

1. PURPOSE

Software and computer systems used in analytical laboratories should be validated for compliance and business reasons. Validation helps to generate accurate, reliable and consistent analytical results. This SOP gives guidelines on how to validate computer systems used in analytical laboratories.

2. SCOPE

Validation of computer systems used in analytical laboratories that have an impact on product quality. Validation includes all lifecycle phases from system planning to retirement. The focus is on validation of commercial off the shelf system. Not in the scope of this SOP are the qualification of analytical equipment, for example testing the baseline noise of an HPLC detector and details of validation activities as required during development of software. Exceptions from this procedure are possible but should be based on risk assessment, and justified and documented and approved by lab management and QA.

3. GLOSSARY/DEFINITIONS

Item	Explanation
Validation	Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specification (<i>Source: FDA guidelines on General Principles of Validation, March 1986</i>).
DQ	Design qualification
IQ	Installation qualification
OQ	Operational qualification
PQ	Performance qualification
URS	User requirement specifications
FS	Functional specification
GAMP	Good Automated Manufacturing Practice (Forum). The GAMP Forum exists to promote the understanding of the regulation and use of computer and control systems within the

5.2.1. Provides inputs for requirement specifications.

5.2.2. Provides resources for testing.

5.2.3. Reviews and approves validation documents.

5.3. Laboratory staff representatives

5.3.1. Provide input for system requirement specifications.

5.3.2. Review system requirement specifications.

5.3.3. Advice on risk assessment.

5.4. IT Department

5.4.1. Advices on risk assessment and extent of testing related to network infrastructure

5.4.2. Reviews and approves validation documentation related to network infrastructure

5.5. Vendor

5.5.1. Provides functional specifications of the software and computer system

5.5.2. Provides documented evidence that the software has been developed in a quality assurance environment and has been validated during development

5.5.3. Accepts vendor audits, if necessary.

5.5.4. Provides information on how to prepare the site for installation of the computer system.

5.6. Plant maintenance

5.6.1. Prepares site for installation of the computer system according to site preparation information provided by the supplier of the computer system.

5.7. Quality Assurance

5.7.1. Advises on regulations and guidelines related to GxP and 21 CFR Part 11.