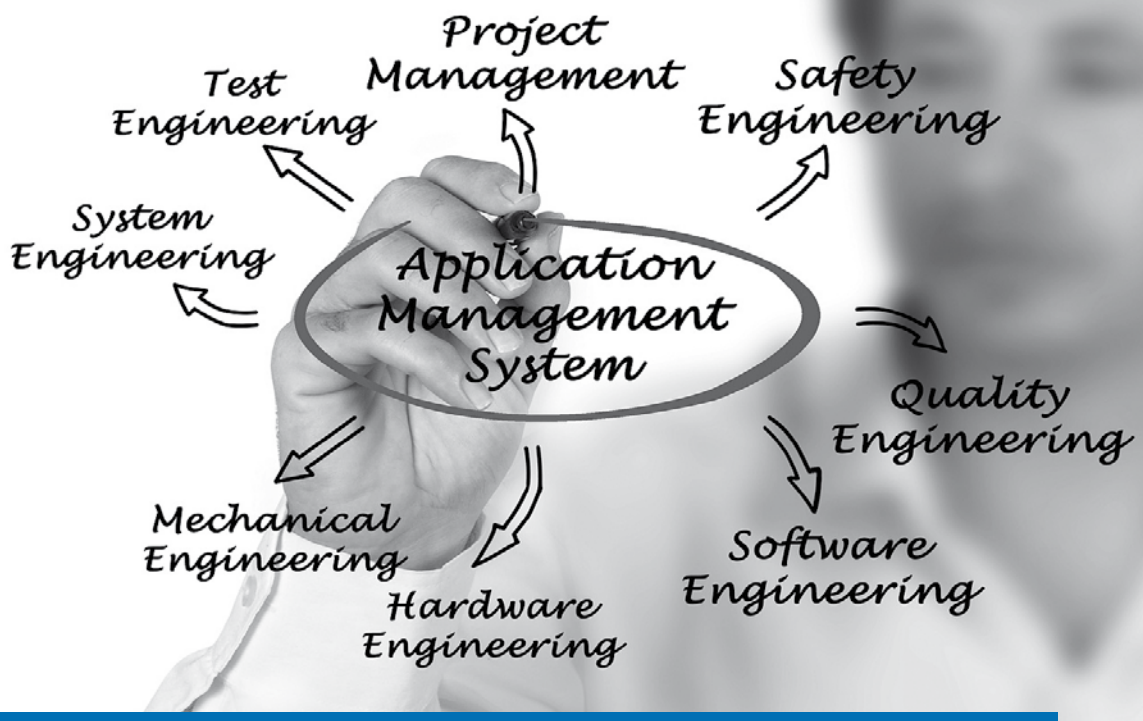


# Computerised Systems Validation for Software Engineers

## 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

# Computerised Systems Validation for Software Engineers

10-11 March 2015, Berlin, Germany

## 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.

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**P.O. Box 10 17 64**
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☐ **Cloud Computing and Outsourcing in a GxP environment,** 12-13 March 2015, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

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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!

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## 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

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**For questions regarding content:**
Dr Andreas Mangel (Operations Director) at
+49 (0)62 21 / 84 44 41, or per e-mail at
mangel@concept-heidelberg.de.

**For questions regarding reservation, hotel, organisation etc.:**
Ms Marion Grimm (Organisation Manager) at
+49 (0)62 21 / 84 44 18, or per e-mail at
grimm@concept-heidelberg.de.


# Cloud Computing and Outsourcing in a GxP Environment

12-13 March 2015, Berlin, Germany

SPEAKERS:

Dr Wolfgang Schumacher
*F. Hoffmann-La Roche Ltd.*

Dr Arno Terhechte
*Bezirksregierung Münster*

Michael Wegmann
*F. Hoffmann-La Roche Ltd.*

LEARNING OBJECTIVES:

- Compliance requirements for cloud computing
- Inspectors' / regulators' expectations and findings during inspections
- Types of cloud computing
- Use of cloud computing in a GxP environment
- Outsourcing and cloud computing – what is important for contracts
- IT security and data protection requirements
- Pros and cons

ECA ACADEMY

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# Cloud Computing and Outsourcing in a GxP Environment

12-13 March 2015, Berlin, Germany

## Objectives

- Get to know the different types of cloud computing, their technical basics and their validation approaches.
- What are the pharmaceutical authorities' requirements with regard to cloud computing and what regulations have to be observed? An inspector will present his perspective to these questions and the experience gained so far in audits and will further cover critical points.
- You can assess the use of cloud computing from the perspective of IT security and data protection rules, and based on that you can formulate requirements for cloud service providers.
- You can evaluate the opportunities and risks of cloud computing in the GxP environment.

