

Betreff Audit Report BDD OQ Prototyp
Thesis Sabrina Leuenberger

Contents

1	Summary.....	2
1.1	Audit purpose.....	2
1.2	Audit scope.....	2
1.3	Audit Process.....	2
1.4	Conclusion	3
2	Classification of findings.....	3
3	Audit checklist: Testing.....	4
4	Observations and recommendations.....	5
5	References.....	6

1 Summary

Audit date: 22-JUN-2020 (10h-12h, 13h30-16h)

Attendees: Sabrina Leuenberger (auditee), Mathias Fuchs (partially)

Performed by: Evelyne Daniel (auditor)

1.1 Audit purpose

This audit is performed in the context of the thesis "BDD - A Practicable Approach for Computerised System Validation" from Sabrina Leuenberger, student in the University of Applied Sciences Northwestern Switzerland.

The goal of the thesis is the evaluation of test automation for OQs within a BDD (Behavior Driven Development) framework and in accordance to GAMP5 for a category 5 software. In the context of this evaluation, a prototype based on automation tools has been developed.

The purpose of the audit is to assess if the prototype incl. related documentation meets quality standards for GMPs quality systems (e.g. GAMP5).

1.2 Audit scope

- Thesis "BDD - A Practicable Approach for Computerised System Validation"
- OQ testing process using automation tools
- OQ execution for the JBA application v.1.1.0.0 (business application, test object for the prototype) using automation tools
- OQ test evidences, traceability and documentation

Out of scope of the Thesis and therefore of the audit:

- Document management (versioning, electronic signatures, template optimization, template handling, Approvals of executed test documents)
- Validation of the Testing Tools (Selenium, Scenariio, Cucumber/Gherkin, Cucumber Selenium plugin, OQ Test App)
- SOP Software development with BDD (assumption: SOP covers change management, Set up OQ test app, Glue code versioning in sync with App version, code review of glue code, tester training).
- Test plan describing the entire verification process, related required roles, IQ process, explorative testing.

Note: At the time of the audit, an "OQ rational" document was handed out to the auditor explaining several aspects relevant for the development of the test strategy especially regarding the risk based approach. As outcome of the audit it has been agreed to include these explanations into the thesis work.

- User requirements

1.3 Audit Process

The audit was performed as follow:

- Step by step explanation of the OQ Process considering BDD, set up and use of test automation tools by the auditee
- Review of the OQ documentation templates to be used for test execution & test review
- Review of the OQ documentation generated for the OQ of the JBA application v.1.1.0.0
- Additionally, in order to better assess the suitability of the process,

- Execution of the OQ test by the auditee using the “OQ Test app” on the JBA application v.1.1.0.0
- Review of the Test results in Scenarioo by the auditor using the Test Report form

1.4 Conclusion

Repeatable processes have been demonstrated for the OQ testing of GMP computer systems. Processes related to the definition, development, and validation, release, maintenance and retirement were not in scope of the audit. However especially aspects around definition (specification), release and maintenance were also considered where required for the OQ testing process.

Some minor deficiencies and recommendations have been identified, those are mainly needed to improve the robustness of the OQ process. These findings should not be regarded as being a comprehensive inventory of all existing GMP deficiencies; they represent only those deficiencies identified by the auditor. However, the recommendation made have no major impact on system or process quality.

Overall the audited area meets GxP quality standards and demonstrates compliance to GxPs quality systems.

2 Classification of findings

- **Critical**

A deficiency, which has produced, or leads to a significant risk of operating a system which is evaluated to present a major breakdown of a quality system element, including any finding that involves fraud, misrepresentation or falsification of products or data. Critical findings will compromise the success of inspections by health authorities / customers or could possibly lead to a recall of product.

- **Major**

A non-critical deficiency which has produced or may produce a system / process that does not comply with GMPs and / or internal quality systems or which indicates a failure to carry out satisfactory procedures for the operation of a system. Major findings may potentially compromise the success of inspections by health authorities / customers.

- **Minor**

A deficiency which cannot be classified as either critical or major, but which indicates a departure from current Good Manufacturing Practice, or applicable software procedures or industry standards

- **Recommendation**

A recommendation is not considered a deviation from current Good Manufacturing Practice but represents a departure from best practice; represents an opportunity for process / quality improvement.

