Approvals are captured electronically on the organization's Document Management System [6]. The required approvers of this document include the following:

| Name | Role |
|---|---|
| Andreas Grossmann | Product Manager |
| Steffen Landes | Development Manager |
| Eva Mueller | Test Manager |

# Revision History

The following table describes the history of this document. Each version has been approved per Document Management System [6].

| Version | Author | Description |
|---|---|---|
| 1.0 | Eva Mueller | Initial document creation |
| 1.0 | Ignaz Wangler | Final update of Appendix B: Test Equipment |

# Appendix A: System Boundary Definition

## Current Situation

PharmaSuite provides audit trail as required by regulations in different ways, see "Implementation of 21 CFR Part 11 – FT PharmaSuite 10.02.00" [40].

In addition, raw data is recorded for creation, modification, and deletion of objects in *Process Designer*. However, this data is neither exposed nor usable as is for audit trail review, reporting etc., but requires additional steps to become meaningful (*not subject to standard PharmaSuite product offering*).

Audit trail data for objects in *Process Designer* are not required by any regulation. The rationale is explained in further detail in subsequent sections.

*Process Designer* allows to implement a fine-granular authorization scheme on two levels: Access can be granted or denied on *object type* (e.g. "Lists") or *individual object* (e.g. list "CostCenters") level. Furthermore, different privileges can be assigned for different actions like creation, modification, and deletion.

## Controls for GMP Data

The basic question is: "Do all changes to data and records that (may) have an impact on data integrity or product quality need to be subject to a computer-generated audit trail or not?" From a compliance perspective, the answer is clearly "No".

Instead, a risk assessment should be applied. The result of this risk assessment identifies the critical data and records, describes the criticality and risk of uncontrolled changes and deletion, and defines risk management measures to eliminate, mitigate, or accept an identified risk.

Implementing (or activating) an audit trail is one amongst several possible measures, but clearly not the only one. Alternative measures must provide adequate controls and include, but are not limited to

1. the application of rigorous, documented change or version control (in combination with access control) or
2. security measures to prevent or avoid accidental and unauthorized changes (e.g. storage on read-only media).

## PharmaSuite's Boundary

### Drawing the Line

As any other system, PharmaSuite has a boundary. Within this boundary, PharmaSuite fully complies with GMP aspects, specifically the tracking of changes to GMP data that may have an impact on data integrity or product quality.

Some data that is managed in PharmaSuite – it should be distinguished from other data managed in other applications (e.g. *Process Designer*), thereby defining the boundary. This chapter should help with the disambiguation.

### Inside

All master and runtime data that can be created, altered, or deleted *by means of the PharmaSuite UI* is considered *inside*. "Implementation of 21 CFR Part 11 – FT PharmaSuite 10.02.00" [40] describes the various manifestations of audit trail for this data – the 'classical' audit trail for material, the transaction history for inventory objects, the change history and logbook for equipment, the batch record for produced batches, etc. All this data resides *inside* the boundary of PharmaSuite.

### Outside

All configuration and build-time data that *cannot* be created, altered, or deleted by means of the PharmaSuite UI (this data is typically setup once during system deployment) is considered *outside*. This data is subject to system validation and installation qualification processes. Changes in the operational phase may be recorded and made available via 'audit trail', but this is not a regulatory requirement. However, changes need to be controlled by means of good engineering practices.

This applies to many objects managed in *Process Designer* – incl. forms, reports, flexible state models etc. As changes to these objects can have a severe impact on the PharmaSuite application itself, access to this data needs to be strictly limited to dedicated persons. This is no different than access control to other deployment-relevant components like database or application server.

### Example

As an example and to highlight the different dimension and scope of a change, alterations to a master recipe can be made visible by the comparison capabilities in PharmaSuite and will be reviewed and approved before going into production. While an error (that would affect all future orders based on this master recipe) would already be serious, all other master recipes are not affected at all when changing a master recipe. In contrast to this, changes to the *MESMasterRecipeVersionGraph* flexible state model (FSM; the default version graph for master recipes) have a global impact on the review and approval workflow of all master recipes. This kind of change clearly requires different handling.

## Recommendation

When combining the previous sections, it becomes obvious that (changes to) GMP data *inside* PharmaSuite is handled differently compared to (changes to) GMP data *outside* this boundary: Whereas a comprehensive audit trail is available for the first, data outside of PharmaSuite requires rigorous, documented controls.

The basic assumption is that changes to configuration and build-time data are not daily business, but rather exceptions, justifying a more rigorous and securer process.

### Implementation of Controls

The various options to set up, administer, and configure PharmaSuite are described in several *Technical Manuals*. After the initial system setup (and validation), any changes to configuration and build-time data made outside of PharmaSuite require a defined change control process.

### Separation of Duties

The change control process applied to data in *Process Designer* should be reinforced by making adequate use of *Process Designer's* access privileges, thereby implementing a scheme to support clear *separation of duties*.

