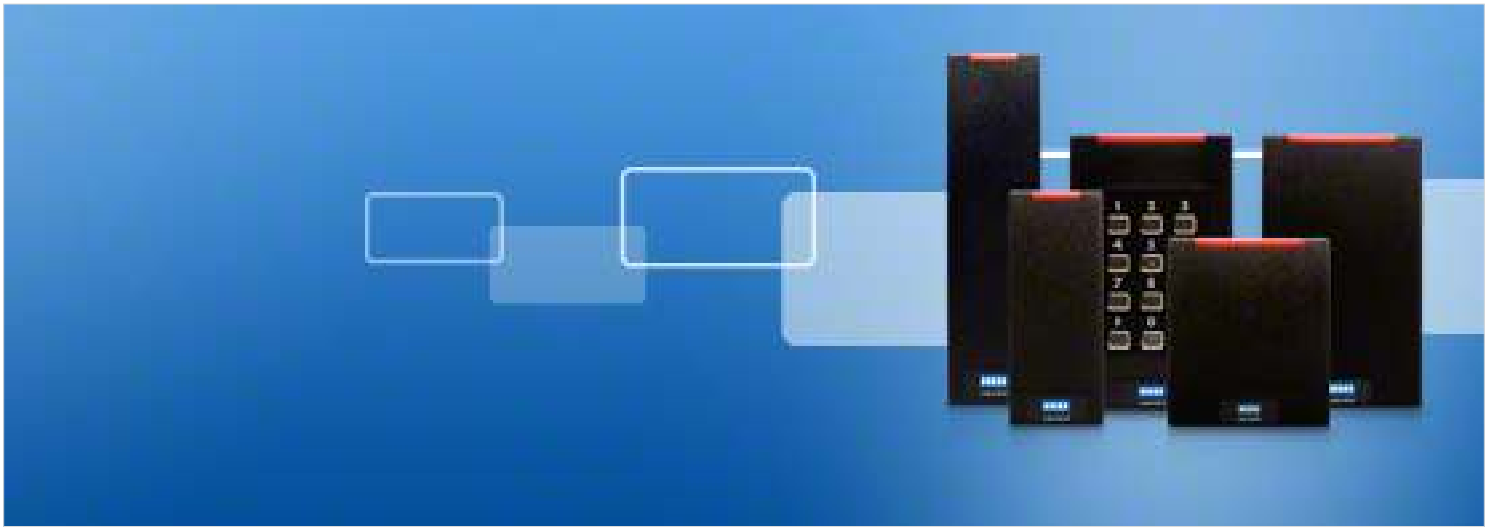
2-day In-person Seminar:

Validation and Part 11/Annex11 Compliance of Computerized Analytical Systems and Data

Location: Singapore | November 13th & 14th, 2014

By: Dr. Ludwig Huber

Course "**Validation and Part 11/Annex11 Compliance of Computerized Analytical Systems and Data**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



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Agenda:

Day 1:

Lecture 1: Requirements and approaches for Analytical Instrument Qualification and Computer System Validation

- FDA/EU, ICH and PIC/S requirements
- Lessons from recent FDA Warning Letters and how to avoid them
- Understanding the terminology: qualification, calibration, verification, validation.
- USP Chapter <1058> for analytical instruments: current and proposed changes
- Lessons from GAMP®5 and from the GAMP® guide: "A Risk based Approach to Laboratory Computerized Systems"
- Selecting the right validation approach for commercial off-the-shelf systems
- Planning for cost-effective qualification and validation

Lecture 2: Going through the equipment qualification phases

- The instrument qualification lifecycle
- Writing requirement specifications
- Documenting installation and installation qualification
- Testing for initial operational qualification
- Leveraging system suitability testing for on-going performance qualification
- Preparing inspection ready documentation

Lecture 3: Dealing with specific USP <1058> requirements

- Qualification of firmware.
- Unplanned and routine maintenance
- Change control
- Time and event based requalification: the implortance of risk assessment
- Definition and handling of like-for-like changes

Lecture 4: Cost Effective Validation of Laboratory Computer Systems: Step-by-Step

- Writing a validation project plan
- Going through a complete laboratory computer system validation from beginning to end
- Setting specifications, vendor assessment, IQ, OQ, PQ, and writing the validation report

Day 2:

Lecture 1: Maintaining the validated State of computer systems

- System maintenance
- Change controlled: Handling planned and unplanned changes
- How to deal with security patched
- Periodic review vs. revalidation of chromatographic data systems
- The approach and practice of periodic review
- Using periodic review to reduce frequency of revalidation
- Criteria for time based revalidation

Lecture 2: Validation and Use of Excel Spreadsheet applications

- Designing spreadsheets for compliance
- Validation approach for spreadsheet applications
- When, what and how much to test?
- Recommendations from GAMP®5 for testing native Excel functions
- How to ensure spreadsheet and data integrity
- Going through examples
- Excel spreadsheet validation from beginning to the end: A case study that can be used by everybody

Lecture 3: Introduction to FDA 21 CFR Part 11 and EU/PICS Annex 11

- Objective, scope, current situation and future of Part11
- Requirements overview and spirit of the regulation
- Requirements for electronic records
- Requirements for electronic and digital signature
- Additional requirements from the PICS/EU Annex 11
- FDA/EU inspection and enforcement practices of electronic records: examples of recent FDA warning letters and EU inspection reports

Lecture 4: Ensuring and documenting Integrity of Laboratory (Raw)data and other Records

- Definition of raw data: FDA/EMA requirements
- Defining and documenting 'complete records'
- What to archive for hybrid systems: paper records or electronic records

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