Virtual IT-Systems in a GxP Environment

17-18 September 2014, Prague, Czech Republic

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
- 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

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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

Workshop: Qualification Documentation

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

Change & Configuration Management

- Regulatory requirements
- What is a change?
- Definitions of change management & configuration management
- An outline change management process

Qualification of IT-Infrastructure

- General Principles of IT infrastructure qualification
- Qualification activities
- Roles and responsibilities
- Installation and testing

Risk Management
- ASTM E 2500-07
- Good Engineering Practice (GEP)
- Q 9 – Quality risk management
- GAMP 5, M 3
- GEP, qualification, validation reconciliation

Making of a Virtual Data Centre
- Specification of virtual data centre requirements
- Building and qualifying a virtual data centre

Virtualisation of Laboratory Equipment / Desktop Virtualisation
- Use cases for virtualisation in a laboratory environment

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 17 September, 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)

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+ 49 6221 84 44 34

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

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

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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 at January 2012)

Date

Wednesday, 17 September 2014, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 18 September 2014, 08.30 h – 16.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Tel +420 261 191 111
Fax +420 261 225 011

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.

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.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language

The official conference language will be English.

Organisation and Contact

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