Live demonstration:
Using SAP Solution Manager as a Validation platform

SAP – Validation and GMP Compliance

23-24 September 2014, Prague, Czech Republic

SPEAKERS:

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LEARNING OBJECTIVES:

- Validation
  - Validation strategies
  - What needs to be validated?
  - Process oriented vs. transaction oriented
  - Global versus local
  - Best practice approach
- Operation
  - Change management
  - Lifecycle management
  - Periodic evaluation
  - Data Migration
- Audit trail in SAP

ECA ACADEMY

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

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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.

Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 180.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, The conference folder will not be available until 2 weeks after the event.

Programme

Introduction SAP Validation
- Legal requirements
- Process oriented vs. transaction oriented validation
- Best practice approach

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

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

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?

Live demo

Audit trail in SAP

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

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, *Defiance Tech GmbH, Köln, Germany; formerly Sandoz GmbH, Kundl, 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 Defiance Tech in 2012.

Maximiliane Bretz, *Dräger Medical GmbH, Lübeck, 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, Saarbrücken*
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, Saarbrücken*
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, Bülach, 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).

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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☐ 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

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☐ I herewith order the course folder for EUR 380,- plus VAT and postage

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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.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- 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.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, 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)! (As of January 2012)

Date

Tuesday, 23 September 2014, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 24 September 2014, 08.30 h – 16.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 261 191 111
Fax +420 261 225 011

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.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language

The official conference language will be English.

Organisation and Contact

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