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

14-15 November 2017, Copenhagen, Denmark

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

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 for the 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

Data Integrity and SAP

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

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?

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**
*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

**SAP – Validation and GMP Compliance,** 14-15 November 2017, Copenhagen, Denmark

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<th>Date</th>
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<td>Tuesday, 14 November 2017, 09.00 h – 18.00 h (Registration and coffee 08.30 h – 09.00 h)</td>
<td>Radisson Blu Royal Hotel Hammerichsgade 1 I611 Copenhagen V, Denmark</td>
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**Virtual IT Systems in a GxP Environment,** 16-17 November 2017, Copenhagen, Denmark

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### 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” (16-17 November 2017) 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 44-41
info@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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**Reservation Form (Please complete in full)**

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

I note that I can ask for the modification, correction or deletion of my personal data at any time via the contact form on this website.

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We are happy to welcome a substitute colleague at any time. If you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

- **- until 2 weeks prior to the conference 10 %,**
- **- until 1 weeks prior to the conference 50 %,**
- **- within 1 week prior to the conference 100 %,**

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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For questions regarding reservation, hotel, organisation etc.:

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  - email royal.meetings.events@radissonblu.com

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  - Phone +45 3342 6000
  - Fax +45 3342 6100
  - email royal.meetings.events@radissonblu.com

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[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

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