20 YEARS ECA Academy
Your GMP/GDP Information Source

SAP – Validation and GMP Compliance

- Specific focus on SAP S/4HANA
- Validation Approach for Cloud and On-Prem
- Hands-On experiences from SAP customers
- Live demonstration: SAP Solution Manager 7.2 as a Validation platform

SPEAKERS:

Dr Thilo Jania
DP/O

Christian Kunath
Vifor Pharma AG

Florian Rauch
DHC Dr. Herterich and Consultants

Stefan Staub
DHC AG

Stefan Temps
DHC AG

12/13 November 2019, Berlin, Germany

LEARNING OBJECTIVES:

- SAP S/4 HANA in a GxP environment
- Validation
  - Best practice approach
  - Process oriented vs. transaction oriented
  - Agile vs. V-Model
  - Cloud vs- On-Prem
- Operation
  - Change management
  - Lifecycle management
- Audit trail in SAP S/4HANA
- Data Integrity and SAP S/4HANA
- Insights from the Pharma Validation Group (PVG)

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager“. Please find details at www.gmp-certification.eu

SAP – Validation and GMP Compliance

12-13 November 2019, Berlin, Germany

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 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 Group

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.

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.

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

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?

Process Landscape and IT System Landscape
- Changes in SAP Product Landscape
- SAP System Landscapes
- System Landscapes for Transformation Projects

Validation Approach for SAP S/4HANA on premise
- Legal requirements
- Process oriented and riskbased approach
- Best practices
- Agile vs. V-Model

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

SAP S/4HANA at Vifor Pharma
- The global CSV Framework
- Implementation and Operation of computerized Systems
- The risk-based approach
- Inspection experiences

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

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

LIVE DEMO
Using SAP Solution Manager 7.2 as a Validation platform (incl. live demo)

- SolMan as Application Lifecycle Management Tool
- Incident Management
- Change Management
- How can SAP Solution Manager support the S/4HANA transformation?

Managing an 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

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

Data Integrity

- Regulatory Requirements
- Data Integrity Assessment
- Data Governance System

LIVE DEMO
SAP Audit Trail in SAP S/4HANA

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

Transformation to SAP S/4HANA and Data Migration

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

Speakers

Dr Thilo Jania
DP/O, Bremen, Germany
Thilo Jania studied Industrial Engineering at the University Paderborn. After 10 years in different management functions at DAIMLER AG and UNITY AG, he founded the DP/O GmbH in 2008. For his company he managed several IT implementation and process improvement programs in the Medtech business. From 2013 until 2016 he was the responsible Program Manager of the successful SAP Implementation at OLYMPUS SURGICAL TECHNOLGIES EUROPE.

Christian Kunath
Vifor Pharma AG, St. Gallen – Switzerland
After many years as global CSV (computerized system validation) manager in different pharmaceutical and medical device companies, Mr Kunath is now Head of End-to-End Processes at Vifor Pharma AG and responsible for all Quality processes of Vifors SAP and MES systems. Mr Kunath is also Certified Information Security Professional (T.I.S.P.), Supplier Auditor and Chairman of the Pharma Validation Group (PVG).

Florian Rauch
DHC Dr. Herterich & Consultants GmbH, Germany
Florian Rauch joined DHC Dr. Herterich & Consultants as a Consultant in 2013. During the last years he worked in multiple SAP Solution Manager implementation and SAP authorization projects in medical devices industry. Florian studied Computer Science at the University of Applied Sciences in Schmalkalden (Germany).

Stefan Staub
DHC AG, Bülach, 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, Bülach, 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).

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

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☐☐ **SAP – Validation and GMP Compliance,** 12/13 November 2019, Berlin, Germany
Virtual IT Systems in a GxP Environment, 14/15 November 2019, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

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GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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

Tuesday, 12 November 2019, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 13 November 2019, 08.30 h – 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0)30 2127 0
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 both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Would you like to save money?

If you book "SAP – Validation and GMP Compliance and "Virtual IT Systems in a GxP Environment" (14/15 November 2019) simultaneously the fee reduces as follows:
ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,690

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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