



## Speakers



Maurice Kerens  
Rescop



Michael Osburn  
Cornerstone OnDemand



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



Dr. Arno Terhechte  
GMP Inspector



Michael Wegmann  
F. Hoffmann-La Roche Ltd.

# Cloud Computing in a GxP Environment

## Challenges and Solutions

26-28 February 2020 | Berlin, Germany



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

## Objective

- 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 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.

## 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

### 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.

### 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

### Cloud computing in a GxP environment from a Service Provider perspective

- Why SaaS
- Find a partner who understand your business
- Leverage documentation

### 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

### The technology behind cloud services

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

### Compliance requirements for the cloud infrastructure

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

## 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

## 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

## 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



## Panel 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: 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

### Maurice Kerens Rescop BV, Netherlands

Maurice is CTO of Rescop BV. He is working in IT for over 30 years and built up an extensive knowledge and experience in the areas of business information management, Enterprise Architecture, supply chain management and IT compliancy.

### Michael Osburn Cornerstone OnDemand, Indianapolis, US

Michael has over 25 years of IT and quality experience supporting all aspects of software development life-cycle. He is a member of GAMP Americas Steering Committee, Co-Chair of the GAMP Cloud SIG and Head of Quality at Cornerstone OnDemand.

### 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 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 member of the German expert group 11 “computerised systems”.

### Michael Wegmann F. Hoffmann-La Roche Ltd., 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; 26-28 February 2020, Berlin, Germany

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

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D-69007 Heidelberg  
GERMANY

E-Mail (Please fill in)

#### 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 %
    - Cancellation until 1 week prior to the conference 50 %
    - Cancellation within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

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.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation.

cellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at [http://www.gmp-compliance.org/eca\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.html)). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date

Wednesday, 26 February 2020, 09.00 h - 18.00 h  
(Registration and coffee 08.30 h - 09.00 h)  
Thursday, 27 February 2020, 08.30 h - 17.30 h  
Friday, 28 February 2020, 08.30 h - 13.00 h

## Venue

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany  
Phone +49 (0)30 212 7 - 0  
Email [berlin@steigenberger.de](mailto:berlin@steigenberger.de)

## Fees (per delegate, plus VAT)

ECA Members € 1,790  
APIC Members € 1,890  
Non-ECA Members € 1,990  
EU GMP Inspectorates € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on first and second day and all refreshments. VAT is reclaimable.

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## 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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## 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.