## Background

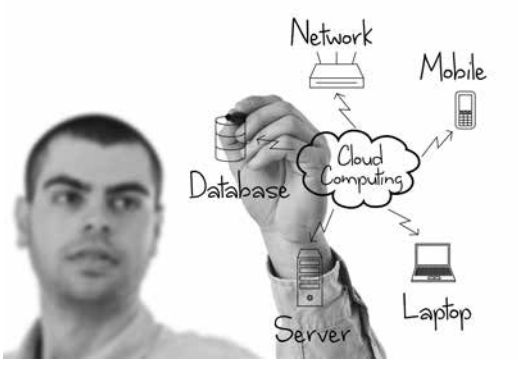
As well as in other sectors, the use of cloud computing is discussed in the pharmaceutical industry. For commercial reasons there is a lot speaking for the use.

However, is cloud computing an acceptable way in a GxP environment of the pharmaceutical industry? And, if yes, what has to be observed from the point of view of IT and quality assurance, as well as from the perspective of a pharmaceutical inspector?

From the points of view of the user and the pharmaceutical inspector this event gives you an overview of the current state of the technical possibilities. The speakers evaluate opportunities and risks of the use of cloud computing in the GxP environment and make recommendations for the pharmaceutical practice.

## Target Audience

The event is aimed at employees who are entrusted with the planning and implementation of "cloud" projects in the GxP environment. The event also offers support for decision-making, whether cloud services are available as an alternative in the GxP environment.




## Programme

### Regulatory Background – important issues to consider from the point of view of an inspector

- Requirements for CSP (cloud service providers) resulting from Annex 11
- To do's for regulated users with respect to chapter 7 of the EU GMP Guide
- German drug law – does the German drug law or European Law effect the business of CSP; enforcement of corrective actions

### Definition and types of Cloud Computing

- Service models: Private Cloud, Public Cloud, Community Cloud, Hybrid Cloud
- Infrastructure as a Service (IaaS)
- Platform as a Service (PaaS)
- Software as a Service (SaaS)
- Cloud computing scenarios, reference architectures, examples

### Cloud Computing: IT Security

- Examples of incidents
- Strategic planning and preparation for going to cloud services
- Security management and security architecture
- Security certifications (e.g. ISO 27001) and what they really mean
- Physical and logical security, encryption
- Incident prevention and response
- Professional security patch management
- Identity management, authentication, authorization
- Integration of cloud services with internal IT landscape

### Workshop: Contracts with service providers

Participants will define in working groups the basic requirements for a contract and SLA

### Contracts with cloud service providers

- Business & Technology Risks
- Intellectual Property
- Service Access / Service Quality KPIs
- Data Storage requirements
- Inspection & audit support
- Example Contract/SLA
- Lessons learnt

### Cloud Computing: Use cases in a GxP environment

- Risk-based approach
- Specific responsibilities of the cloud service provider
- Specific responsibilities of the cloud customer
- Separation of GxP vs. non GxP
- Examples

### Compliance requirements for the cloud infrastructure
- Regulatory requirements
- Qualification of the cloud
- Validation of the cloud

### Inspections and Findings
- European Framework to conduct inspections
- Availability, data integrity and confidentiality of data
- Possibility to perform inspections of CSP
- State of the art defined by BSI, ENISA and NIST
- Inspections: experiences and findings

### Inspections and audit experiences: The pharmaceutical industry perspective
- Inspection Trends EMA – Annex 11
- Inspection Trends FDA
- Inspection Trends other countries
- Hot Buttons

### Cloud Computing: Data protection
- Data protection and privacy – legal requirements
- Responsibilities of the cloud service provider
- Responsibilities of the cloud customer

### Workshop: Which types of data needs to be protected especially well?
Participants will define and discuss the critical data elements and their protection

### Data classification
- Responsibility and integration in the IT project management framework
- Handling, processing, commissioned processing of data
- Forced disclosure
- Applicable regulations
- Examples and lessons learnt

### Business continuity management
- Necessity for Sales/Patients/Annex 11?
- Assessing the Business Continuity Risk
- Buss. Cont. Plan – BCP
- Disaster Recovery - MTPD - RTO - RPO

### Government agencies and cloud computing
- Objectives and capabilities of government agencies
- How and where do they hook in
- Internet surveillance and specific attacks
- Industry espionage
- Countermeasures and their limitations

### Experiences with outsourcing and cloud computing
- QA involvement
- Pain points

### Cloud computing: Pros and cons – includes closing discussion
- Opportunities and risks of cloud computing
- Rationale for using cloud services
- Rationale for not using cloud services
- Conclusions and recommendations

## Speakers

**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.

**Dr Arno Terhechte**
*Bezirksregierung Münster, Germany*
After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group 11 "computerised systems".

**Michael Wegmann**
*F. Hoffmann-La Roche Ltd., Switzerland*
Since 1989, Michael Wegmann has been working as IT expert in the pharmaceutical industry. From 2000 to 2011, he was globally responsible for IT security in the Roche Pharmaceuticals Division. In his current role as Global Head of Integration Competency Center, he is responsible for system integration (EAI), interfaces and middleware in the Roche Diagnostics Division.

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### Date

Thursday, 12 March 2015, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Friday, 13 March 2015, 08.30 h - 16.00 h

### Venue

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