Includes a set of IT security documents for the day-to-day business

IT System and Data Security:
New Developments in Cloud Computing, Virtualisation and GMP Compliance

18-19 September 2012, Barcelona, Spain

SPEAKERS:

Karl-Heinz Menges

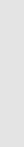*Regierungspräsidium Darmstadt, Germany*

Dr Wolfgang Schumacher

F. Hoffmann-La Roche Ltd, Switzerland

Michael Wegmann

F. Hoffmann-La Roche Ltd, Switzerland

LEARNING OBJECTIVES:

- To be able to assess the influence of GMP requirements on IT and data security
- Practical implementation of technical and organisational measures for establishing GMP-compliant IT security
  - Recognising and assessing the risks
  - Building up a security architecture
  - GMP-compliant implementation of these measures
- GMP-compliant handling of patches
  - Properties of patches
  - Patching strategies
  - Necessary or GMP-critical?
- Security within new IT developments
  - Cloud Computing
  - Virtualisation
- Outsourcing services; insourcing risks?

ECA

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IT System and Data Security

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Objectives

- You get to know the current European and American (GMP) requirements on IT system and data security including the new GAMP®5 and Annex 11 approach
- You get to know the current threat scenarios and how to master them technically and organisationally
- You are presented with the possibilities of implementing technical aspects of system and data security, especially the handling of patches, in a GMP-compliant way
- New technologies like Cloud Computing and Virtualisation influences IT-Security; find out how you can handle these technologies in a GMP environment

Background

The pharmaceutical regulations require the manufacturer to give proof of his data and systems security.

EU GMP Guide Annex 11 "Computerised Systems"
5.: Computerised systems exchanging data electronically with other systems should include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks
7.1: Data should be secured by both physical and electronic means against damage. Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period
7.2: Regular back-ups of all relevant data should be done. Integrity and accuracy of back-up data and the ability to restore the data should be checked during validation and monitored periodically
12.1:... Suitable methods of preventing unauthorised entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas.

GAMP®5 Appendix O 11 Security Management
Measures should be implemented to ensure that GxP regulated computerized systems and data are adequately and securely protected against wilful or accidental loss, damage, or unauthorized change.

Target Audience

This Education Course is directed at employees from
- IT & IT Cloud Service Providers
- Quality Assurance
- Production / Engineering
who have to deal with IT and Data security.

Moderator

Dr Wolfgang Schumacher

Programme

Introduction: What the delegates expect?
Wolfgang Schumacher

IT-Security – Legal requirements and Regulations / GAMP®5 and security requirements
Karl-Heinz Menges
- Annex 11 requirements
- ISMS
- GAMP 5 security requirements
- Product Liability Law

Processes and Organisation incl. Case Study
Michael Wegmann
- Assessment of security vulnerabilities and resulting risks
- Assessment of patching / change risks
- Focused testing
- Template for documenting of IT security alerts
- Real-life examples

Patch Management
Michael Wegmann
- What is a patch?
- What are the risks of patching?
- Handling of patches
- State-of-the-art patch management

Patch Management: Regulatory Point of View
Karl-Heinz Menges
- Security patches / maintenance patches
- Collection of patches
- Minimum test requirements

IT Security Inspections: Technical Aspects
Michael Wegmann
- Main focal points
- Which departments should be involved?

IT Security inspections: Findings
Wolfgang Schumacher
- European Authorities
- FDA

Technical Aspects of IT Security: Cloud Computing
Michael Wegmann
- How to secure Cloud Services / Risks
- Private/Public Cloud
- Saas-PaaS-IaaS
- Questions to ask Cloud Providers

Contracts with Cloud Computing Providers
Wolfgang Schumacher
- SLAs
- Key Performance Indicators
- Traps and Pitfalls

Contracts (with Cloud Computing Providers): Inspector's point of view

Karl-Heinz Menges

- Regulatory requirements
- EU GMP Chapter 7
- Annex 11

Technical Aspects of IT Security: Virtualisation

Michael Wegmann

- How to secure a virtual environment

Technical Aspects of IT Security: Others

Michael Wegmann

- Secure remote access
- Wireless Solution Security
- Consumer devices (Tablet PCs, Handhelds, Smart-phones)

Data Backup, Archiving and Business Continuity: Industry's point of view

Wolfgang Schumacher

- Data Backup
- The data backup strategy
- Data recovery process – common pitfalls
- Long time data retention in the System Lifecycle
- Business continuity management
- Disaster recovery - experience

Data Backup and Archiving: Inspector's point of view

Karl-Heinz Menges

- Annex 11 requirements
- Frequency of backups
- Storage of backups
- Archiving and migration

How to ensure plant security

Michael Wegmann

- Protection of MES Environments
- Shielding
- Stuxnet, Duqu and Co.

