

Validation of computer networks

The Situation

Integrated and disseminated computer networks belong to the standard of GxP regulated industrial areas. Qualification and validation of this part of computerized systems is mandatory and in the focus of relevant authorities.

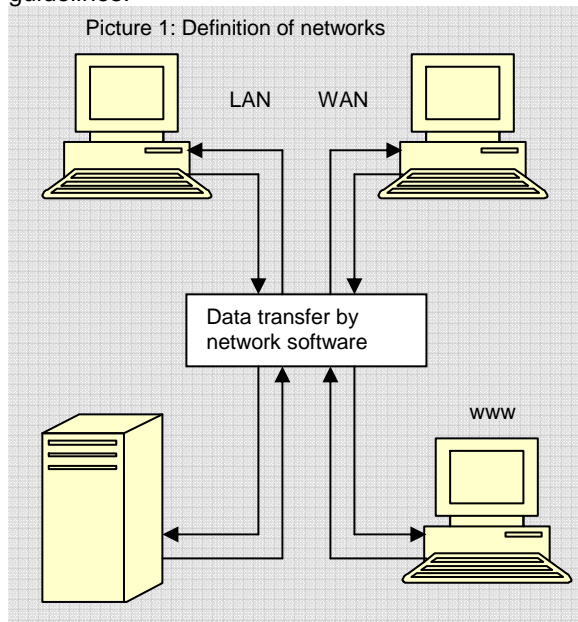
System description (Picture 1):

(W)LAN	(Wireless) Local Area Network
WAN	Wide Area Network
MAN	Metropolitan Area Network
GAN	Global Area Network

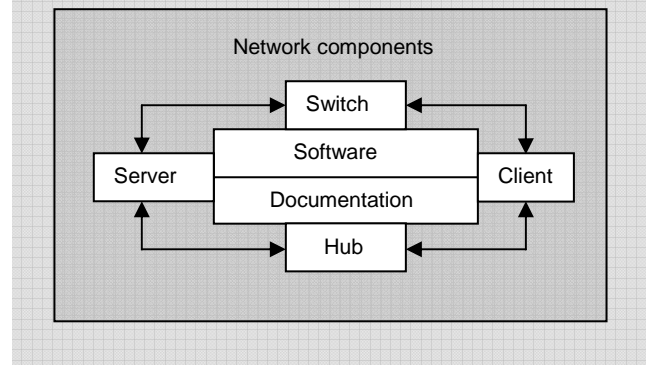
Setup of a validation procedure

There is a main difference in execution and structure and amount of validation activities between a new system (prospectively, V-model, lifecycle) and an established system (retrospectively, experience reports, evaluation) is considered.

A validation plan is the basis for all activities. In this plan the sequential steps of the validation, risk analysis, DQ, IQ, OQ and PQ are named in accordance with the responsibilities and relevant guidelines.



Picture 2: Network validation



Examples for current laws and guidelines:

AMG (German Drug Law), PharmBetrV (Pharmaceutical regulation), 21 CFR 210/211 cGMP, CFR 21 part 11, ICH, GAMP 4, PLS GAMP, Namur, ANSI / IEEE 828, 1042, IT protection booklet

Important aspects of validation (Picture 2):

Risk analysis:

Evaluation of single components (Hard-, Software) of the computer network as the functional and regulatory prerequisite for safety of data transfer.

Design Qualification (DQ):

Cross check of the user requirements specifications and supplier documentation.

Installation Qualification (IQ):

Test of correct installation of hardware (e. g. clients, surfers, hubs, switches) and of software components.

Operation Qualification (OQ):

Examination of functionality of all hard- and software components and security integrity of data delivered via network.

Performance Qualification (PQ):

The System will be checked under standard conditions.

Summary:

Using a knowledge based and well documented risk assessment approach we are able to minimize the required IQ, OQ and PQ tests to the necessary amount.