

Computer System Validation (CSV) Training

This course gives an introduction and overview to Computerized System Validation (CSV), as well as of the laws and regulations applicable. You will get to know the typical set of documentation and the GAMP5 approach. Furthermore, the course will also provide an overview on current and future trends, as e.g. Data Integrity, Agile Validation, Cloud Computing, Computer Software Assurance.

Agenda

- **Introduction – Expectations of the participants**
- **Laws and Regulations for CSV**
- **The GAMP approach to CSV**
- **The Elements of Computer Validation**
 - Inventory
 - Validation Planning and Reporting
 - Supplier Management
 - User Requirements
 - Functional, Configuration and Design Specifications
 - Risk Management – tools, complex vs. simple systems
 - System Build Phase
 - Testing / Verification – phases, deviation handling
 - Requirements Traceability
 - System Transition – SOPs, Business Continuity, Training
 - System Operations – Change and Configuration Management, Periodic Review, System Retirement
- **Data Integrity**
What is the role for validation specialists?
- **Agile Validation**
Which methodologies shall be used?
- **Cloud Computing**
How shall risks for systems in the cloud be handled?
- **Computer Software Assurance**
An outlook on new FDA trends
- **Q&A**



Details

Audience:

- Line managers or employees working in regulated CSV environments (GxP) – no prerequisites necessary
- Up to 12 participants per session

Session:

- 1 day training divided in two sessions of 4 hours per MS Teams
- Alternatively, on-site training can be organized if presence on-site possible
- Session Language is English

Cost:

800 CHF, incl. training certificate

Registration:

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