Cloud Computing in a GxP Environment
Challenges and Solutions

SPEAKERS:

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Including workshops on cloud computing risk assessment and audit of a cloud provider

2-3 March 2017, Berlin, Germany

LEARNING OBJECTIVES:

- 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
- 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

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager“. Please find details at www.gmp-certification.eu
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 to be said for its 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 event 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 deciding, whether cloud services are available as an alternative in the GxP 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

## 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 do’s 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

## 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 cloud services

- Service provided and their delivery processes
- Technology and resource pools
- Risk and challenges

### Workshop: 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.

## 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 learnt

## Cloud provider contract walk-through

- Typical pin points for cloud providers
- GxP relevant issues
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

Compliance requirements for the cloud infrastructure
- Regulatory requirements
- Qualification of the cloud
- Validation of the cloud

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

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

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

Business continuity management
- Necessity for Sales/Patients/Annex11?
- Assessing the Business Continuity Risk
- Buss. Cont. Plan – BCP
- Disaster Recovery-MTPD-RTO-RPO

Moving to the cloud: Working out how to do it
- Requirements from different starting points
- Mapping your needs to the different options in cloud services
- Defining a strategy to move to the cloud
- Learn how cloud service provider business can impact yours
- Prepare for action: Plan the move

Workshop: 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

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 – includes closing discussion
- Opportunities and risks of cloud computing
- Rationale for using cloud services
- Rationale for not using cloud services
- Conclusions and recommendations

Speakers

Ingeborg Baars, Iperion BV, The Netherlands
Ingeborg is Managing Director of the Cloud Computing business unit at Iperion. For years she has been hosting audits of customers with GxP requirements and has been end responsible for the GxP compliance of a CSP. She holds a Master Degree in Business Administration.

Msc Karel Bastiaanssen, Iperion BV, Netherlands
Karel is founder and owner of the Iperion Life Sciences group. Karel holds a master degree in Business engineering and Management Science from the Eindhoven technical university in Netherlands. Iperion is specialised in QA, ERP and RA information systems, GxP cloud computing and consultancy services for companies operating in the pharmaceutical, medical device, biotechnology and health care sectors.

Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche Ltd., 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, Bezirksregierung Münster, Germany
After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the Bezirks-regierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group 11 “computerised systems”.

Michael Wegmann, F. Hoffmann-La Roche Ltd., 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.
### Reservation Form (Please complete in full)

**Cloud Computing in a GxP Environment**  
2-3 March 2017, Berlin, Germany

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**Ms**

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### General terms and conditions

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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:**
   - until 2 weeks prior to the conference 0%,
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### Fees (per delegate plus VAT)

- **ECA Members:** €1,490
- **APIC Members:** €1,590
- **Non-ECA Members:** €1,690
- **EU GMP Inspectors:** €845

The conference fees are 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. Reservation should be made directly with the hotel. Early reservation is recommended.**

### Conference Language

The official conference language will be English.

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For questions regarding reservation, hotel, organisation etc.:  
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Tel +49 (0) 62 21 / 84 44 18 or per e-mail at: grimm@concept-heidelberg.de.

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ECA has entrusted Concept Heidelberg with the organisation of this event.

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