

viedocTM

Validation Summary

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Document History

Version	Author	Date	Change
1	Alan Yeomans	2018-03-08	Initial version
2	Alan Yeomans	2019-09-11	Renamed to "Validation Summary" (from "Validation Policy")
3	Alan Yeomans	2021-09-15	Updated company name to Viedoc from PCG Added IQ/OQ on Training and Production instances
4	Alan Yeomans	2023-09-26	2.1 – replaced "user stories" with "acceptance criteria" 2.2 – updated reference to TFS to Azure DevOps 2.3 – updated description of scripted tests, simplified explanation about linking of text cases and test results. Moved to new template.
5	Marialuisa Baldi	2024-09-24	Update in chapter 2.3: Regression testing details
	Tobias Jakobsson	2024-09-24	Update in chapter 2.4 to reflect the current procedure

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1 PURPOSE

This document describes the principles and methods used for validation of products at Viedoc Technologies. This is a summary of the validation activities performed, the details of each respective activity are covered in SOPs from the department responsible for the activity in question.

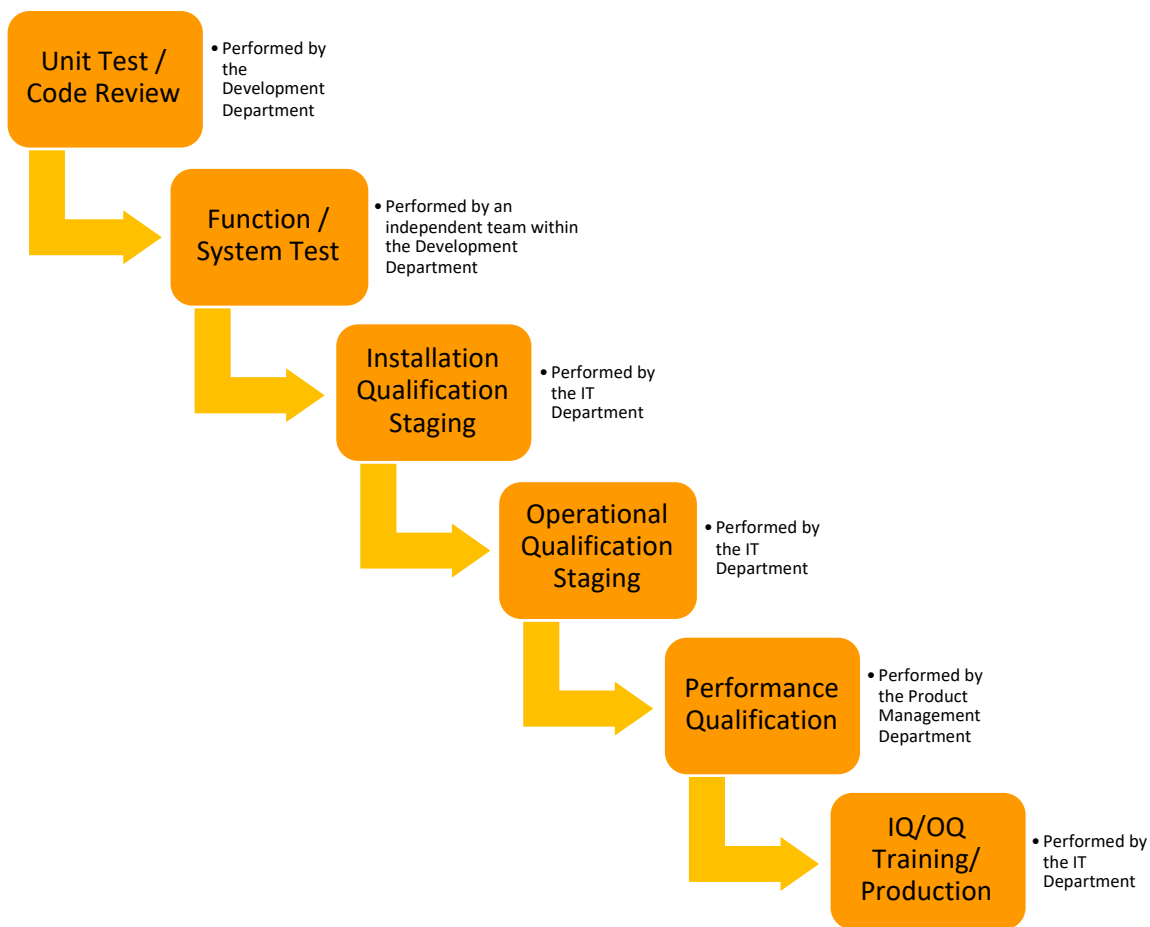
1.1 Scope

This Validation Summary covers the traceability of the validation performed (how to trace the validation back to the requirements) and how the results of the validation are documented for each activity.

2 VALIDATION ACTIVITIES

Viedoc Technologies does not use projects for product development and therefore at Viedoc we have chosen to document how we perform validation in our SOPs, and this document summarises the content of those SOPs. The same validation principles and methods are employed for all products and releases developed by Viedoc Technologies.

The following are the validation activities performed at Viedoc Technologies. After the diagram a summary of each validation activity is given.



