# Virtual IT-Systems in a GxP Environment

26-27 November 2015, Berlin, Germany

SPEAKERS:

Bob McDowall
*McDowall Consulting*

Yves Samson
*Kereon AG*

Jürgen Schmitz
*Novartis Vaccines and Diagnostics*

LEARNING OBJECTIVES:

- Advantages and disadvantages of virtual systems in a GxP environment
- Differences between virtual systems and real systems
- What are the critical points
  - during implementation
  - during qualification and
  - during operation of virtual systems
- Case studies from virtualisation projects
- From virtualisation to cloud computing

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

# Virtual IT-Systems in a GxP Environment

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## Objectives

- Get an overview of technologies discussed currently in the pharmaceutical environment and their potential fields of application,
- Assess how to use and implement GMP requirements and provisions for virtual IT systems and, where appropriate, for cloud computing,
- Learn more about the qualification and use of virtual systems in the GMP environment, and
- Evaluate whether the use of virtual IT systems and cloud computing would be profitable if your company.

## Background

Virtual systems, cloud computing, and GMP; does this fit together? What are the advantages and disadvantages of these systems in a GMP environment? Are there any limits with their use?

The increasing use of virtual IT systems and cloud computing in a GMP regulated environment is getting more and more discussed. The virtualisation of computer systems offers a great number of advantages, such as the simultaneous use of multiple operating systems, the simple and low-cost construction of test environments, and the improved utilisation of multi-core processors.

Can these advantages also be used in a GMP environment and which aspects have to be specifically considered from the "GMP view" for virtual systems and cloud computing?

This event considers virtual systems and cloud computing from the GMP point of view and provides practical support to determine measures regarding the use of such systems.

## Target Audience

The event is aimed at managers in the pharmaceutical industry, suppliers and service providers that operate virtual IT systems and cloud computing in a GMP environment or intend to use them in the future

## Programme

### IT Infrastructure in a GxP Environment

- Regulatory requirements
- Definitions
- Validation and qualification

### What is Virtualisation?

- Definitions
- Physical platform foundation requirements
- Software for virtualisation
- Virtual platform options

### Compliance Requirements for Virtual Systems

- IT infrastructure platform
- Server platform qualification
- Virtual Platform considerations
- Maintaining the qualified state during operation

### Planning of Virtualisation Projects

- User / Technical Requirements Specification
- Definition of the installation and deployment approach
- Definition of backup cycles and scenarios
- From a virtual server to a virtual farm
- Efficient planning
- Qualification planning

### Qualification of IT-Infrastructure

- General Principles of IT Infrastructure Qualification
- How to do qualification in a real environment vs. what to do in a virtual environment
- Qualification Activities
- Roles and responsibilities
- Installation and Testing

### Workshop: Qualification Documentation

- Designing reusable documentation for virtual systems
- Key requirements for reusable qualification documents

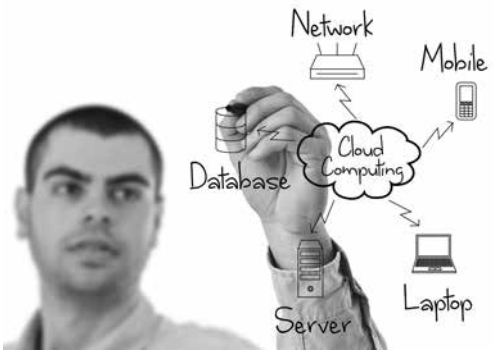
### Risk Management

- ASTM E 2500-07
- Good Engineering Practice (GEP)
- Q 9 – Quality risk management
- GAMP 5, M 3
- GEP, Qualification, Validation reconciliation
- NIST-SP 800-30 Risk Management for IT systems
- HA-Op

### Making of a Virtual Data Centre
- Specification of virtual data centre requirements
- Do I qualify or validate the hypervisor software?
- Building and qualifying a virtual data centre

### Virtualisation of Laboratory Equipment / Desktop Virtualisation
- Use cases for virtualisation in a laboratory environment
- Operating a virtual system

### Disaster Recovery Planning
- Regulatory requirements for disaster recovery
- Disaster recovery or business continuity planning?
- Mitigating physical faults
- Triggers for the plan
- Testing the plan
- Keeping the plan up to date




**Workshop:**
**Planning of Virtualisation Platform**

### From Virtualisation to Cloud Computing
- What is cloud computing really?
- Abstraction of services and IT infrastructure
- Virtualisation vs. cloud computing
- Recommendations for a GxP-compliant cloud computing

## Speakers

### Dr Bob McDowall
*McDowall Consulting, Bromley, Kent, UK*
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems. He was also a contributor to the GAMP GPG IT Infrastructure control & compliance.

### 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 Jürgen Schmitz
*Novartis Vaccines and Diagnostics AG, Basel, Switzerland*
Jürgen Schmitz was from 1994 until 2000 at RELAB AG and from 2000 - 2003 at KPMG Consulting AG responsible for computer systems validation. Since 2003 he in different positions at global IT Quality Management at Novartis, now at Novartis Vaccines and Diagnostics, in Basel.

## Social Event

On 26 November 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**

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐☐ **Virtual IT-Systems in a GxP Environment,** 26-27 November 2015, Berlin, Germany
☐☐ **SAP – Validation and GMP Compliance,** 24-25 November 2015, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

**Important: Please indicate your company's VAT ID Number** **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

**General terms and conditions**
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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**Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
**Important**: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

### Date

Thursday, 26 November 2015, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 27 November 2015, 08.30 h – 16.30 h

### Venue

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

### Would you like to save money?

If you book the course "Virtual IT Systems" on 26-27 November AND the course "SAP – Validation and GMP Compliance" on 24-25 November simultaneously the fees reduce as follows:
ECA Members € 2,780
APIC Members € 2,880
Non-ECA Members € 2,980
EU GMP Inspectorates € 1,690

### Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form when you have registered for the event. 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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