

2-Day EDUCATION COURSE

Includes the new
GAMP®5 approach

IT System and Data Security: GMP requirements and technical measures

18-19 March 2010, Barcelona, Spain

SPEAKERS:

Norbert Moeren
Merck, Germany

Dr Wolfgang Schumacher
F. Hoffmann-La Roche, Switzerland

Michael Wegmann
F. Hoffmann-La Roche, Switzerland

HIGHLIGHTS:

- 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



IT System and Data Security: GMP requirements and technical measures

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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

Background

IT system security forms the foundation of trust in the generated and managed data. It is indispensable for maintaining the validated state of quality-relevant IT systems.

The pharmaceutical regulations require the manufacturer to give proof of this security.

Draft EU GMP Guide Annex 11 „Computerised Systems“
8.2 Access to applications, folders, files and data should be controlled via the permission detailed within the manufacturing authorisation holder's Information Security Management System (ISMS)

8.3 Suitable methods, commensurate to the criticality of data, should be in place to deter and record unauthorised entry and/or modification of data. These methods may include time limiting logging, encryption, and re-entry of unique identifier for critical data.

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.

In daily practice, diverse threat scenarios arise, which have to be mastered by the pharmaceutical user both technically and organisationally. Here, especially security patches can lead to goal conflicts between Change Control requirements and the necessity to react quickly.

Target Audience

This Education Course is directed at employees from

- IT
- Quality Assurance
- Production
- Engineering

who have to deal with IT and data security.

Moderator

Dr Wolfgang Schumacher

Programme

Introduction: What the delegates expect?

IT-Security – Legal requirements

- European Law
- Guidelines and Standards
 - BSI IT-Security Manual
 - PICs Guide
 - GAMP

Wolfgang Schumacher

GAMP[®]5 and security requirements

- Security concept of GAMP[®]5 Life Cycle approach
- Security management in GAMP[®]5
- Operational security requirements in GAMP[®]5
 - Security in development process
 - Security in operations process

Norbert Moeren

Processes and Organisation

- Security incident handling (prevention and response)
- Overview of current IT and information security risks

Michael Wegmann

Patch Management

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

Michael Wegmann

Processes and Organisation – Case Study

- Assessment of security vulnerabilities and resulting risks
- Assessment of patching / change risks
- Focused testing
- Template for documenting of IT security alerts
- Real-life examples

Michael Wegmann

IT Security inspections / Vendor audits

- Inspections and audit approaches
- Inspection management process
- Process audits versus technical inspections
- Examples: Process audits, vulnerability assessments, penetration tests
- Follow up of audit findings

Norbert Moeren

Technical Aspects of IT Security

- Basics
- Physical security, logical security
- Malicious code (computer viruses, worms, trojans, etc.)
- Internet security
- Virtual Private Networks (VPNs)
- Wireless networks (WLAN, Bluetooth, 3G, UMTS)

Michael Wegmann

Security Findings and Observations from Health Authority Inspections

- The inspector comes
- Audit / Inspection organization
- Access to documentation
- Security findings by European and FDA investigators

Wolfgang Schumacher

Data Backup and Archiving

- Data Backup and compliance requirements
- Creating a data backup concept
- Data recovery process
- Long time archiving
- Business continuity management and disaster recovery planning

Norbert Moeren

Security within new IT developments

- SaaS (Software as a Service)
- SOA (Service-oriented architecture)
- Virtualisation
- Cloud Computing
- Web Portals

Michael Wegmann

IT Security Framework and Security Architectures

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

Michael Wegmann

IT Security KPIs

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

Michael Wegmann

Certification according to IT Security Standards

- Overview about IT Security Standards
- Benefits and risks of Certification activities
- Example: ISO 27001 Certification approach

Norbert Moeren

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

Norbert Moeren

Merck KGaA, Darmstadt, Germany



Norbert Moeren joined Merck KGaA Darmstadt in October 2001 as IT-security specialist. In his current position as Team Manager of the Corporate Information Security team he is in charge of maintaining the ISO 27001 certified Corporate Information Security management system, e.g. maintaining information security policies, providing awareness trainings and security audits. Beside the security knowledge he is experienced in aligning IT security with IT risk management, IT compliance, IT Quality management and embedding in an overall IT Governance program.

Dr Wolfgang Schumacher

F. Hoffmann-La Roche Ltd., Basle, Switzerland



Dr Schumacher studied chemistry and pharmacy. After he entered Asta Medica he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is in the Quality Unit of information technology, the quality assurance of global applications and the qualification of the IT infrastructure.

Michael Wegmann

F. Hoffmann-La Roche Ltd., Basle, Switzerland



Since 1989, Mr Wegmann has been working in various informatics functions in the pharmaceutical industry. From 2000 to 2006 he was „Head of Global Network Security“ and „Global Informatics Security Manager“ and leading the security incident prevention and response team. Since then he is „Global Head of Information Security“ at Hoffmann-La Roche Ltd. In this role, he is responsible for all aspects of informatics security including security strategies and architectures.

Social Event

On 18 March 2010, 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:
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e-mail:
info@concept-heidelberg.de



Internet:
www.gmp-compliance.org

wa/vers.1/131008

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Reservation Form (Please complete in full)

IT System and Data Security: GMP requirements and technical measures

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Mr. Ms.

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Department

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 - until 1 weeks prior to the conference 50 %
 - within 1 week prior to the conference 100 %.

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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).

Date

Thursday, 18 March 2010, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 19 March 2010, 08.30 h – 16.30 h

Venue

nh-Hotel Constanza
C/Deu i Mata, 66-99
08029 Barcelona, Spain
Phone +34 93 2811500
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Fees

Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
APIC Members € 1,605.- per delegate plus VAT
(does not include ECA membership)
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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6243 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 4 February 2010. 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

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