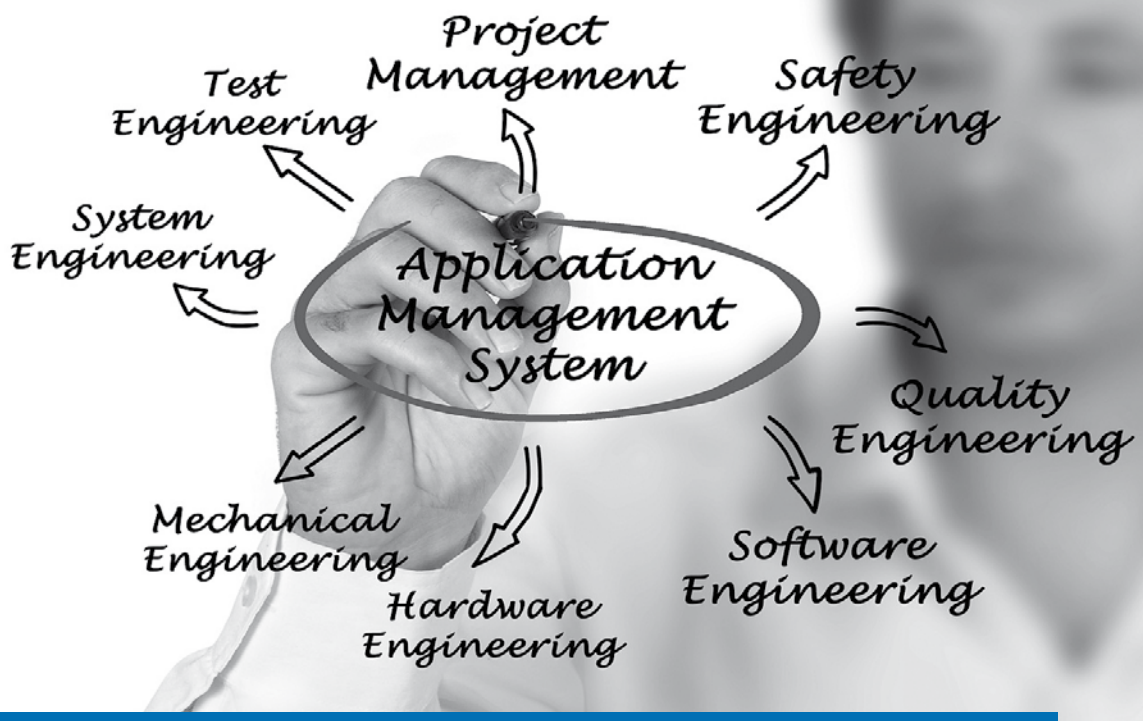

Computerised Systems Validation for Software Engineers

Become acquainted with your customers expectations

10-11 March 2015, Berlin, Germany

SPEAKERS:

Stefan Münch
Rockwell Automation

Yves Samson
Kereon

Wolfgang Schumacher
F. Hoffmann-La Roche

HIGHLIGHTS:

- The importance of software engineers in the GMP environment
- Relevant specifications for the software developer
  - GMP regulations
  - Requirements regarding the quality management system
  - Participation in validation
  - Requirements on testing
  - Documentation requirements
- What needs to be considered for risk management?
- Alternative software development methods in the GMP environment: What has to be taken into consideration?

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager“. Please find details at www.gmp-certification.eu

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Learning Goals

- Learn about the requirements of the pharmaceutical industry on computerised systems validation (csv).
- Evaluate the expectations of the pharmaceutical industry on supplier's validation activities.
- Learn as a supplier how to establish and defend a quality management system complying with the GMP requirements
- Get a picture of the frequent observations and problems from a supplier as well as a customer point of view and how to overcome them.
- Learn about the GMP aspects to consider with regard to alternative software development methods.

Background

Regulatory requirements (on the validation) of computerized systems directly address the pharmaceutical industry only. Software engineers are rarely aware of them. While the pharmaceutical industry is regularly audited by GMP inspectors, suppliers of this industry aren't subject to any official GMP supervision.

However, the pharmaceutical industry has to assess the suppliers with regard to their quality. Appropriate evaluation (audit) reports are expected and also reviewed by the GMP inspectors. Indirectly and consequently, the software engineer has to know the regulations of its customers and understand them. The development of the software must be accordingly qualitative and documented. The course will decidedly address the aspects to consider.