2.1 The Viedoc Repository

The Viedoc product development environment uses Azure DevOps from Microsoft as a repository for all:

1. High level feature descriptions (high level EDC functions, such as Randomization, Medical Coding, etc.)
2. Individual requirements (described by acceptance criteria) detailing the implementation of those features
3. Bugs
4. Source code
5. Builds
6. Test Cases (Manual, Automated, Regression, UAT)
7. Test Results

Azure DevOps links all the above with version specific links and maintains a full 21 CFR Part 11 compliant audit trail to cover all changes to everything in the repository. The Viedoc Azure DevOps repository is available for audit/inspection by appointment with the QA department at Viedoc Technologies.

2.2 Unit Test / Code Review

Unit test and code review are validation activities performed by the system developers during the programming phase. Risk evaluation is part of the sprint planning process.

Unit tests are written by the programmer while they are writing (or modifying) the source code. Unit tests are automatic test cases. All Viedoc unit tests are automatically executed every time the source code is built. Viedoc implements daily builds, so these tests are run daily (or more often). The results of the unit testing are reported by the build tool, which is integrated into the Viedoc repository. The build automatically fails if any of the unit tests fail, and the source code needs to be corrected and the unit test passed before the next build will pass. Records of all builds are kept in Azure DevOps so that the history of the release build of any version of Viedoc can be examined, as well as the builds leading up to that release. The results of the unit testing are summarized in the Validation Summary Report for the release.

Code review is mandatory before the code is merged into the destination branch in the code repository. Code review is performed either by another programmer or by the system architect. The results of the code review are documented when the source code is merged with the main branch in Azure DevOps. In addition, static code analysis tools are used to analyse the code for anti-patterns or security issues.

2.3 Function / System Test

Function and system testing are different names for the same thing at Viedoc. The name function test is derived from the fact that most of the testing performed at this level is with regards to functional requirements. The name system test simply recognizes that occasionally non-functional requirements are also tested (i.e., performance requirements). The same methodology is employed irrespective of whether the requirements are functional or non-functional.

The goal of this testing is to confirm that the implementation fulfils the requirements, i.e., to validate the product implementation against the requirements placed on the product. Function testing is performed by a different member of the system development team than the programmer and consists of exploratory testing and scripted testing. In addition to function testing, regression testing is part of the development process to verify that existing functionality is not broken by the new implementation.

Exploratory tests are not predefined but are rather focused on testing a given requirement using an approach of simultaneous learning, test design, test execution and test result documentation. Exploratory tests are documented in one test result object in the Viedoc repository, i.e., the test steps and the test results are documented together and linked to the requirement being tested.

Scripted tests are predefined test cases with detailed preconditions, steps to be executed and expected outcomes listed. Scripted test cases are designed in collaboration between the product owner, programmer(s) and tester(s). The collaboration of these three roles ensures a shared understanding of the acceptance criteria and that the test case covers and verifies the expected behaviour of the implemented functionality. The results of scripted tests are stored in separate test result objects linked to the test cases in the Viedoc repository. Regression testing is performed continuously during development by running automated tests.

At the time of code freeze for the release,

regression testing is performed on the release candidate and consist of both automated and manual testing. The manual tests are selected based on the impact assessment analysis performed on new functionality introduced in the new Viedoc release. The regression testing is summarized in Azure DevOps in a test report, with reference to different manual and automated test results.

All test cases and test results are stored in the Viedoc repository and are linked to the requirements they test.

2.4 Installation Qualification on the Staging Server

When a new product or a new version of Viedoc is to be released, a build for the version is delivered by the development department. IT operations are then responsible for deploying this build on the staging servers.

Installation Qualification ensures that the exact content released by the development department (in terms of modules and versions of the modules) and the exact configuration of the server environment (operating system version, database version, other software infrastructure products) are included in the installation. This is done by utilising the version(s) output from the deployment pipeline to ensure the integrity of the build and verifying that all software components are in place and on the correct version. The versions outputted from the deployment pipeline resides in an

immutable release bundle artifact which contains all the versions of the modules that are included in a release. Installation Qualification on the staging server is performed and documented as part of the release documentation for every release of the product.

2.5 Operational Qualification on the Staging Server

After completing the Installation Qualification an Operational Qualification is executed on the staging server to ensure that all core functionality operates as expected.

Operational Qualification of the staging instance of Viedoc (used to perform Performance Qualification) is documented as part of the release documentation for that release.

2.6 Performance Qualification

The goal of performance qualification is to confirm that the delivered product is fit for use, i.e., that Viedoc will work as intended. While function testing will typically find errors where the product implemented does not fulfil the requirement as stated, performance qualification will typically identify weaknesses where the requirements themselves are faulty (for example have been incorrectly analysed or have missed certain conditions).

Performance qualification is scenario-based, designed around using Viedoc in the same way it will be used in a clinical research setting. Performance qualification includes a great deal of regression testing, aimed at ensuring that existing functionality is not affected in new releases. Performance Qualification is performed and documented for every release of Viedoc. These documents are stored together with the other release documentation for that release.

2.7 Installation Qualification and Operational Qualification on Training and Production Servers

Once the Performance Qualification has been performed on the staging server and Viedoc has been approved for release it is ready to be released to the training and production servers.

Installation Qualification and Operational Qualification are performed on every instance that is upgraded to the new version of Viedoc, and on every new instance of Viedoc taken into operation. The results of these qualifications are documented and stored as part of IT Operations documentation.