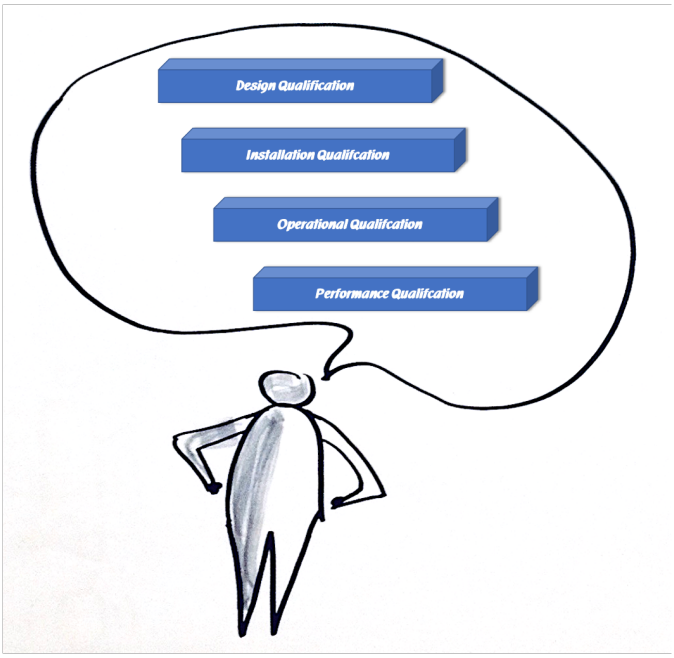
CHRISTIAN ALEXANDER GRAF
QUALITÄTSSICHERUNG & STATISTIK



Computer-System-Validation in Medical & Pharmaceutical Engineering

(CSV-EN)

Computer system validation (CSV) is intended to minimize the risks resulting from defects in software used in the production and quality management for medicinal products and medical devices.
Such defects can result in high losses, production downtime and even the delivery of defective products. The safety of users, especially patients, can be endangered. In this seminar, you will learn how to reliably minimize the risks associated with the use of software-controlled systems while efficiently complying with the applicable regulatory requirements.

What you will learn:

You will receive a systematic introduction to all essential aspects of CSV.
You will know which systems need to be validated and how to perform a risk analysis as a basis for CSV.
You will be able to plan all activities necessary for CSV and reliably estimate the costs involved.
You will know which documents you need to create and how to maintain the validated status of your systems throughout their entire lifecycle.
You know what is important when selecting service contractors to execute CSV activities.

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Target Audience:
IT managers, quality managers, decision-makers, test leads and test engineers, senior consultants in medical and pharmaceutical engineering

Course content:

- Regulatory requirements specified in
  ISO 13485, 21 CFR 820, 21 CFR part 11, ANNEX 11 for medicinal products
- Risk-based approaches according to GAMP 5, FDA and PIC/S guidance
- Supporting processes
- Required validation activities
- Necessary documents and records
- Planning a validation incl. scope and cost estimates
- Synergies with IT governance and information security management
- Criteria for evaluating CSV service providers

Recommended Experience:
A general background in Medical or Pharmaceutical Engineering is recommended

Duration: 1 day (approx. 6,5 h)

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