

4 Conferences  
4 Parallel Workshops  
14 Speakers

# Pharma IT Week 2006

in Copenhagen, Denmark, from 6–10 March 2006



- IT Infrastructure Compliance and Control
- Maintaining the Validated State
- Computer Validation for Suppliers
- Recent FDA/EU Requirements on Laboratory Computers and Records

Combine 2 events  
and save 25%!

14 Speakers from Industry  
and Inspectorates:

**Finn Andersen**

*NNIT, Denmark*

**Dr Akos Bartha**

*AstraZeneca Sweden Operations, Sweden*

**Christian Baumgartner**

*Arcondis, Switzerland*

**Valery Cottet**

*Arcondis, Switzerland*

**Hasse Greiner**

*Novo Nordisk, Denmark*

**Dr Ludwig Huber**

*Agilent Technologies, Germany*

**Jan Anton Norder**

*Dutch Pharmaceutical Inspectorate,  
The Netherlands*

**Yves Samson**

*Kereon, Switzerland*

**Kate Samways**

*KAS International, UK*

**Jürgen Schmitz**

*Novartis Pharma, Switzerland*

**Dr Wolfgang Schumacher**

*F. Hoffmann-La Roche, Switzerland*

**Dr David Selby**

*Selby Hope International, UK*

**David Stokes**

*Mi Services Group, UK*

**Michael Wegmann**

*F. Hoffmann-La Roche, Switzerland*

**Four Parallel Pre-conference Workshops  
on 6 March 2006**

- IT Security
- Qualification of Network Infrastructure
- Sarbanes Oxley Act and GxP in the IT Environment
- Elaborating Good Requirements



EUROPEAN COMPLIANCE  
ACADEMY

Dear Colleagues,



IT-based systems are becoming more and more important in the pharmaceutical industry. Their influence on quality-relevant processes and data is obvious.

In recent years, validation – in particular the validation of stand-alone systems – was the scope of regulatory inspections. However, the focus is now shifting towards the following questions:

- Which influence does the IT infrastructure have on the validated /qualified environment?
- How can the validated state of IT systems be maintained throughout the whole life cycle?
- Which roll do the suppliers of technology and software have to play?
- Which new requirements are defined for computerised systems in the lab?

Each of these questions will be answered by a dedicated event during the Pharma ITWeek, which will be held by ECA in co-operation with CONCEPT HEIDELBERG in Copenhagen from 6 to 10 March 2006.

4 Pre-conference workshops on further hot topics concerning IT are the perfect complement to the events.

Experts from industry, health regulatory bodies and consulting – many of them members of committees that develop new guidelines – will give you first-hand information, discuss current regulatory trends and demonstrate how you can transfer the requirements into practice.

We are looking forward to your participation.

Dr Wolfgang Schumacher  
ECA Advisory Board



## Table of Content

	Page
<b>Speakers List</b> .....	3

### Conferences on 7–8 March 2006

<b>IT Infrastructure Compliance and Control</b> .....	4–5
<b>Maintaining the Validated State</b> .....	6–7

### Conferences on 9–10 March 2006

<b>Computer Validation for Suppliers</b> .....	8–9
<b>Recent FDA/EU Requirements on Laboratory Computers and Records</b> .....	10–11

### Parallel Pre-conference Workshops on 6 March 2006

<b>IT Security</b> .....	12
<b>Qualification of Network Infrastructure</b> .....	12
<b>Sarbanes Oxley Act and GxP in the IT Environment</b> .....	13
<b>Elaborating Good Requirements</b> .....	13
<b>Organisational Information</b> .....	14–15
<b>Registration Form</b> .....	16

### Social Event

On 7 and/or 9 March (depending on the conference(s) you have booked) 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

## Speakers



### **Finn Andersen, NNIT, Denmark**

After different positions in the Royal Danish Navy he changed career and became a service consultant. He then switched to Novo Nordisk A/S in 1993 and took up the position as system manager on Unix systems in a GXP-regulated environment. Following the de-merger of NNIT A/S from Novo Nordisk A/S in 2002, Finn became team leader for the operational unit with **responsibility for Unix, storage, backup and data centre.**



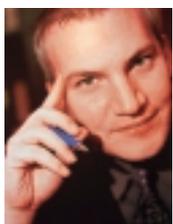
### **Dr Akos Bartha, AstraZeneca Sweden Operations, Sweden**

Dr Akos Bartha studied chemical engineering and obtained Ph.D. in analytical chemistry. In 1990 he joined Astra. Between 1999 and 2003 he served as a technical and quality adviser in AstraZeneca's Part 11 project. Currently, he works at AstraZeneca Sweden Operations as a **Quality Manager for computerized systems.**



### **Christian Baumgartner, Arcondis, Switzerland**

Graduate in information management at the Technical University of Furtwangen. From 1992 to 1998 he had been employed by Hoffmann-La Roche. In 2001 he became **managing director of Arcondis AG** and management consultant for IT governance, computer system validation and IT service management.



### **Valery Cottet, Arcondis, Switzerland**

From 1996 to 2003, external and internal IT auditor as Manager for the Enterprise Risk Service Department of Deloitte. Since 2004, independent **Sarbanes Oxley advisor** for industrial, financial and pharmaceutical sectors in relation with general computer controls, applications controls and end user computing controls.



