ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers


Andreas Busse
Carl Zeiss, Germany


Károly Földesi
SAP Deutschland, Germany


Christian Gasper
DHC Dr. Herterich & Consultants, Germany


Robert Geiger
SAP SE, Germany


Christina Kiefer
Reusch Rechtsanwaltsgesellschaft, Germany


Thomas Pauly
DHC Dr. Herterich & Consultants, Germany


Dr Wolfgang Schumacher
Formerly F. Hoffmann-La Roche, Switzerland


Stefan Staub
DHC, Switzerland


Nicole Steffensky
DHC Dr. Herterich & Consultants, Germany


Christian Vogler
Raumedic, Germany

SAP – Validation and GMP Compliance

Live Online Training on 18/19 February 2025

Specific Focus on SAP S/4HANA Implementation and Validation

Highlights

- New Regulations and Guidelines
- Qualification of SAP as a Supplier
- SAP Cloud Solutions – Legal Challenges and Compliance in Practice
- Validation Approach for Cloud and On-Prem Solutions
- Hands-On Experiences from SAP Customers
- Trends and Innovations

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Programme

Objectives

You will learn

- How to validate SAP S/4HANA 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

SAP S/4HANA has been launched in 2015 as the New Intelligent ERP system. The software is available in both Cloud and On-prem edition. SAP S/4HANA is being called the biggest update to its ERP system in over two decades. Together with the shift to In-Memory database SAP HANA a new user interface (SAP Fiori) was introduced. One of the biggest changes is cloud deployment, parts of SAP Enterprise Architecture are now only available as public cloud software (e.g. SAPs Digital Manufacturing Cloud DM). This has immense implications for deployment in the Life Sciences industry.

The mainstream maintenance for the predecessor products will end in 2027, and SAP has a strong presence in the Life Sciences industry with over 3800 customers. Owing to this timeline a lot of SAP customers have already started the transformation journey to SAP S/4HANA or at minimum have initiated a pre-project.

How will all these technical and functional changes in the surrounding of SAP S/4HANA (user interface, in-memory database, different deployment types) impact the validation approach and the validation scope?

This ECA Live Online Training will provide comprehensive knowledge about how to validate SAP S/4HANA for new SAP Life Sciences customers (for On-prem and Cloud deployments) as well as for installed base customers who are planning a system conversion. Expect two days full of shared best practices for the validation of SAP S/4HANA considering regulatory requirements like EU GMP Guide Annex 11, GAMP® 5 2nd Edition, 21 CFR Part 11 and FDA CSA draft.

Target Audience

This ECA Live Online Training is directed at experienced employees from

- IT & IT Service Providers
- Quality Assurance / Quality Control
- Production / Engineering

who have to deal with SAP S/4HANA in the regulated environment of the Life Sciences Industry (Pharmaceutical & Medical Devices).

Programme

New Regulations and Guidelines Covering Computer System Compliance in the GMP Area

- EMA New Annex 11 Draft - Pros and Pain Points
- FDA CSA Draft – meaningful or missing the target?

Validation Approach for SAP S/4HANA

- Risk-based validation approach for SAP S/4HANA implementation
- Risk-based validation approach for transformation SAP ECC to SAP S/4HANA
- How to harmonize validation and implementation

Case Study: SAP S/4HANA Conversion @ RAUMEDIC - Challenges in Implementation and GxP Compliance

- Transformation from SAP ECC 6.0 to SAP S/4HANA
- Various GxP compliance requirements must be met by using an integrated approach
- Added value of the approach
- Challenges and lessens learned from this ongoing project

Qualification of SAP as a Supplier of GxP relevant IT Solutions

- General supplier qualification requirements
- Possible approaches for the qualification of SAP
- SAPs general and GxP-specific offerings to support the supplier qualification

Audit Trail in SAP S/4HANA

- Compliance for audit trails: definitions and requirements
- A risk-based approach to audit trails
- Implementing and testing audit trails

Implementation of SAP S/4HANA and Data Migration

- A strategic approach to data migration
- Regulatory requirements and data migration
- Validating

SAP Validation and GMP Compliance - Experience from Inspections and Audits

- SAP cloud systems in pharmaceutical and medical technology companies
- Main investigator focus during inspections of a SAP system
- Operation of SAP on cloud hyperscalers (MS Azure/AWS)
- Validation and control of SAP updates
- Use of SAP test automation tools

