ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Dr Thilo Jania
OLYMPUS EUROPA

Christian Kunath
Santhera Pharmaceuticals

Dennis Leblang
DHC Dr. Herterich and Consultants

Stefan Staub
DHC AG

Stefan Temps
DHC AG

SAP – Validation and GMP Compliance

10/11 November 2020 | Berlin, Germany

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)

- Specific Focus on SAP S/4HANA
- Validation Approach for Cloud and On-Prem
- Hands-on Experiences from SAP Customers
- SAP Solution Manager 7.2 as a Validation platform

Objective

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 course 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 Education Course 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

Validation Approach for SAP S/4HANA On Premise
Stefan Staub

- 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

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

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

Speakers

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 Staub
DHC AG, Switzerland
Stefan Staub joined DHC AG as a Consultant in 2006. He is a specialist in Computerized System Validation with a strong focus on large SAP ERP implementation projects. Since 2012 he is part of the DHC AG management team. Prior joining DHC AG Stefan studied Business Administration with an emphasis on Information and Technology Management at the University of St. Gallen (Switzerland).

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).

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.

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GERMANY

Reservation Form (Please complete in full)

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

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)

General terms and conditions
If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation until 1 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 10 November 2020, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 11 November 2020, 08.30 h – 17.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
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Email 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 first and second day and all refreshments. VAT is reclaimable.

Would you like to save money?
If you book "SAP – Validation and GMP Compliance" and "IT Infrastructure Qualification and Operation" (12-13 November 2020) simultaneously the fee reduces as follows:
ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,690

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.

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