ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

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

22-24 May 2024, Copenhagen, Denmark

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

Programme

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

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

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

Automation and system engineer with over 25 years experience, including 11 years as regulated user, Yves is the founder of Kereon AG, Basel. He supports his customers as consultant, trainer, and e-compliance auditor. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone. He 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.

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GERMANY

Reservation Form (Please complete in full)

IT / OT Infrastructure Qualification and Operation, 22-24 May 2024, Copenhagen, Denmark

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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Date
Wednesday, 22 May 2024, 09.00 – 17.15 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 23 May 2024, 08.30 h – 17.15 h
Friday, 24 May 2024, 08.30 h – 12.15 h

All times mentioned are CEST

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone: +45 (0)33 96 50 00
Email: guest.copenhagen@radissonblu.com

Fees (per delegate, plus VAT)
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,045
Including: Conference documentation, lunch and social event on the first day, lunch on the second day, all refreshments. The conference fee is payable in advance after receipt of invoice.

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 couse 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.
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