SPEAKERS:

- Thomas Brandacher
  Defiance Tech

- 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

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

Live demonstration:
Using SAP Solution Manager as a Validation platform

SAP – Validation and GMP Compliance

23-24 September 2014, Prague, Czech Republic

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

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).
Reservation Form (Please complete in full)

**SAP – Validation and GMP Compliance**
23-24 September 2014, Prague, Czech Republic

- [ ] 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**

**City**

**Zip Code**

**Country**

**Phone/Fax**

**E-Mail (please fill in)**

---

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

---

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

**CONCEPT HEIDELBERG**

P.O. Box 101764

D-69007 Heidelberg

GERMANY

---

**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 will charge the following processing fees:
   - Cancellation until 2 weeks prior to the conference 10%,
   - until 1 week prior to the conference 50%,
   - within 1 week prior to the conference 100%.

**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)

---

**Terms of payment**

- **EUR 380,- plus VAT**

---

**Fees (per delegate plus VAT)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECA Members</td>
<td>€ 1,490</td>
</tr>
<tr>
<td>APIC Members</td>
<td>€ 1,590</td>
</tr>
<tr>
<td>Non-ECA Members</td>
<td>€ 1,690</td>
</tr>
<tr>
<td>EU GMP Inspectors</td>
<td>€ 845</td>
</tr>
</tbody>
</table>

---

**Registration**

- Via the attached reservation form, by e-mail or by fax
- On registration online at www.gmp-compliance.org

---

**Accommodation**

- Early reservation is recommended.
- 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 will charge the following processing fees:**
    - Cancellation until 2 weeks prior to the conference 10%,
    - until 1 week prior to the conference 50%,
    - within 1 week prior to the conference 100%.

---

**Conference Language**

- The official conference language will be English.

---

**Date**

Tuesday, 23 September 2014, 09.00h - 18.00h

Wednesday, 24 September 2014, 08.30h - 16.30h

---

**Venue**

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