

# Cost effective test management Quality Center – 21 CFR Part 11 Compliant test management tool

## Test – the crucial part of validation.

Short time-to-market is crucial for the life sciences industry. And the industry increasingly relies on IT solutions in all phases from R&D to Manufacturing.

All IT solutions and equipment which may have a direct or indirect impact on a pharmaceutical product must be validated. Test is a core validation activity - and validation and test activities which meet FDA requirements are very time and resource consuming.

Quality Center from HP is a test management tool which optimises test planning, execution and monitoring significantly.

NNIT's implementation of Quality Center is qualified and 21 CFR Part 11 compliant. Quality Center includes:

- Traceability to requirements
- Testcases are prepared, approved, executed and filed in Quality Center
- 21 CFR Part 11 compliant electronic signature on test cases and test results
- Easy reporting on test coverage, test progress, defects, retest etc
- Easy reuse of test cases
- Possibility for execution of automatic test scripts.

## Business Case

Typical test tools are Excel spreadsheets and Word documents - especially in the pharmaceutical industry where formal approval - including signature - of test plans, test cases and test results are required.

Most project and test managers will recognise the following time consuming challenges:

- Breakdown of Excel and Word documents when they become too large
- Difficult to find and reuse test cases or test steps
- Paper copies of test cases and test result are lost e.g. mislaid or someone else took the print by mistake
- Distribution logistics of test cases and test results when test takes place at more sites
- Problems of getting an overview – how many test cases have been prepared and executed, how many defects have been found, corrected and retested
- Reporting is difficult – manual review and calculation of test cases and defects

All the above challenges – and many more – take time and resources - besides giving less test coverage and larger risk of malfunctioning solutions.

Calculations show that projects can achieve considerable time savings in test planning and test execution – up to 50% or even more.

This means ROI can easily be achieved for the investment in the necessary tools – and the additional benefit of a much higher test quality.

## Quality Center – a Software as a Service (SaaS) solution

A Quality Center SaaS solution includes:

- Access to a unique and secure test repository for each project
- Specific number of simultaneous testers as agreed
- Customer administration of own test project
- NNIT operation and surveillance of server, database and Quality Center application
- Technical and functional support
- Backup of test data
- User administration.

Recommended services are:

- 1 day introductory course to Quality Center for testing personnel
- 2 day introductory course to Quality Center for test project administrator/test manager
- Test Management consultancy – planning and monitoring of test activities on time and material basis.

NNIT also uses Quality Center in-house to plan and execute tests in projects delivered to clients, and has through that achieved significant benefits.

We provide a Quality Center SaaS solution directly to customers that want to optimise their test and validation efforts.

## Further information

Please contact us at [nnitcontact@nnit.com](mailto:nnitcontact@nnit.com) for further information.

Date: 2008.10.06., Ver. 1, Author: BjW App.: ToT  
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