SPEAKERS:

- Thomas Brandacher  
  RheinBrücke IT Consulting

- Maximiliane Bretz  
  Dräger

- Andreas Jung  
  DHC Dr. Herterich and Consultants

- Christoph Keppner  
  DHC Dr. Herterich and Consultants

- Stefan Temps  
  DHC Dr. Herterich and Consultants

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

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 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
- 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
- Big Data in the regulated environment
- Differences between conventional and the in memory database
- What will be new in S/4 HANA Datamigration from old Systems
- Validation efforts fort he cloud solution

Pharma process landscape
- IT systems and pharma processes
- Special features of pharmaceutical processes
- Processes, IT systems and GxP compliance

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

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
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.

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

Processes and experiences with validation of SAP within a regulatory context
- Change management; IT Validation and electronic recordkeeping 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?

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

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, RheinBrücke IT Consulting GmbH, Köln, Germany; formerly Sandoz GmbH, Austria
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 RheinBrücke in 2015.

Maximiliane Bretz, Dräger Medical GmbH, Germany
Maximiliane studied biomedical engineering at Hamburg University of Applied Science. Since 2012 she is Quality Manager at Dräger Medical GmbH (Software Validation Officer and Global Process Owner Software Validation).

Andreas Jung, DHC Dr. Herterich & Consultants GmbH, Germany
Andreas Jung joined DHC Dr. Herterich & Consultants as a Consultant in 2008. Since 2011 he is Competence Center Manager for Compliance. During the last years he was project quality manager for worldwide SAP ERP implementation projects and GxP compliance in the pharmaceutical and medical devices industry. Prior to joining DHC in 2008, Andreas studied Molecular Genetics, Virology and Biochemistry at the University of Saarbrücken (Germany) and worked for 10 years in medical research.

Christoph Keppner, DHC Dr. Herterich & Consultants GmbH, Germany
Christoph Keppner joined DHC Dr. Herterich & Consultants as a Consultant in 2007. Since 2014 he is Competence Center Manager for IT Service Management. During the last years he worked in multiple SAP Solution Manager implementation projects. Prior to these projects he was project quality manager and test manager for worldwide SAP ERP implementation projects in the pharmaceutical industry. Christoph studied Computer Science at the University of Saarbrücken (Germany).

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).
Date
Thursday, 3 November 2016, 09.00 h – 18.00 h
(Reservation and coffee 08.30 h – 09.00 h)
Friday, 4 November 2016, 08.30 h – 16.30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0) 30 2127 0
Fax +49(0) 30 2127 117

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. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotels.

Early reservation is recommended.

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
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For questions regarding content:
Dr Andreas Mangel (Operations Director)
at +49(0) 6221 / 84 44 41 or at mangel@concept-heidelberg.de.

For questions regarding registration, 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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