Overview SAP in Life Sciences

- SAP Solution Strategy mapped to Life Sciences
  - SAP Industry Solution Portfolio for Life Sciences
  - Industry Cloud for Life Sciences Solutions (SAP and SAP Store Partner Solutions)
- Business Transformation to enable a composable IT-Platform to support agility and regulations - intertwined implementation and validation
- Key takeaways

Validation of SAP (Public) Cloud Solutions

- Challenges in a public cloud deployment model
- How can customers gain trust in a public cloud solution?
- Validating a cloud solution and staying validated

Case Study: Introduction and Validation of SAP Digital Manufacturing Cloud (SAP DMC) in ZEISS's Highly Regulated Manufacturing Environment

- Manufacturing process template-based validation approach
- Agile DevOps and roll-out deployment
- Keep IT validated – operation of cloud-based services

Data Protection and Cyber Security in the Cloud - Legal Challenges and Compliance in Practice

- Requirements of the GDPR and the data protection supervisory authorities
- Innovative use of health data and the planned European Health Data Space
- The EU's new cybersecurity law: cloud services and the NIS-2 Directive
- Practical tips on cloud compliance from a lawyer's perspective

Trends and innovations in computer-aided systems validation

- AI
- Digitalisation
- Automation

How to Streamline and Speed Up the Validation Process

- What are prerequisites to streamline and speed up the validation process?
- Steps to streamline the validation process
- Efficient, fast methods and tools to speed up the process
- The role of the supplier(s)

Speakers

Andreas Busse, Carl Zeiss AG, Oberkochen, Germany

Andreas Busse has been working as Business Process Consultant at ZEISS since 2019. In his role as MES template process owner he is responsible for implementation and operation of SAP Digital Manufacturing at ZEISS.

Károly Földesi, SAP Deutschland, Walldorf, Germany

Since May 2016 responsible for German Life Sciences customer at SAP Deutschland as a Senior Director Digital Business for Life Sciences in Customer Advisory.

Christian Gasper, DHC Dr. Herterich & Consultants, Saarbrücken, Germany

Christian Gasper is with DHC since 2015 and became Partner there in 2021. Acting as data migration manager, integration manager and solution architect in regulated industry projects he gathered experience in both implementation and validation of SAP ERP systems.

Robert Geiger, SAP SE, Walldorf, Germany

Robert Geiger joined SAP in 2023 to globally coordinate the GxP Compliance activities for SAPs public cloud offerings as Product Manager GxP Compliance in the central Security and Compliance Organization of SAP.

Christina Kiefer, Reusch Rechtsanwaltsgesellschaft, Saarbrücken, Germany

Advises companies and public institutions on complex issues in the areas of data protection and cybersecurity as well as IT and contract law. One focus of her work is supporting clients in the introduction of digital products.

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Thomas Pauly, DHC Dr. Herterich & Consultants GmbH, Saarbrücken, Germany

Thomas joined DHC in 2020 as Managing Consultant and his areas of focus are IT Compliance in general as well as the qualification and validation of cloud-based IT infrastructure and systems in particular.

Dr Wolfgang Schumacher, Formerly F. Hoffmann-La Roche Ltd., Basel, Switzerland

After 9 years in the IT quality unit, Dr. Schumacher headed the Quality Computer Systems department of Hoffmann-La Roche Ltd until his retirement.

Stefan Staub, DHC AG, Zürich, Switzerland

Joined DHC 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 management team.

Nicole Steffensky, DHC Dr. Herterich & Consultants, Saarbrücken, Germany

Joined DHC in 2015 and has since gained extensive experience in a large number of SAP validation projects. As Practice Manager for SAP Validation, she is responsible for the DHC methodology and the DHC validation team.

Christian Vogler, Raumedic AG, Helmbrechts, Germany

Christian Vogler has been working at Raumedic for 19 years. He is currently responsible for SAP S/4HANA Conversion and the implementation of SAP Digital Manufacturing as project lead.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
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Reservation Form (Please complete in full)

SAP – Validation and GMP Compliance, Live Online Training on 18/19 February 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training

Tuesday, 18 February 2025, 09.00 h – 18.00 h
Wednesday, 19 February 2025, 09.00 h – 17.00 h

All times mentioned are CET.

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045

The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21605

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

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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 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or per e-mail at
mangel@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de