

Validation of laboratory information and management systems (LIMS)

The situation

Nowadays laboratory information and management systems are an essential part of modern laboratory organisation. These systems are in use for tests description planning and execution and provide modern tools of data acquisition, analysis and storage. It is not relevant, whether an LIMS is established in a standard configuration or whether it is a flexible system directly adapted to its environment. In both cases validation has to be carried out according to actual GxP guidelines.

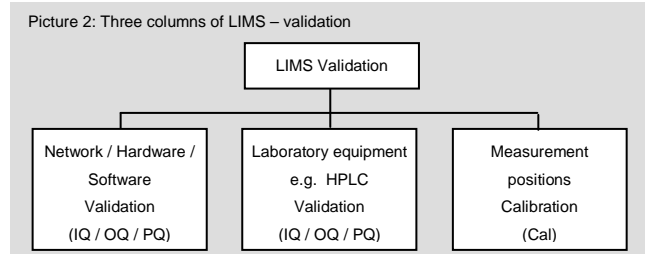
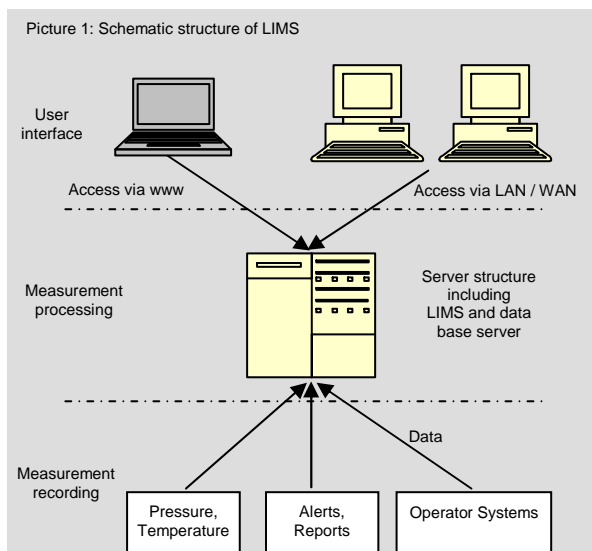
System description (picture 1)

LIMS, mostly configured as application systems operating with data bases, normally display the following components:

- Data base server (with LIMS data base)
- Desktop computer
- Network infrastructure
- Hardware clients (e.g. HPLC)

Setup of validation

A validation plan describes the necessary activities (RA, DQ, IQ, Cal, OQ, PQ), the responsibilities, basic guidelines and regulations (e.g. 21 CFR Part 11 / 210 / 211 / 820, EU-GMP, USP, AMG, DIN-ISO, etc.).



Important aspects of validation (picture 2)

Design Qualification (DQ)

Cross check, whether the LIMS user requirements specifications correspond to the supplier documentation.

Risk analysis (RA)

In a risk analysis all components and functionalities of a LIMS are evaluated according to quality relevance. Especially requirements resulting from 21 CFR Part 11 (e.g. audit trail, user administration or special safety means preventing manipulation of data are considered). Based on the result of the risk analysis further validation steps are carried out.

Installation Qualification (IQ)

During this phase installation of hard- and software and of correct configuration of the system will be checked. Further on system documentation and all relevant user documents, e.g. SOPs, will be evaluated.

Calibration (Cal)

All quality relevant measurement positions identified throughout risk analysis will be calibrated.

Operation Qualification (OQ)

During operation qualification functionality of hard- and software, example given data acquisition, processing and display or data exchange at internal and external intersections, e.g. with SAP R3 system will be tested.

Performance Qualification (PQ)

During this phase relevant functionality of the LIMS is checked under realtime conditions.