



# Cloud Computing and Outsourcing in a GxP Environment

12-13 March 2015, Berlin, Germany

## SPEAKERS:

Dr Karel Bastiaanssen  
*Iperion*

Dr Wolfgang Schumacher  
*F. Hoffmann-La Roche Ltd.*

Dr Arno Terhechte  
*Bezirksregierung Münster*

Michael Wegmann  
*F. Hoffmann-La Roche Ltd.*

## 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
- Cloud Computing from the suppliers point of view
- Pros and cons



# Cloud Computing and Outsourcing in a GxP Environment

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## Objectives

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- 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

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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

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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 decision-making, whether cloud services are available as an alternative in the GxP environment.

## Social Event

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On 12 March, 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

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### Regulatory Background – important issues to consider from the point of view of an inspector

- Requirements for CSP (cloud service providers) resulting from Annex II
- 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 cloud service provider business

- Service provided and their delivery processes
- Technology and resource pools
- Business model(s) and achieving sound economics
- Risk and challenges

### Operating as a Cloud service Provider

- Chain of command: How do SaaS cloud providers manage their PaaS or IaaS providers or the other way around
- Inspections by customers (or authorities)
- Cooperations between cloud providers (e.g. for common standards)
- How to become the ideal customer for a CSP?

### 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 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

### Inspections and audit experiences: The pharmaceutical industry perspective

- Inspection Trends EMA – Annex 11
- Inspection Trends FDA
- Inspection Trends other countries
- Hot Buttons

### 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

### Business continuity management

- Necessity for Sales/Patients/Annex 11?
- Assessing the Business Continuity Risk
- Buss. Cont. Plan – BCP
- Disaster Recovery - MTPD - RTO - RPO

### 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

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#### Dr Karel Bastiaanssen

*Iperion Life Sciences, The 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

*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 is now Head of the department of Quality Computer Systems. 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 Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group IT “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.

## Easy Registration



Reservation Form:  
**CONCEPT HEIDELBERG**  
P.O. Box 1017 64  
69007 Heidelberg  
Germany



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+ 49 6221 84 44 34



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[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)



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Reservation Form (Please complete in full)

- Cloud Computing and Outsourcing in a GxP Environment**, 12-13 March 2015, Berlin, Germany
- Computerised Systems Validation for Software Engineers**, 10-11 March 2015, Berlin, Germany

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Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

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

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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 week prior to the conference 50 %
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structors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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### Date

Thursday, 12 March 2015, 09.00 h - 18.00 h  
(Registration and coffee 08.30 h - 09.00 h)  
Friday, 13 March 2015, 08.30 h - 16.00 h

### Venue

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany  
Phone +49(0)30 2127 0  
Fax +49(0)30 2127 117

### Fees (per delegate plus VAT)

ECA Members € 1,490  
APIC Members € 1,590  
Non-ECA Members € 1,690  
EU GMP Inspectorates € 845  
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.

### Save up to € 390!

If you register both for "Cloud Computing and Outsourcing in a GxP environment" and "Computerised Systems Validation for Software Engineers" (10-11 March 2015, Berlin) the fees reduce as follows:  
ECA Members € 2,790  
APIC members € 2,890  
Non-ECA Members € 2,990

### 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.

### Organisation and Contact

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

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