ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Elke Brodbeck
DHC AG

Dr Thilo Jania
OLYMPUS EUROPA

Christian Kunath
Santhera Pharmaceuticals

Dennis Leblang
DHC Dr. Herterich and Consultants

Stefan Temps
DHC AG

SAP – Validation and GMP Compliance

Live Online Training 10/11 November 2020

Highlights

- SAP S/4 HANA in a GxP Environment
- Validation
  - Best Practice Approach
  - Process Oriented vs. Transaction Oriented
  - Agile vs. V-Model
  - Major Changes and Impact on Validation Approach
  - Solution Manager 7.2 as a Validation Platform
  - Case Study: Validation of SAP Cloud Products
- Operation
  - Change Management
  - Lifecycle Management
  - Data Migration
  - Case Study Olympus
- Audit Trail / Data Integrity in SAP S/4HANA
- Artificial Intelligence / Machine Learning and GxP Compliance
- Insights from the Pharma Validation Group (PVG)

Programme

Objectives

You will learn

- How to validate SAP S/4HANA in a GMP environment
- Which specific requirements should be taken into consideration in the CSV process
- How to use SAP Solution Manager 7.2 as a validation platform
- What problems could arise during validation and how to solve them
- How to maintain the validated state of SAP with the least efforts

Background

SAP S/4HANA has been launched in 2015 as the new intelligent ERP system. The software is available as cloud edition and as on-prem edition. SAP S/4HANA is being called the biggest update to its ERP system in over two decades. Together with the move to in-memory database SAP HANA a new user interface (SAP Fiori) was introduced.

The mainstream maintenance for the predecessor products will end in 2025. Due to this time line a lot of SAP customers have already started the transformation journey to SAP S/4HANA or at minimum have initiated a pre-project.

How will all these technical and functional changes in the surrounding of SAP S/4HANA (user interface, in-memory database, different deployment types) impact the validation approach and the validation scope?

This ECA Live Online Training will provide comprehensive knowledge about how to validate SAP S/4HANA for new SAP customers as well as for installed base customers who are planning a system conversion.

Expect two days full of shared best practices for the validation of SAP S/4HANA considering recent regulatory requirements like EU GMP Guide Annex 11, GAMP 5 and 21 CFR Part 11.

Target Audience

This ECA Live Online Training is directed at experienced employees from

- IT & IT Service Providers
- Quality Assurance / Quality Control
- Production / Engineering

who have to deal with SAP S/4HANA in a healthcare environment.

Programme Day 1

Validation Approach for SAP S/4HANA On Premise

- Legal requirements
- Process oriented and risk based approach
- Best practices
- Agile vs. V-Model

SAP S/4HANA – Major Changes and Impact on Validation Approach

- S/4HANA - The new digital core
- Major changes in system architecture
- What does this mean for the validation approach?

Case Study: Validation of SAP Cloud Products (Success Factors)

- Challenges and chances of the new Cloud paradigm
- Best Practices in validation
- Supplier qualification of Cloud Providers
- Operation of Cloud systems
- Ensuring Data Integrity with Cloud Products

Process Landscape and IT System Landscape

- Changes in SAP Product Landscape
- SAP System Landscapes
- System Landscapes for Transformation Projects

SAP Configuration Management vs. Validation Approach

- Implementation Approach
- Customizing and Development
- Change and Transport System
- SAP Release Strategy for SAP S/4HANA
- Validation Challenges

Templates

All participants get a set of useful templates for download:

- Validation plan
- User requirement specifications
- Functional specifications
- Test scripts
- Risk assessment questions
- Data Integrity Assessment
- Data migration

Programme Day 2

Using SAP Solution Manager 7.2 as a Validation Platform

- SolMan as Application Lifecycle Management Tool
- Solution Documentation & Test Management
- IT Service Management
- Change Management
- How can SAP Solution Manager support the S/4HANA transformation?