Target Audience

This course is directed at software engineers working for system suppliers and also directed at internal IT employees in companies of the pharmaceutical and medical industry. The customer's and supplier's personnel in the quality assurance departments is also addressed. First experiences in CSV are recommended.

Programme

Software Development: From Good Software Engineering Practice to GxP Compliance

- Software development for GxP relevant applications
- Good (Software) Engineering Practice
- Quality expectations
- Roles and responsibilities
- Leveraging GAMP software categories

Requirements for the Quality System of the Supplier

- Annex 11 – Is there a direct impact for the supplier?
- Are Health Regulatory Bodies allowed to inspect Software companies?
- Essential parts of the Quality System – Hot Buttons
- Design of Service Level Agreements (SLA) and examples
- Customer complaints – Bugs
- Expectation for the management of subcontractors
- Support of inspectors

Programming Standards / Code Reviews

- Customer expectations
- Typical checkpoints in a code review
- When to do it and how to follow up
- Code review vs. design review
- General vs. home-made programming standards

Development Tools / OSS

- Risk assessment of development tools
- What you should consider when using open source software (OSS)

Risk Management / Change Control / Traceability Implemented by the Supplier

- Customer expectations
- Why do we need to do this at all?
- Risk management as an interdisciplinary process
- Impact analysis vs. risk assessment
- Which changes to take into account
- Traceability put into practice

Supplier Testing

- Testing – the most important quality assurance element?
- ISPE's Good Practice Guide "A Risk-Based Approach to Testing of GxP Systems, 2nd Edition"
- Test Automation in regulated industries: Tools, compliance, and ROI

Audit Findings from the Pharma Business Perspective

- Evaluation criteria of the pharmaceutical industry
- May audits be rejected?
- Dos and Don'ts – Recommendations
- Problem areas and trends
- Discussion of audit observations and corrective actions

Audits – A Supplier's View / Real-life Experiences

- Preparation of a supplier audit
- Understanding and achieving audit objectives
- How to handle an auditor
- Improvements – Corrective and preventive actions (CAPA)

Iterative Software Development & V-model

- What „iterative" really means
- Requirements to an iteration
- Why iteration planning is crucial
- How to improve documentation efficiency

Scrum4LS

- Making Scrum work for the Life Sciences industry
- Resolving (potential) conflicts
- How to use an agile approach while still being compliant

Workshop: Software Engineering prejudice

- Engineers are not allowed to test
- Software Engineering always means "complete V-Model"
- Quality management = Quality assurance
- Agile = no specifications

Participants will discuss the pros and cons of various statements concerning Software Engineering

Regulatory management for software developers / Understanding the regulatory requirements

- Electronic Records
- Electronic Signatures
- 21 CFR Part 11
- EU GMP Guide Annex 11 functional requirements

Speakers

Stefan Münch

Rockwell Automation Solutions GmbH, Karlsruhe, Germany

Mr Münch is Campus Quality Manager, leading the quality and test team of Rockwell Software Karlsruhe. He has more than 15 years of working experience in leadership roles in Life Sciences for MES applications. As an active member of ISPE GAMP DACH, he was a member of the SIG Open Source Software, is leading the SIG on Test Automation, and active member of the SIG on Raw Data. Furthermore, Mr. Muench co-authored several articles, contributed to the "Testing GPG", and was a speaker and workshop lead at several ISPE conferences. He graduated in Computer Science at the University of Karlsruhe, Germany.

Yves Samson

Kereon AG, Basel, Switzerland

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

Dr Wolfgang Schumacher

F. Hoffmann-La Roche Ltd., Switzerland

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is now Head of the department of Quality Computer Systems. He is a member of the ECA Advisory Board.

Social Event

On 10 March, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Computerised Systems Validation for Software Engineers,** 10-11 March 2015, Berlin, Germany
☐ **Cloud Computing and Outsourcing in a GxP environment,** 12-13 March 2015, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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- until 2 weeks prior to the conference 10 %,
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Date

Tuesday, 10 March 2015, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 11 March 2015, 08.30 h - 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0) 030 2127 0
Fax +49(0)30 2127 117

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Save up to € 390!

If you register both for "Computerised Systems Validation for Software Engineers" and for "Cloud Computing and Outsourcing in a GxP environment" (12-13 March 2015, Berlin) the fees reduce as follows:
ECA Members € 2,790
APIC members € 2,890
Non-ECA Members € 2,990

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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