ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Robert Gärtner
Veeva Systems, Germany

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

Dr Arno Terhechte
GMP Inspector, Germany

Michael Wegmann
F. Hoffmann-La Roche, Switzerland

NEWS

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Cloud Computing in a GxP Environment

Challenges and Solutions

Live Online Training from 5-7 March 2025

Highlights

- Compliance Requirements for Cloud Computing
- Inspectors' / Regulators' Expectations and Findings during Inspections
- Types of Cloud Computing
- Use of Cloud Computing in a GxP Environment
- Outsourcing and Cloud Computing – What is important for Contracts
- Data Integrity and Cloud Computing
- IT Security and Data Protection Requirements
- Validation of a Cloud Process
- Cloud Computing from the Suppliers Point of View
- Technology Behind Cloud Services
- Moving to the Cloud – Working out how to do it
- Pros and Cons

Including Case Studies on Cloud Computing, Risk Assessment and Audit of a Cloud Provider

Programme

Objectives

- Get to know the different types of Cloud Computing, their technical basics and their validation approaches.
- What are the pharmaceutical authorities' requirements with regard to Cloud Computing and what regulations have to be observed? An inspector will present his perspective to these questions and the experience gained so far in audits and will further cover critical points.
- You can assess the use of Cloud Computing from the perspective of IT security and data protection rules, and based on that you can formulate requirements for cloud service providers.
- You can evaluate the opportunities and risks of cloud computing in the GxP environment.

Background

As well as in other sectors, the use of Cloud Computing is discussed in the pharmaceutical industry. For commercial reasons there is a lot speaking for the use. However, is Cloud Computing an acceptable way in a GxP environment of the pharmaceutical industry? And, if yes, what has to be observed from the point of view of IT and quality assurance, as well as from the perspective of a pharmaceutical inspector? From the points of view of the user and the pharmaceutical inspector this event gives you an overview of the current state of the technical possibilities. The speakers evaluate opportunities and risks of the use of Cloud Computing in the GxP environment and make recommendations for the pharmaceutical practice.

Target Audience

The ECA Live Online Training is aimed at employees who are entrusted with the planning and implementation of "cloud" projects in the GxP environment. The event also offers support for decision-making, whether cloud services are available as an alternative in the GxP environment.

Programme

Regulatory Background – Important Issues to consider from the Point of View of an Inspector

- Requirements for CSP (cloud service providers) resulting from Annex 11
- To dos for regulated users with respect to chapter 7 of the EU GMP Guide
- German drug law – does the German drug law or European Law effect the business of CSP; enforcement of corrective actions

Definition and Types of Cloud Computing

- Service models: Private Cloud, Public Cloud, Community Cloud, Hybrid Cloud
- Infrastructure as a Service (IaaS)
- Platform as a Service (PaaS)
- Software as a Service (SaaS)
- Cloud Computing scenarios, reference architectures, examples

Case Study: Cloud Computing Risk Assessment

In this workshop the participants will perform a risk assessment for a given cloud strategy. A practical exercise that helps to understand and get on top of the risks involved with cloud computing.

Inspections and Findings

- European Framework to conduct inspections
- Availability, data integrity and confidentiality of data
- Possibility to perform inspections of CSP
- State of the art defined by BSI, ENISA and NIST
- Inspections: experiences and findings

Cloud Computing: IT Security

- Examples of incidents
- Strategic planning and preparation for going to cloud services
- Security management and security architecture
- Security certifications (e.g. ISO 27001) and what they really mean
- Physical and logical security, encryption
- Incident prevention and response
- Professional security patch management
- Identity management, authentication, authorization
- Integration of cloud services with internal IT landscape

The Technology behind Multi-Tenant Cloud Services

- Why Multi-tenancy
- Typical service provided and their delivery processes
- Technology and resource pools
- Risk and opportunities

Compliance Requirements for the Cloud Infrastructure

- Regulatory requirements
- Qualification of the cloud
- Validation of the cloud

Cloud Computing in a GxP Environment from a Service Provider Perspective

- Current adoption of Cloud Computing in GxP Areas
- Expectations from a Customer perspective, pre-requisites on the Service Provider side
- Shared operating model and handling of planned/unplanned events
- What information does a CSP need from the customer before signing a contract?
- Transparency & Auditability of CSP operations, e.g., compliance of data storage
- Future progression of partnering models

