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
## 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 II.

## 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 risk-based 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 TECHNOLOGIES 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 Schmallkalden (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).
Reservation Form (Please complete in full)

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**Reservation Form: SAP – Validation and GMP Compliance, 12/13 November 2019, Berlin, Germany**

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