20 YEARS ECA Academy
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Virtual IT Systems in a GxP Environment

SPEAKERS:

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GSK

14-15 November 2019, Berlin, Germany

LEARNING OBJECTIVES:

- Advantages and disadvantages of virtual systems in a GxP environment
- Benefits of virtualisation
- Regulations apply to virtualisation
- Differences between virtual systems and real systems
- What are the critical points
  - during implementation
  - during qualification and
  - during operation of virtual systems
- Virtualisation platform
- Planning and qualification of a virtualisation project
- Case studies from virtualisation projects
- Change management / configuration management and disaster recovery
- From virtualisation to cloud computing

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 for your company.

Background

Virtual IT 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

Principles of IT qualification and validation
- Regulatory requirements
- Definitions
- Validation and qualification

What is Virtualisation?
- Definitions
- Physical platform foundation requirements
- Software for virtualisation
- Virtual platform options

Benefits of Virtualisation
- On demand infrastructure
- Speed of implementation
- Flexibility

Regulations apply to Virtualisation
- Annex 11 key points for consideration
- IT infrastructure shall be qualified
- In-house or hosted system

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

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

Compliance requirements for virtual systems
- IT Infrastructure Platform
- Server Platform Qualification
- Virtual Platform considerations
- Maintaining the Qualified State during operation

Overview of the virtualisation platform
- Platform components
- Platform operation
- Handling of SANs and VMs

Qualification of the virtualisation platform
- Requirements gathering
- Platform design
- Qualification planning
- Supporting processes

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

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

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

Show and tell: Virtualisation documentation
- Technical Requirements Specification
- Configuration Specifications
- Installation Qualification

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

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

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
R.D.McDowall Limited, Bromley, Kent, UK
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. 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. In 2017, Yves launched the e-Compliance Requirements Initiative (eCRI) with the aim to help the regulated pharmaceutical industry and its suppliers to address and to implement accurately, consistently, and effectively the regulatory e-Compliance requirements.

Dr Jürgen Schmitz
GSK, Wavre, Belgium
Jürgen Schmitz was from 1994 until 2000 at RELAB AG and from 2000 - 2003 at KPMG Consulting AG responsible for computer systems validation. Between 2003 and 2015 he was in different positions at global IT Quality Management at Novartis and Novartis Vaccines and Diagnostics. Since 2016 he is Head Quality IT and Compliance at GSK Vaccines.

Social Event

In the evening of the first course day, 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

☐☐ **Virtual IT Systems in a GxP Environment,** 14-15 November 2019, Berlin, Germany
☐☐ **SAP – Validation and GMP Compliance,** 12-13 November 2019, Berlin, Germany

☐ 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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- until 2 weeks prior to the conference 10 %,
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- within 1 week prior to the conference 100 %.

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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, 14 November 2019, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 15 November 2019, 08.30 h – 16.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone 030 2127 0
berlin@steigenberger.de

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/POG when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Would you like to save money?

If you book "Virtual IT Systems in a GxP Environment" and "SAP – Validation and GMP Compliance" (12-13 November 2019) simultaneously the fee reduces as follows:
ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,690

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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