SAP – GMP Compliance and Validation

30-31 October 2012, Vienna, Austria

SPEAKERS:

Sven Bajorat
Dräger

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LEARNING OBJECTIVES:

- GMP: Where do we come from – where do we go?
- Validation
  - Validation strategies
  - What needs to be validated?
  - Global versus local
  - User requirements
  - Risk management
- Operation
  - Change management
  - Lifecycle management
  - Security and authorisation concepts
  - Periodic evaluation
- SAP Solution manager
- E-records and E-signatures within SAP

ECA
EUROPEAN COMPLIANCE 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
- 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 employees from
- IT & IT Service Providers
- Quality Assurance / Quality Control
- Production / Engineering

who have to deal with SAP in a healthcare environment.

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.

Programme

Introduction

Validation Overview
- Guidelines and regulations for companies subject to comply with GxP rules and SOX / ICFR
- V-model
- Risk based approach for efficient validation
- User requirement specifications

Workshop: SAP related User requirements
- Voice of customer – Critical to Quality
- Proper design of User requirements

The Risk management process
- Introducing different methods of risk assessment
- Module risk
- Functional risk
- Batch release in SAP

Workshop: Risk analysis for SAP

Processes and Experience 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?

Process management as a mandatory requirement for lean validation
- Business process master list as the leading document
- Level of details in a SAP environment
- Designing Business Process Flows

Workshop: Process management

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

Global versus local

Security and Authorisation
- Setting up a compliant authorisation concept (roles, access, training)
- Compliant user provisioning and Fire Fighter role within the GRC module of SAP
- ICFR audits – What questions may come up?

Helpful tools
- System management
- Change management
- Incident management
- Discrepancy management
- Document management
- Solution manager from SAP as ultimate answer?

Life cycle management
- Setting up a governance model
- Necessary SOP's
- Rules and responsibilities
- Regression testing
- Periodic evaluation of the system

Audit Trail
- Regulatory requirements
- Audit trail review

E-Signature
- Is the SAP "ESig" functionality 21 CFR Part 11 compliant?
- How to implement the "ESig"

SAP-QM
- Can SAP-QM replace the laboratory LIMS?
- "Lot disposition" decision in SAP

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.

Speakers

Sven Bajorat
Dräger Medical GmbH, Lübeck, Germany
Sven currently has the role of Global IT Validation Officer at Dräger Medical GmbH. Formerly he has worked as a consultant at Accenture GmbH at various IT-related projects. Since joining Dräger in 2003 he has hold different IT and Quality Management positions. His current role includes being the global process owner for validation of quality process software, globally responsible at Dräger since 2009 for compliance to ISO and FDA regulations. Sven is a TÜV-certified Quality Auditor, an EFQM Assessor and a Project Management Professional (PMP)©.

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.

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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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

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Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

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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 %.

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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 at January 2012)

Date

Tuesday, 30 October 2012, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 31 October 2012, 08.30 h – 16.30 h

Venue

Renaissance Wien Hotel
Linke Wienzeile / Ullmannstr. 71
1150 Vienna
Austria
Phone +43 – 189 102
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Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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 or be sure to mention "ECA7387" to receive the specially negotiated rate (single room per night incl. breakfast: € 129,-) for the duration of your stay. Reservation should be made directly with the hotels not later than 1 October 2012. 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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