Contracts with Cloud Service Providers

- Business & Technology Risks
- Intellectual Property
- Service Access / Service Quality KPIs
- Data storage requirements
- Inspection & audit support
- Example Contract/SLA
- Lessons learned

Case Study: Audit of a Cloud Provider
- Audit preparation based on risk-based approach
- How to interpret audit results
- How to manage various CSPs of SaaS solutions
  Tips and tricks about the audit topics

GxP, Data Integrity, Best Practice: How to partner with your Cloud Provider

- Understanding GxP Applicability based on intended use
- Assessing risks that include GxP, but also broader (e.g., Data Integrity, Privacy, Security)
  - Applying intended use to applicable GxPs, regulatory guidance, etc. expectations
  - Effectively leveraging an FRA - What does it drive and where efforts should be focused by the Supplier and Life Science company?
- Review Case Study with examples of risk assessment, validation, and associated deliverables. And, discussion on how to effectively leverage and supplement internal requirements

Discussion: How to effectively partner with your Cloud Provider

This will be a facilitated Panel Discussion that allows the participants to ask the speakers specific questions.

Cloud Computing: Data Protection

- Data protection and privacy – legal requirements
- Responsibilities of the cloud service provider
- Responsibilities of the cloud customer

Impact of the EU Court of Justice Ruling (311/18 – "Schrems-II") on the use of Cloud Services

Data Classification

- Responsibility and integration in the IT project management framework
- Handling, processing, commissioned processing of data
- Forced disclosure
- Applicable regulations
- Examples and lessons learned

Cloud Computing: Use Cases in a GxP Environment

- Risk-based approach
- Specific responsibilities of the cloud service provider
- Specific responsibilities of the cloud customer
- Separation of GxP vs. non GxP
- Examples

How to validate a Cloud Process – Manage the Risks and stay in Compliance

- URS / GxP/functional risk assessment
- Validation planning and testing
- Validation report
- Change control, bug fixes, monitoring

Government Agencies and Cloud Computing

- Objectives and capabilities of government agencies
- How and where do they hook in
- Internet surveillance and specific attacks
- Industry espionage
- Countermeasures and their limitations

Experiences With Outsourcing and Cloud Computing

- QA involvement
- Pain points

Cloud Computing: Pros and Cons

- Opportunities and risks of cloud computing
- Rationale for using cloud services
- Rationale for not using cloud services
- Conclusions and recommendations

Speakers

Robert Gärtner, Veeva Systems, Frankfurt, Germany

Robert Gaertner has been working in quality management for more than 25 years. After starting his career at Fresenius Kabi, he worked for various consulting companies including PwC, IBM and Infosys with a focus on electronic systems implementations in GxP areas. Since 2014, he is leading the quality strategy practice at Veeva Systems in Europe.

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

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the Quality Computer Systems department. He is a member of the ECA Advisory Board.

Dr Arno Terhechte, GMP inspectorate/ Bezirksregierung Münster, Germany

After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is chairman of the German expert group 11 "computerised systems".

Michael Wegmann F. Hoffmann-La Roche, Basel, Switzerland

Since 1989, Michael Wegmann has been working as IT expert in the pharmaceutical industry. From 2000 to 2011, he was globally responsible for IT security in the Roche Pharmaceuticals Division. In his current role as Global Head of Integration Competency Center, he is responsible for system integration (EAI), interfaces and middleware in the Roche Diagnostics Division.

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Reservation Form (Please complete in full)

Cloud Computing in a GxP environment
Live Online Training from 5-7 March 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

Phone / Fax

E-Mail (Please fill in)

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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 4 weeks prior to the conference 10 %,
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- Cancellation until 2 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training
Wednesday, 5 March 2025, 09.00 h - 17.30 h
Thursday, 6 March 2025, 09.00 h – 17.30 h
Friday, 7 March 2025, 09.00 h - 13.30 h

All times mentioned are CET.

Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
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 21549.

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.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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