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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Reservation Form (Please complete in full)

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

Phone / Fax

E-Mail (Please fill in)

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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 http://www.gmp-compliance.org/eca_privacy.html). 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 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

The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

If you book the live online trainings "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

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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