

Validation of SAP-Systems

The Situation

SAP R 3 System is a business management software which is nowadays being more often introduced in GMP regulated industrial applications. For this reason qualification and validation according to actual guidelines is a necessary request.

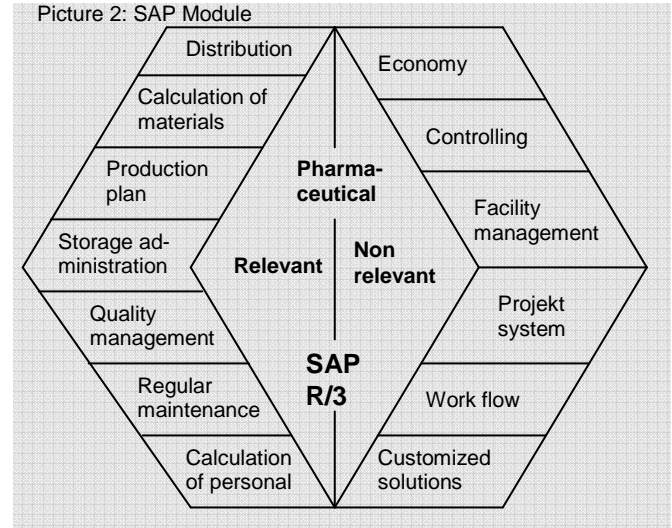
System description (Picture 1 und 2)

SAP R 3 is structured in different levels. User interface, logical connections and data base.

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.



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

Risk analysis: Evaluation of GMP relevant business transactions and defined interfaces (internal/external).

Design Qualification (DQ): Cross check between user requirements specifications and supplier documentation.

Installation Qualification (IQ): Test for correct installation of hard- and software and check of system documentation.

Operation Qualification (OQ): Examination of quality relevant business transactions respectively data exchange over the SAP R 3 intersections.

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.

Picture 1: Data flux SAP

