Verification and Validation

Verification

Verification of a software product will confirm via objective evidence (e.g. via testing) that specified requirement have been fulfilled. In other words, verification is testing against the software- and system requirements.

For verification, a set of tests is executed in order to ensure all requirements are covered. Verification is executed on both software as system level.

Test cases specifications include trace to the requirement under test, test environment, pass / fail criteria, expected outcome and test steps. The specs are reviewed and approved. Tests are executed and results recorded in test reports. If tests fail, problem report are written describing the failed test.

Problem reports are to be evaluated on cause, relevance to safety (via the risk management process) and possible solution. Next, the software including applicable documentation (e.g. design) is updated to solve the problem. Regression tests are defined and executed: retest of certain unit tests and/or system verification tests to show that the change did not adversely affect other parts of the system. If all tests pass, the problem report is resolved.

If all test cases finally pass, the software has passed the verification phase.

Validation (including Clinical Evaluation)

Validation of a software product will confirm via objective evidence that the user needs and intended use as defined in the user requirements has been fulfilled. Methods to obtain the evidence are bench testing (simulation), literature assessment, pre-clinical tests (animal study) and/or clinical investigation (humans involved). For bench tests, verification is used.

Via the Clinical Evaluation process clinical safety and performance is demonstrated. Evidence is based on clinical data (literature assessment and /or clinical investigation). Whether clinical investigations are needed depends on the risk-benefit analysis from the risk management process combined with the results of the literature assessment (providing evidence of equivalent safe software products on the market).

The following standards & guidelines are applicable for Clinical Evaluation.

- EN ISO 14155, Clinical investigation of medical devices for human subjects
- MEDDEV 2.7/1, Clinical evaluation: Guide for manufacturers and notified bodies
- MEDDEV 2.7/4, Guideline on Clinical Investigations
- MEDDEV 2.12/2, Post Market Clinical Follow-up studies

For clinical investigations, a strict protocol according ISO14155 is to be followed.

If all tests have passed and the benefits have been validated, the software has passed the validation phase.