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 GxP Environment

11-13 June 2025, Copenhagen, Denmark

Highlights

- Information Technology (IT) / Operation Technology (OT) Infrastructure Enterprise Model
- Regulatory Requirements
- IT Compliance for the IT Infrastructure
- Supporting Processes
- IT Service Providers: Assessment and Content of an Agreement
- Security and Cybersecurity Concepts
- Agile Infrastructure / Infrastructure as Code (IaC)
- Case Studies for Qualification
  - 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" correspond 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

Workshop: "How can you ensure IT and QA work together?"

Although there needs to be quality oversight of IT operations and associated records, what is the best way for IT and Quality to collaborate? Suggestions made in the workshop will be discussed with the course attendees.

Content of an Agreement with an IT Service Provider

Annex 11 clause 3 requires that there is a formal agreement between an IT service provider and the business but provides little detail other the document should include clear statements of the responsibilities of the third party. What else is required in an IT agreement?

- Scope of the IT services provided
- Roles and responsibilities of both parties
- Reporting with metrics against defined service levels
- Escalation pathway
- Is an agreement for an internal IT department the same as a cloud service provider?

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 tool; Training; Risks and benefits

Change and Configuration Management

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

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

Incident and Problem Management

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

Qualification Documentation

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

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 / RTO – Recovery Point / Time Objective

Workshop: Disaster Recovery Planning

Business continuity is an Annex 11 requirement. What should a disaster recover plan cover? How detailed should it be? What would be the triggers to activate a plan? How should it be tested? Does it need to be reviewed? If so how frequently? Could the same plan apply equally to an on-premises and cloud computerised system?

IT Service Provider Assessment

Annex 11 clause 3.2: The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.

- What facilities, services and operations should be covered in an assessment or audit of an in-house IT Department?
- Are there any differences if the IT department was outsourced to a third party but operated on site?
- What would an audit of a Cloud Service or SaaS Provider cover differently?

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

Infrastructure as a Platform for various Applications

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

Case Study: Central Backup Management System

- Requirements
- Verification
- Risk assessment
- Configuration specification:
  - Server / Agent / Operating parameters
- Configuration Testing (IQ)
- Functional Testing (OQ)
- Supporting SOPs
- Operation

Case Study: Firewall Qualification

- Requirements
- Risk assessment
- Configuration specification
- Configuration Testing (IQ)
- Functional Testing (OQ)
- Operation

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

Bob has been involved with the validation of computerised systems for over 30 years. He was a contributor to the GAMP IT Infrastructure control & compliance guide. He is member of the ECA DI&IT Interest Group.

Yves Samson, Kereon AG
Basel, Switzerland

Automation and system engineer with over 25 years experience, including 11 years as regulated user. Yves is chairman and co-founder of GAMP Francophone. He edited the French version of GAMP 4 and GAMP 5.

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Reservation Form (Please complete in full)

IT / OT Infrastructure Qualification and Operation in a GxP Environment
11-13 June 2025, 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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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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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 https://www.gmp-compliance.org/privacy-policy). 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
Wednesday, 11 June 2025, 09.00 – 17.15 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 12 June 2025, 08.30 h – 17.15 h
Friday, 13 June 2025, 08.30 h – 13.00 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 € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
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 – or search and register directly at www.gmp-compliance.org under the numbers 21759.

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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