Security Risk Management

Wolfgang Schumacher

- Case Study
- Tools and Experience
- Integration in the SDLC and implementation lifecycle

IT Security Framework and Security Architectures

Michael Wegmann

- Practical implementation on an Information security Management System (ISMS)
- IT and information security policies, directives, guidelines
- Security architecture

IT Security KPIs

Michael Wegmann

- Meaningful Security metrics / Key Performance Indicators (KPIs) for IT security
- Measuring success (and failure)
- Early warning signals

Outsourcing

Wolfgang Schumacher

- Contracts
- QA involvement
- Pain points
- Experience from audits

Outsourcing from the inspector's point of view

Karl-Heinz Menges

- Types of outsourcing
- Contracts
- Responsibility matrix

Additional documentation:

All participants will get IT security documents for their day-to-day business

- Information Security Policy
- Information Security Directive according ISO 27002 (ISO 17799)
- Password Policy
- List of Banned Software and Services
- Security Alerts (some practical examples)
- Evaluation of security gaps according CVSS

Speakers

Karl-Heinz Menges,
Regierungspräsidium Darmstadt, Germany
He is Inspector for over 25 years and currently **Head of the German Inspectors Working Group**. He is also a member of GAMP D-A-CH steering committee and the German delegate of the PIC/S Expert Circle for computerised systems. Mr Menges has also contributed to Annex 11, PIC/S document PI 011 Recommendations on Computerised Systems and several GAMP GPGs.

Dr Wolfgang Schumacher
F. Hoffmann-La Roche Ltd., Basel, Switzerland
Dr Schumacher studied chemistry and pharmacy. At Asta Medica, he headed different positions in Research and QA. In 2001 he joined the Pharma Division of F. Hoffmann-La Roche, Basel, where he is now Head of the Quality Computer Systems Area in Global Technical Operations. He is a member of the ECA Advisory Board.

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.

Social Event

On 18 September 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.

Easy Registration

📪 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

📠 **Reservation Form:**
+ 49 6221 84 44 34

@ **e-mail:**
info@concept-heidelberg.de

🖱 **Internet:**
www.gmp-compliance.org

🖶 + 49 6221 84 44 34

Reservation Form (Please complete in full)

☐ **IT System and Data Security:** New Developments in Cloud Computing, Virtualisation and GMP Compliance
18-19 September 2012, Barcelona, Spain

☐ **Computer Validation: Maintaining Control of Operation,** 20-21 September, 2012 Barcelona, Spain

☐ Mr.   ☐ Ms.

_____
Title, first name, surname

_____
Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number if applicable

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D-69007 Heidelberg
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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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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Date

Tuesday, 18 September 2012, 09.30 h – 18.00 h
(Registration and coffee 09.30 h – 09.00 h)
Wednesday, 19 September 2012, 08.30 h – 17.00 h

Venue

NH-Hotel Constanza
C/ Deu i Mata 69-99
08029 Barcelona, Spain
Phone   +34 93 281 15 00
Fax   +34 93 281 15 25

Fees

ECA Members € 1,490 per delegate plus VAT
APIC Members € 1,590 per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690 per delegate plus VAT
EU GMP Inspectorates € 845 per delegate plus VAT
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 and book "Computer Validation: Maintaining Control of Operation" on 20-21 September simultaneously:
ECA Members € 2,790.- per delegate plus VAT
APIC Members € 2,890.- per delegate plus VAT
Non-ECA Members € 2,990.- per delegate plus VAT
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EU GMP Inspectorates € 1,495.- per delegate plus VAT

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "ECA7307" to receive the specially negotiated rate (single room € 143,- + 8% VAT per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 21 August 2012. 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.

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64, 69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content: Dr Andreas Mangel (Operations Director) at +49-(0)62 21 / 84 44 41, or per e-mail at mangel@concept-heidelberg.de.

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

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