

Speakers



Frank Behnisch
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IT / OT Infrastructure Qualification and Operation in a GMP Environment

8-10 May 2023, Heidelberg, Germany



Highlights

- Information Technology (IT) / Operation Technology (OT) Infrastructure Enterprise Model
- Regulatory Requirements
- IT Compliance for the IT Infrastructure
- Supporting Processes
- Virtualisation as Part of the IT Infrastructure
- Security and Cybersecurity Concepts
- Agile Infrastructure / Infrastructure as Code (IaC)
- Case Studies for Qualification
 - Virtualisation Platform
 - Firewall
 - Central Backup Management System

Objectives

- Get an overview of technologies discussed currently in the pharmaceutical environment
- Learn what requirements are placed on the IT infrastructure and its qualification within the scope of GMP regulations
- Principles outlined can be applied to Operation Technology (OT) for production systems
- IT security and cybersecurity has now taken on a central role; here you will learn about the importance of the IT infrastructure in terms of an appropriate IT security concept
- Case studies show you qualification approaches for key IT infrastructure components
- Virtualization is a part of the IT infrastructure; learn strategies for qualifying the virtual machine and the virtualization platform

Background

In today's pharmaceutical environment, the IT infrastructure is the backbone for the application of a wide range of software solutions. The requirements for IT security are becoming increasingly important. Only a robust IT infrastructure with suitable network topologies and security concepts can guarantee the appropriate security here.

Pharmaceutical regulations contain few or only indirect requirements for the IT infrastructure. The principles of the EU GMP guidelines state "The application should be validated; the IT infrastructure should be qualified". Here the phrase "should" corresponds to a "must"! Further information can be found in the revised version of the GAMP® Good Practice Guide "IT Infrastructure Control and Compliance" published in August 2017.

Target Audience

The event is aimed at managers from the pharmaceutical industry, suppliers and service companies who plan, qualify and operate IT infrastructure in a GxP environment

Programme Day 1

IT/OT Infrastructure Model

- Overall IT/OT infrastructure enterprise model
- GAMP IT infrastructure model
- Applying GAMP software categories
- OT specifics
- Applicable to all options: on premise / data hotel / SaaS IT

Regulatory and Legal Requirements / Agreement for IT/OT infrastructure

- GxP regulations with focus on Annex 11 and Chapter 7
- Supplier assessment and agreements for IT suppliers
 - Risk management
 - Quality and technical agreements and service levels
 - Governance and Quality oversight
 - Time synchronisation
- Brief summary of legal requirements
 - e.g. GDPR, HIPAA, etc.

Effective and Efficient Compliance

- Supporting life cycle model
- Specification
- Design
- Verification

Security and Cybersecurity for a Robust IT/OT Infrastructure

- IT infrastructure security requirements
- Cybersecurity: ransomware and malware
- Sizing / Availability / Reliability
- Basic security rules
- Network topology
- Network segregation
- IT infrastructure monitoring
- Recommendation for data archiving support
- PEN testing

Planning Virtualisation Projects

- User / Technical Requirements Specification
- Definition of the installation and deployment approach
- Risk management
- Definition of backup cycles and scenarios
- Efficient planning
- Qualification planning
- Life cycle of virtual environment
- Differences between virtual, physical, and as-a-Service installation and deployment

Virtualisation Platform: Overview

- Platform operation
 - SANs and VMs handling
- RAID technology

Qualification of the Virtualisation Platform

- Platform design
 - Requirements and constraints
 - Data management
 - Disaster recovery
- Qualification planning
 - Specifications
 - Verifications

Qualification Documentation

- QP – Qualification Plan
- TRS – Technical Requirements Specification
- CS – Configuration Specifications
- IQ – Installation Qualification a.k.a. Configuration Testing

Programme Day 2

Design Review of IT Infrastructure

- Design Review and Risk Management purpose
- Performing Design Review
- What might go wrong?
- Critical review of the IT infrastructure
- Design and monitoring of mitigation measures