3 Audit checklist: Testing

Question	Answer
Do planned testing activities include unit, integration, system, and release testing? Please shortly explain all types of testing performed before release of software products.	Yes, focus here is on OQ, well explained in the "OQ rational" [Ref-1] (content to be included in the thesis, see note in 1.2 out of scope)
Is there written policy for testing process? If yes, please provide a reference (ID).	Yes, test specification v.1.1.0.0 [Ref-2] Note: Test specification is referring to test plan and SOP (which are out of scope of the thesis)
Does the testing procedures describe: <ul style="list-style-type: none"> • How test documents are developed and managed (reference) • What types and levels of testing are required? (reference) • How test outcomes are analysed for acceptability? (reference) 	Yes, focus here is on OQ, see test specification v.1.1.0.0 [Ref-2] Note: Test specification is referring to test plan and SOP (which are out of scope of the thesis)
Do the written procedures describe which organizational groups are responsible for testing, reviewing, release, track of errors etc.? If yes, please provide a reference.	Written procedures in the test specification v.1.1.0.0 [Ref-2]
Does all testing documentation contain the information like Document Title and Version, or Accountability Signatures?	Principally Yes, test result v.1.1.0.0 [Ref-3], test report v.1.1.0.0 [Ref-4], feature files. Review approval feature files according to defined process: file consent_management feature is signed from SME and PO. See observation #6 Note: document management is out of scope of the thesis, see 1.2
Does test design documentation contain <ul style="list-style-type: none"> • References for traceability to the component's design and requirements specification? • Data and test equipment specification? • Criteria for acceptance/release of test component? 	Yes, see feature file and test specification v.1.1.0.0 [Ref-2] and referring to test plan and SOP (which are both out of scope of the thesis, see 1.2)
Do completed test cases contain the following information: Documented test cases with defined inputs, expected outputs, and actual outputs, tester and eye witness if necessary.	Yes, see test specification v.1.1.0.0 [Ref-2] test result v.1.1.0.0 [Ref-3], test report v.1.1.0.0 [Ref-4], referring to test plan and SOP (which are both out of scope of the thesis, see 1.2) See observation #4

Question	Answer
Are automated testing tools in use? If yes, which tool and is that procedure validated? If so: for what tests and is it verified?	Yes, tools are used and validated. Validation of those itself is out of scope of the thesis. Only the use of it in the OQ context is part of the thesis and the verification process is well defined especially using the test results form to document the test set up and test execution. Automated test scripts should be controlled in accordance with a documented procedure. Feature files & glue code are described in the test specification v.1.1.0.0 [Ref-2]. Could be integrated in the "Software Coding Guideline SOP" in future. See observations #1, #2, #3, #5, #7

4 Observations and recommendations

#	Checkpoint	Observations	Classification
1	Specification document for JBA v1.1.0.0	The boundaries between "OQ test app" as part of the testing environment Tools and it's "configuration" in order to perform the OQ of the JBA application could be better described. It could also be described how the "OQ test app" is managed (change of glue code files). Validation of the Tools, see "assumptions and out of scope".	Minor
2	Specification document for JBA v1.1.0.0	Changes between JBA v1.0.0.0 and JBA v1.1.0.0 are not clearly documented. Recommendation: refer to a change document or describe the changes. Document why partial or why full review is needed based on the changes.	Minor
3	Result document for JBA v1.1.0.0	Documentation of integration of glue code in the "OQ Test app" not clearly stated (see observation #1). Segregation IQ app and set up OQ app to be better addressed (see observation #1).	Recommendation
4	Result document for JBA v1.1.0.0	Address clearly which steps are verification steps and which steps are execution steps e.g. set up of the "OQ Test app".	Recommendation

#	Checkpoint	Observations	Classification
5	The computer generated logs resulting from the execution of the automated test scripts are normally automatically from the execution of the scripts.	Yes, however the logs are not kept, only the files being then viewed in Scenarioo. Logs could be additionally kept or it should be documented why there is no added value in keeping those.	Minor
6	Review process	Location of files: test reviewer must perform some "setup" steps (unpack zip and save folder at right place) in order to be able to review test results in scenario. This is a Workaround that could be automated in future (OQ test app to create folder at right place).	Minor
7	Review process	Process is well defined, some improvements of the Test Report form can be done. Furthermore the use of the compare function in Scenarioo could be implemented in future.	Recommendation

5 References

#	Document
Ref-1	OQ Rational
Ref-2	Test Specification Version 1.0 – ID: Doc_JBA_v.1.1.0_TS_OQ
Ref-3	Test Results Version 2.0 – ID: Doc_JBA_v.1.1.0_TER_OQ
Ref-4	Test Report Version 2.0 – ID: Doc_JBA_v.1.1.0_TRep_OQ