SAP – Validation and GMP Compliance

LEARNING OBJECTIVES:

- Validation
  - Validation strategies
  - What needs to be validated?
  - Process oriented vs. transaction oriented
  - Global versus local
  - Best practice approach
  - Agile vs. V-Model

- Operation
  - Change management
  - Lifecycle management
  - Periodic evaluation
  - Data Migration

- Audit trail in SAP

- Data Integrity and SAP

- SAP S/4 HANA in a GxP environment

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

SPEAKERS:

- Thomas Brandacher
  PVC Consulting

- Lasse Janz
  Dräger

- Florian Rauch
  DHC Dr. Herterich and Consultants

- Stefan Staub
  DHC Dr. Herterich and Consultants

- Stefan Temps
  DHC Dr. Herterich and Consultants
Objectives
You will learn
- How to validate SAP in a GMP environment
- Which specific requirements should be taken into consideration in the CSV process
- How to use SAP Solution Manager 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
The leading Enterprise Resource Planning (ERP) System in industry is SAP. Meanwhile it has also become the standard solution for pharmaceutical companies.

As the system is used for GMP critical operations (e.g. inventory, master data management, batch release) validation is a must and a critical element of the SAP implementation.

Controlled operations, including Change Control will ensure the validated state is maintained.

This ECA course will offer you shared best practices for the validation of SAP 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 in a healthcare environment.

Programme
Introduction SAP Validation
- Legal requirements
- Process oriented vs. transaction oriented validation
- Best practice approach
- Agile vs. V-Model

SAP Configuration Management vs. Validation Approach
- Implementation Approach
- Customizing and Developments
- Change and Transport System
- Enhancement Packages and Business Functions

System landscape of SAP
- Pharma process landscape
- What is needed and what needs to be validated (high level risk assessment)
- Introducing the SAP modules
- Standard risk assessment for each module

Live demo
Using SAP Solution Manager as a Validation platform
- Project Tool in a regulated environment
  - Document management
  - Test management
  - Document status report
- Support Tool
  - Incident management
  - Integrative change management

Special features of SAP HANA
- SAP S/4 Hana innovation highlights
- Transformation scenarios to SAP S/4 HANA
- Challenges for the validation approach
- Validation of S/4 HANA as cloud deployment

Process harmonisation and standardisation using a template strategy / SAP and GMP Compliance
- Functional gaps
- Process driven system functionality
- Compliance driven system functionality

Managing a global SAP program in a validated environment
- Governance and global framework
- Vendor selection & staffing (including offshoring)
- Ramp up and training
- Documentation approach
- Milestones & key deliverables
- Toll gate reviews
- Data migration approach
- SOX in a project
- Handover to support
- Including templates and selected guidelines.

Templates
All participants get a set of useful templates for download
- Validation plan
- User requirement specifications
- functional specifications
- Test scripts
- Risk assessment questions
- SOPs for operating the validated system
- Data migration
Data Migration
- A strategic approach to data migration
- Regulatory requirements and data migration
- Validating the data migration

Data Integrity and SAP
- Regulatory requirements (FDA, EU, MHRA)
- Critical processes (QC)
- Roles and responsibilities
- SAP support tools (MDG)

Audit trail in SAP
- Compliance for audit trails: definitions and requirements
- A risk-based approach to audit trails
- Implementing audit trails
- Audit trail reviews

Processes and experiences with validation of SAP within a regulatory context
- Change management; IT Validation and electronic record keeping for quality relevant process software as a manufacturer of medical devices
- How to ensure that quality relevant impacts are evaluated when changing a validated SAP system?
- How to ensure that efforts for validation are kept on an efficient level without compromising quality and regulatory requirements?
- How to effectively link system, process and validation documentation?
- How to manage electronic records within SAP?

GMP compliance for SAP authorisation
- User and authorisation management
- Documentation approach for authorisation
- Testing of authorisation requirements

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.

Speakers

Thomas Brandacher
PWC Consulting LLC, Tokyo, Japan
Thomas Brandacher was Head Global ERP Project Management Office (PMO) at the Sandoz site in Holzkirchen close to Munich. Within Sandoz and other companies he managed SAP projects over a period of more than 10 years. He joined PWC Consulting as Managing Director in 2016.

Lasse Janz
Drägerwerk AG & Co. KGaA, Germany
Lasse Janz studied Business Informatics at Kiel University of Applied Science. Since 2015 he is a Quality Manager at Drägerwerk AG & Co. KGaA (Software Validation Officer, Global Process Owner Software Validation and Global Process Owner Electronic Signature).

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 Dr. Herterich & Consultants AG, Switzerland
Stefan Staub joined DHC Dr. Herterich & Consultants 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 Dr. Herterich & Consultants AG, Switzerland
Stefan Temps joined DHC Dr. Herterich & Consultants as a Senior Consultant in 1996. Since 2000 he is Managing Director of DHC AG, Switzerland. During the last years he was engaged as project manager for SAP ERP implementation projects and GxP compliance in the pharmaceutical 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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SAP – Validation and GMP Compliance, 6-7 November 2018, Berlin, Germany

Virtual IT Systems in a GxP Environment, 8-9 November 2018, Berlin, Germany

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

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

Phone +49 (0)62 21/84 44 34
Fax +49 (0)62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

Date

Tuesday, 6 November 2018, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 7 November 2018, 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 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” (8-9 November 2018) 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.

CONCEPT HEIDELBERG, P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andreas Mangel (Operations Director)
at +49(0)62 21 / 84 44 41 or at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Rouwen Schopka (Organisation Manager)
at +49(0)62 21 / 84 44 13 or per e-mail at schopka@concept-heidelberg.de.

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