# Appendix B: Test Equipment

The following sections describe the hardware and software components used for testing of FT PharmaSuite 10.02.00. This does not mean that other hardware or software is unsuitable to run FT PharmaSuite 10.02.00.

In general, FT PharmaSuite 10.02.00 can run on any standard hardware that is sufficiently equipped regarding CPU, RAM, etc., so the listed servers and clients should be taken as examples only.

For suitable software components, please refer to the Supported Platforms Guide [27].

If different hardware or software components are used, the impact and risk of the different components should be evaluated and testing conducted, as appropriate.

## Server Hardware Components

All testing has been performed with logical servers running on Virtual Machines (VMs) using VMWare ESXi (nine logical server VMs for application (JBoss) and database (Oracle) servers and four server VMs for migration, running both). The five physical servers used for the system tests are listed in the following table:

| Server Name | CPU[4] | HDD | RAM |
|---|---|---|---|
| QAS003 | 2x Intel XEON 5110 / 1.6 GHz (4 cores) | 400 GB | 20 GB |
| QAS004 | 2x Intel XEON 5110 / 1.6 GHz (4 cores) | 350 GB | 20 GB |
| EUDEKARQAESXI1 | 2x Intel XEON X5660 / 2.8 GHz (24 cores) | 1.9 TB | 96 GB |
| EUDEKARQAESXI2 | 2x Intel XEON E5-2640 / 2.5 GHz (24 cores) | 1.9 TB | 262 GB |
| EUDEKARQAESXI4 | 2x Intel XEON E5-2620 / 2.4 GHz (24 cores) | 2x 5.46 TB | 196 GB |

The virtual machines for the twelve logical application (JBoss) and database (Oracle) servers running on the above-mentioned HW servers have been configured as follows:

| VM Name | Server Name | Purpose | HDD | RAM |
|---|---|---|---|---|
| QAS001 | EUDEKARQAESXI2 | JBoss | 50 GB | 12 GB |
| QAS002 | QAS003 | JBoss | 50 GB | 12 GB |
| QAS003[5] | QAS004 | JBoss | 50 GB | 12 GB |
| QAS004[3] | EUDEKARQAESXI2 | Oracle | 40 GB | 4 GB |
| QAS005 | QAS003 | Oracle | 40 GB | 4 GB |
| QAS006 | QAS004 | Oracle | 40 GB | 4 GB |
| QAS008 | EUDEKARQAESXI1 | Oracle | 40 GB | 4 GB |
| QAS012 | EUDEKARQAESXI2 | JBoss | 50 GB | 12 GB |

[4] The number of cores is based on hyper-threading, i.e. the physical number of cores is half of it.

[5] The “identical” names do not create any conflict, as the name spaces of logical VMs and HW servers is isolated.

| VM Name | Server Name | Purpose | HDD | RAM |
|---|---|---|---|---|
| QAS013 | EUDEKARQAESXI2 | JBoss | 50 GB | 12 GB |
| QAS014 | EUDEKARQAESXI4 | Oracle | 40 GB | 4 GB |
| QAS015 | EUDEKARQAESXI4 | JBoss | 50 GB | 12 GB |
| QAS016 | EUDEKARQAESXI4 | JBoss | 50 GB | 12 GB |

The virtual machines for the logical migration servers running on the above-mentioned HW servers have been configured as follows:

| VM Name | Server Name | Purpose | HDD | RAM |
|---|---|---|---|---|
| QAS010 | EUDEKARQAESXI4 | JBoss + Oracle | 40 GB | 8 GB |
| QAS011 | EUDEKARQAESXI4 | JBoss + Oracle | 40 GB | 8 GB |

## Client Hardware Components

The physical VMWare ESXi servers EUDEKARQAESXI1, EUDEKARQAESXI2, and EUDEKARQAESXI4 (see above) also host the 22 client VMs (EUDEKARQAESXI1 hosts 11 logical clients, EUDEKARQAESXI2 seven, and EUDEKARQAESXI4 4). All logical clients are configured with disk space (HDD) of 50 GB and memory (RAM) of 4 GB.

In addition, 2 physical clients have been used, e.g. for tests requiring access to physical hardware like barcode scanner or scale. Both physical clients are equipped with an Intel Core i5-2400 3.1 GHz CPU, disk space (HDD) of 250 GB, and memory (RAM) of 8 GB.

## Server Software Components

Please note that the language configuration of the operating system for the test system must be English[6].

### Database Server

| Type of Software | Software and Version |
|---|---|
| Operating System | Microsoft Windows 2016 Server Standard |
| DBMS | Oracle 12c Server (Enterprise), 12.2.0.1 |

### Application Server

| Type of Software | Software and Version |
|---|---|
| Operating System | Microsoft Windows 2016 Server Standard |
| Application Server | JBoss Enterprise Application Platform 7.2.6 |

## Client Software Components

| Type of Software | Software and Version |
|---|---|
| Operating System | Microsoft Windows 10 Enterprise LTSC |
| Browser | Google Chrome<br>Version: 92.0.4515.131 |

[6] Locale = English (U.S.)