ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers


Andreas Busse
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Christian Gasper
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Stefan Hessel
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Dr Anne Leutzgen
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Thomas Pauly
DHC Dr. Herterich & Consultants, Germany


Thomas Peter
Geistlich Pharma, Switzerland


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


Stefan Staub
DHC, Switzerland


Dr Laura Stopper
DHC Dr. Herterich & Consultants, Germany

SAP – Validation and GMP Compliance

Live Online Training on 7/8 November 2023

Highlights

- New regulations and guidelines
- Specific focus on SAP S/4HANA implementation and validation
- SAP Cloud Solutions – Legal Challenges and Compliance in Practice
- Validation Approach for Cloud and On-Prem Solutions
- Hands-On experiences from SAP customers
- "Tools for IT Compliance and Software Validation"

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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 DMC). 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 recent regulatory requirements like EU GMP Guide Annex 11, GAMP® 5, 2nd Edition and 21 CFR Part 11.

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 a healthcare environment.

Programme

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

- GAMP® 5, 2nd edition
- EMA New Annex 11 Concept Paper
- 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-Implementation and Validation in the Medical Device/ Pharmaceutical Industry

- SAP Multi Product Template build and Roll-Out (S/4, Concur, E-Commerce, Success Factors)
- Impact on system landscape(s) based on regulatory requirements
- Resulting challenges for the validation

Agile vs. Waterfall Validation - Is Agile Incompatible with SAP Implementations?

- Challenges of SAP implementations
- Applying agile to a large-scale implementation
- Agile approach to Validation

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 the data migration

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 Strategy – enable your success
  - Business agility, supply chain resilience and sustainability outcomes
- How pharmaceutical solution are embedded in an intelligent & sustainable Enterprise
- SAP Industry Cloud for Life Sciences – highlighted SAP and Partner Solutions
- 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

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)

Toolbased Support for Validation and Compliant System Operation

- Requirements for the digitalisation of validation processes
- Digitisation of content
- GxP-compliant release of content, change processand test automatisation
- Tools

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

Károly Földesi is 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 integration manager and solution architect in regulated industry projects he gathered experience in both implementation and validation of SAP ERP systems.

Stefan Hessel, Reusch Rechtsanwaltsgesellschaft, Saarbrücken, Germany

Salary Partner and Head of Digital Business at Reusch Rechtsanwaltgesellschaft in Saarbrücken.

Dr Anne Leutzgen, DHC Dr. Herterich & Consultants, Saarbrücken, Germany

After her PhD, she worked as a product developer in the cosmetics industry and as a product safety manager for consumer products. She joined DHC as a consultant for Computer System Validation. Here, she focuses on tool-supported SAP S/4HANA validation on premise as well as in the cloud.

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

Thomas Pauly has been working in the pharmaceutical industry since 2005. 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.

Thomas Peter, Geistlich Pharma, Wolhusen, Switzerland

Thomas Peter has been working for Geistlich Pharma since 2008 and is responsible, among other things, for the operation of the SAP ERP landscape and, together with his team, acts as a link between IT and business stakeholders.

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

Stefan Staub 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.

Dr Laura Stopper, DHC Dr. Herterich & Consultants GmbH, Saarbrücken, Germany

After her PhD she joined DHC as a consultant for Computer System Validation. Here, she focuses on methodological SAP S/4 HANA validation on premise as well as in the cloud.

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Reservation Form (Please complete in full)

SAP – Validation and GMP Compliance, Live Online Training on 7-8 November 2023

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

Thuesday, 7 November 2023, 09.00 h – 18.00 h
Wednesday, 8 November 2023, 09.00 h – 17.30 h

All times mentioned are CET.

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

Registration

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

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.

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