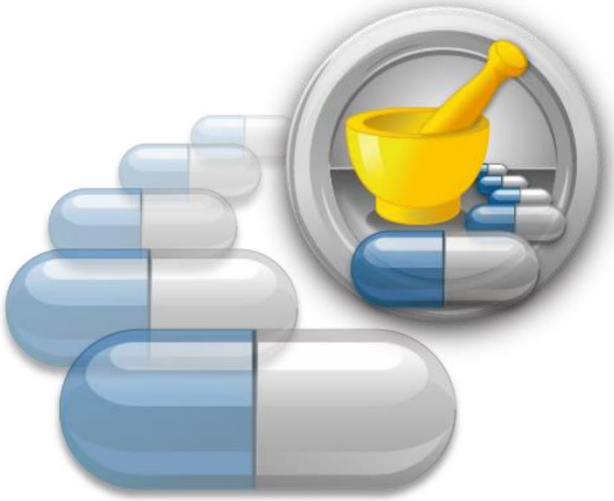
PharmaSuite 8.4

Quality Certificate



This document has been reviewed and approved electronically via Rockwell's Document Management System [1].

This document contains information which is confidential and proprietary.

DIR: 10003305481/PUB

Revision: 1.0

Period of Validity

This document is valid for the release on the cover page – PharmaSuite 8.4.

Introduction

PharmaSuite® is a suite of software applications that is tailored to the needs of the Pharmaceutical and Biotech manufacturing industry. Special regulations are in place for these industries, and many of them also apply to software that is used during the course of production of a drug product or medical device. Therefore, the software has to be developed under consideration of the pertinent regulations and related requirements. In addition, appropriate validation of the deployed software system has to be performed before it can be used in the production environment.

PharmaSuite® is developed under consideration of all pertinent regulations that are relevant for its use in the Pharmaceutical and Biotech manufacturing industry. This is particularly true for the features of the software itself, but also for the process how the software is developed, which is based on a mature Quality Management System. Moreover, PharmaSuite® includes extensive technical, functional, and quality documentation. With that, PharmaSuite® includes all prerequisites required for a successful deployment and validation at customer's site.

Quality Certificate

This Quality Certificate provides evidence that the activities that were planned and subsequently executed to design, develop, and test PharmaSuite 8.4 have been successfully completed according to the principles defined in PharmaSuite's Quality Management System (QMS) [2]. Product- and project-specific adaptations have been described in the Project Plan [6], the Configuration Management Plan [7], and the Test Plan [8] for PharmaSuite 8.4.

The Quality Document [13] provides a more detailed elaboration of quality-related activities performed for this release. It also includes a list of all qualification documents supporting this Quality Certificate. Registered customers can obtain the Quality Document on request. In addition to that, Rockwell Automation provides customers access to the complete quality documentation of every release during an official audit.

PharmaSuite 8.4 underwent extensive tests in several test phases. Testing results have been summarized in the Test Summary Report [10]. All completed test cases and their result are listed in the Final Test Status Report that has been generated out of the test management tool [11]. All acceptance criteria of the single tests of the different test phases are fulfilled as described in the Testing Guideline [9] and as mandated by the underlying QMS procedures [2]. This Quality Certificate certifies that these tests have successfully demonstrated the functional correctness of PharmaSuite 8.4 in all GxP-relevant aspects.

All deviations have been managed according to the change control procedures and guidelines ([3] and [4]) in the deviation management system. Deviations relevant for customers have been documented in the Release Notes [12].

In case of changes applied to PharmaSuite 8.4, additional testing may be limited to changed or enhanced parts only. For all unchanged parts, the release documentation of PharmaSuite 8.4 may be referenced, provided appropriate change control mechanisms are being applied.

Released Product Information

Product Name / Version	PharmaSuite 8.4
Release Build Number[1]	8.4.0.6

Note:

PharmaSuite 8.4 is an extension of PharmaSuite 8.3 (see [4]). It is backward compatible except for the changes listed in the Release Notes [12]. [2]

[1] For individual build numbers of phases released in conjunction with PharmaSuite 8.4, please refer to the *PharmaSuite 8.4 – Building Blocks – Compatibility Matrix* [14] which also documents compatibility between PharmaSuite and building block versions.

Test Scope Statement

Functionality provided by the underlying software,

- ProductionCentre 10.4 Build 106677,
- and various commercial (COTS) and open source software (OSS) components used,

has generally not been tested explicitly (unless otherwise mentioned), but implicitly through the functionality tested for PharmaSuite 8.4.

As an example, the JGraph library listed as one of several 3rd party components used within PharmaSuite 8.4 (see Release Notes [12], Appendix C - Open Source License Agreements) is used to draw the graphical layouts of S88 master recipes and master workflows, thereby supporting the recipe and workflow authors. Many test cases have been specified and executed to verify the correctness of inserting new elements, moving or replacing elements etc.

Another example is the usage of ProductionCentre functionality. Working with activity sets is implicitly tested by generating and executing production orders or workflows out of S88 master recipes or master workflows, whereas user and user group management is explicitly tested, as these functions are used 1:1 in PharmaSuite 8.4.

References

Copyright of all reference documents by Rockwell Automation:

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

[2] Life Sciences Quality Management System (QMS), https://rockwellautomation.sharepoint.com/teams/AS/ISPB/PMO/MES/pharmasuite/LSQMS/

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

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

[5] PharmaSuite 8.3 – Quality Certificate, DIR 10002925761/PUB, Rev. 1.0

[6] PharmaSuite 8.4 – Project Plan, DIR 10003202609/PRJ, Rev. 1.3

[7] PharmaSuite 8.4 – Configuration Management Plan, DIR 10003202610/PLN, Rev. 1.1

[8] PharmaSuite 8.4 – Test Plan, DIR 10003202611/PLN, Rev. 1.0

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

[10] PharmaSuite 8.4 – Test Summary Report, DIR 10003547210/REV, Rev. 1.0

[11] PharmaSuite 8.4 – Final Test Status Report , DIR 10003547212/REV, Rev. 1.0

[12] PharmaSuite 8.4 – Release Notes, DIR 10003224098/PUB, Rev. 1.1

[13] PharmaSuite 8.4 – Quality Document, DIR 10003305482/PUB, Rev. 1.0

[14] PharmaSuite 8.4 – Building Blocks – Compatibility Matrix, DIR 10003224093/FRM, Rev. 1.0

Revision History and Approvals

Revision History

The following table describes the history of this document. Each version has been approved per Document Management System [1].

Version	Author	Description
1.0	Martin Irmisch	Initial document creation

Approvals

Approvals are captured electronically on the organization's Document Management System [1]. The required approvers of this document include the following:

Name	Role
Martin Dittmer	Product Manager
Steffen Landes	Development Manager
Martin Irmisch	Test Manager