Case Study: Managing a European SAP Program in a Validated Environment (Olympus Surgical Technologies Europe)

- Project Set-up at Olympus
- Risk based approach
- Experiences / Success factors
- Further implications for the strategic IT-landscape

Transformation to SAP S/4HANA and Data Migration

- A strategic approach to data migration
- Regulatory requirements and data migration
- Validating the data migration

Insights from the Pharma Validation Group (PVG)

- PVG: Tasks, Objectives, Members
- Quo Vadis SAP? The journey from Software Manufacturer to Service Provider
- SAP Audit - change in focus: Frequency and content on the test bench

Data Integrity

- Regulatory Requirements
- Data Integrity Assessment
- Data Governance System

SAP Audit Trail in SAP S/4HANA

- Audit Trail functionality in SAP S/4HANA
- Review of Audit Trail
- Audit Trail in CSV documentation

Intelligent ERP: Artificial Intelligence / Machine Learning and GxP Compliance

- How can AI / ML support future processes
- Impact on system design
- How to handle AI / ML during system validation

Speakers

Elke Brodbeck, DHC AG, Switzerland

After completion of her doctorate at the ETH Zuerich, Elke joined DHC AG as a specialist in Computerized System Validation with a strong focus on the methodological approach for SAP S/4 HANA implementation/ validation. Elke also has special competencies in the areas of data integrity and the requirements of the 21 CFR Part 11

Dr Thilo Jania, OLYMPUS Europa SE & Co. KG

From 2013 until 2016 he was the responsible Program Manager of the successful SAP Implementation at OLYMPUS Surgical Technologies Europa. In his current position as General Manager at OLYMPUS EUROPA SE & CO. KG he is in charge of a EMEA-wide process transformation program.

Christian Kunath, Santhera Pharmaceuticals Ltd, Switzerland

After many years as global CSV (computerized system validation) manager in different pharmaceutical and medical device companies, Mr Kunath is now Head of Quality Systems/CSV at Santhera Pharmaceuticals Ltd and responsible for all Quality processes of Santhera. Mr Kunath is also Certified Information Security Professional (T.I.S.P.), Supplier Auditor and Chairman of the Pharma Validation Group (PVG).

Dennis Leblang
DHC Dr. Herterich & Consultants GmbH, Germany

Dennis Leblang joined DHC Dr. Herterich & Consultants as a Consultant in 2016. During the last years he worked in multiple SAP Solution Manager implementation and SAP authorization projects in medical devices industry. Dennis studied Business Administration with focus on Business Informatics at the University of Applied Sciences of Saarbruecken (Germany).

Stefan Temps
DHC AG, Switzerland

Stefan Temps joined DHC as a Senior Consultant in 1996. In 2004 he became Partner of DHC AG, Switzerland. Core competences of Stefan are SAP S/4HANA solution architecture and GxP compliance in the regulated industry. Prior to joining DHC in 1996, Stefan studied Industrial Engineering and Management at the Technical University of Hamburg (Germany).

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:„… All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,…". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

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Live Online Trainings

☐ SAP – Validation and GMP Compliance, 10/11 November 2020

☐ IT Infrastructure Qualification and Operation, 12/13 November 2020

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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Date of the Live Online Training

Tuesday, 10 November 2020, 09.00 h – 18.00 h
Wednesday, 11 November 2020, 09.00 h – 17.00 h

All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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Organisation and Contact

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For questions regarding organisation etc. please contact:
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Speakers

Frank Behnisch
CSL Behring GmbH

Bob McDowall
R.D.McDowall Ltd.

Yves Samson
Kereon

IT Infrastructure Qualification and Operation in a GMP Environment

Live Online Training 12/13 November 2020

Information Technology and Operation Technology GMP Compliance

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 Live Online Training 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: Introduction to Infrastructure as Code (IaC)

- 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”.

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☐ IT Infrastructure Qualification and Operation, 12/13 November 2020 ☐ SAP – Validation and GMP Compliance, 10/11 November 2020

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Thursday, 12 November 2020, 09.00 h – 17.30 h
Friday, 13 November 2020, 09.00 h – 16.45 h

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