Case Study: Firewall Qualification

- Requirements
 - Purpose
 - Operation
- Risk assessment
- Configuration specification
 - Definition of the security rules
 - Operating parameters
- Configuration Testing (IQ)
- Functional Testing (OQ)
- Operation
 - Monitoring
 - Change & Configuration Management
 - Incident Management

Disaster Recovery Planning

- Regulatory requirements for disaster recovery
- For virtual and physical environment
- Disaster recovery or business continuity plans?
- Disaster recovery plan and testing
 - Order of application recovery with associated data
 - RPO – Recovery Point Objective
 - RTO – Recovery Time Objective



Case Study: Central Backup Management System

- Requirements
- Verification
- Risk assessment
- Configuration specification
 - Server / Agent / Operating parameters
- Configuration Testing (IQ)
- Functional Testing (OQ)
- Supporting SOPs
 - System management
 - Backup / Restore
 - Disaster Recovery
- Operation

Incident and Problem Management

- Definition of incident and problem
- Incident investigation
- Collating incidents into problems and their resolution
- Linking with change control

Infrastructure as a Platform for Various Applications

- Definition of Platform
- Generic approach
- Standard changes
- Infrastructure lifecycle challenges for applications & GxP
- Specialties in automation – challenge for infrastructure in 24/7 real-time applications

Change and Configuration Management

- Regulatory requirements
- Definitions of change control and configuration management
- Outline of a change management process

Agile Infrastructure: Leveraging to Infrastructure as Code (IaC) for Efficiency

- Definition & scope
- Toys or tool?
 - 40 years evolution
- Flexibility & Agility
 - From installation to provisioning
- The costs of Agility
 - Rigorous planning
 - Adequate tools
 - Training
 - Risks and benefits

Speakers



Frank Behnisch
CSL Behring GmbH, Germany

Frank is Senior Manager Project Engineering at CSL Behring GmbH in Marburg, Germany. He is member of the GAMP® D-A-CH „steering committee“ and chairman of a GAMP® Special Interest Group (SIP) for “Small Systems”.



Dr Bob McDowall
R.D.McDowall Limited, Bromley, Kent, UK

Analytical chemist with over 45 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 30 years and is the author of a book on the validation of chromatography data systems. He was also a contributor to the GAMP IT Infrastructure control & compliance and Lab System Validation 2nd edition Good Practice Guides. He is a core member of the GAMP Data Integrity SIG. He recently published his book on Data Integrity and Data Governance: Practical Implementation in Regulated Laboratories.



Yves Samson, Kereon AG
Basel, Switzerland

Yves joined the industry where he served as project and site engineer automation. In 2002, he founded Kereon AG. He is member of GAMP® Europe Steering Committee, co-founder and chairman of GAMP® Francophone and edited the French version of GAMP® 4 / 5. Membership: Active member of the GAMP working group ‘IT Infrastructure Compliance and Control’ / ECA “DI & IT Compliance Group”.

Reservation Form (Please complete in full)

IT / OT Infrastructure Qualification and Operation, 8-10 May 2023, Heidelberg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

ZIP Code

Phone / Fax

E-Mail (Please fill in)

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Date

Monday, 8 May 2023, 13.00 – 17.15 h CEST
(Registration and coffee 12.30 h - 13.00 h)

Tuesday, 9 May 2023, 09.00 h – 17.45 h CEST

Wednesday, 10 May 2023, 09.00 h – 16.30 h CEST

Venue

Qube Hotel Bahnhof

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Fees (per delegate, plus VAT)

ECA Members € 1,890

APIC Members € 1,990

Non-ECA Members € 2,090

EU GMP Inspectorates € 1045

Including: Conference documentation, lunch and social event on the first day, lunch on the second day, all refreshments.

Accommodation

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

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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.

Organisation and Contact

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

CONCEPT HEIDELBERG

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