### **Hasse Greiner, Novo Nordisk, Denmark**

Hasse Greiner is manager of the global IT quality and security support group in Novo Nordisk A/S. He has been with Novo Nordisk for many years in positions starting with automation engineering, programming, and project management, got into system administration and validation leading up to the current position in the firm's world wide quality division. He is member of ISPE and he's on the **board of GAMP® Nordic. He co-chaired**

**the Infrastructure GAMP® Special Interest Group, edited and compiled the Good Practice Guide.**



### **Dr Ludwig Huber, Agilent Technologies, Germany**

Dr Ludwig Huber is worldwide compliance fellow at Agilent Technologies and the editor and primary author of [www.labcompliance.com](http://www.labcompliance.com) the on-line resource for validation and compliance. He is on the **advisory board of the European Compliance Academy**, of IVT's GxP journal and has been a **member of the PDA Task Force on 21 CFR Part 11 and of the GAMP Special Interest Group on Laboratory Systems.**



### **Jan Anton Norder, Dutch Pharmaceutical Inspectorate, The Netherlands**

Jan Anton Norder is a pharmacist, graduated from Groningen University in 1989. After working in industry, he joined the inspectorate in 1993. His function is senior inspector for Industry and Trade. His fields of special attention are **validation of computer systems**, manufacturing of APIs and medicinal gases. **He was co-author of the document PIC/S PI 011.**



### **Yves Samson, Kereon, Switzerland**

Automation and system engineer, after his education in France and Germany, he worked for Ciba-Geigy and Novartis Pharma AG in Basle. In 2002, he founded the consulting company Kereon AG, Basle. He is also strongly engaged within ISPE and is an **active member of the IT infrastructure SIG.** He also edited the French version of GAMP® 4 as well as of PIC/S PI 011-2. He is member of ISPE French affiliate board.



### **Kate Samways, KAS Associates, UK**

Kate Samways qualified as a pharmacist and has more than 25 year's experience in the pharmaceutical industry. For the last six years, she has been consulting within the industry on computer systems validation. Kate joined the GAMP Forum in 1994 and currently serves as the **Secretary to the GAMP Europe Steering Committee.**



### **Jürgen Schmitz, Novartis Pharma, Switzerland**

Dr Jürgen Schmitz is **Head of Quality Management, Global IT-Infrastructure of Novartis Pharma AG** in Switzerland. Before joining Novartis in 2003, he worked for several years for one of the major global consultancies, where he managed validation aspects of large IT projects.



### **Dr Wolfgang Schumacher, F. Hoffmann-La Roche, Switzerland**

Dr Schumacher studied chemistry and pharmacy. After he enters 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.**



### **Dr David Selby, Selby Hope International, UK**

David Selby, BSc., PhD., was with Glaxo for many years in different positions. He is a **founder member of the GAMP Forum** and 2004 Chairman on the International Board of ISPE. He has established his own consultancy, Selby Hope International, specialising in the compliance of computerised systems and automated equipment.



### **David Stokes, Mi Services Group, UK**

David Stokes is a Principal Validation Consultant with over 20 years experience in Life Sciences, originally as a process control engineer. He is now Life Sciences Industry Manager at Mi Services Group. He is an **active member of the GAMP® Forum**, Chairing and participating in a number of Special Interest Groups including the **IT Infrastructure SIG.**



### **Michael Wegmann, F. Hoffmann-La Roche, Switzerland**

Since 1989 Mr Wegmann has performed different functions as an information scientist in the pharmaceutical industry. Since the beginning of 2000, he is **head of the 'Global Network Security' with Hoffmann-La Roche AG.**

# IT-Infrastructure Compliance and Control

7–8 March 2006

## Objectives

If it is not possible to imagine the pharmaceutical industry working without the support of computerised systems, likewise it is not possible to ignore the importance of IT infrastructure on the operation of such systems. For this reason, it is crucial to keep systems as well as IT infrastructure under control and to maintain them in a compliant state.

This conference will help you to get know the GAMP® Good Practice Guide on 'IT Infrastructure Control and Compliance'. Based on various experience reports from industry practitioners, consultants as well as regulators, the participants will receive a wide vision of current Good Practice concerning the different aspects of IT infrastructure from risk management through the qualification of networks, servers and workstations to quality assurance and outsourcing.

This conference is designed to give attendees the opportunity to discuss their experience and concerns about the various and complex topics regarding IT Infrastructure.

## The New GAMP® IT Infrastructure Good Practice Guide

GAMP® recently has introduced the new Good Practice Guide on IT Infrastructure Control and Compliance. This has the objective of providing guidance and recommendation to the regulated industry and its IT service providers by designing, implementing, qualifying and operating IT infrastructure in a compliant manner. Attendees will get a good understanding of the new guide and learn how to implement it in an effective way.

## Target Group

Everybody who is either directly or indirectly involved in the design, implementation, qualification and operation of IT infrastructure systems. These are collaborators of IT departments, QA managers, IT personnel of IT service providers, validation specialists, internal auditors, industry consultants and inspectors.

## Moderators

Hasse Greiner,  
*Novo Nordisk, Denmark*

Yves Samson,  
*Kereon, Switzerland*

## Programme

### Introduction to the GAMP Good Practice Guide

- Background for the infrastructure SIG
  - Structure of the good practice guide
  - Risk levels
  - Infrastructure model
  - Platforms, processes, and people
  - Packaged qualification concepts
- Hasse Greiner

### Risk Management and IT Infrastructure

- General principles of risk-based infrastructure qualification
  - Applying the GAMP Risk assessment model to IT infrastructure
  - Leveraging ISO 14971 to develop a 'through-life' model for IT infrastructure risk assessment
  - Successfully combining technical and procedural controls with physical and logical security
- David Stokes



### Network Qualification Principles

- Identification of network qualification requirements and constraints
  - Identification of network configuration items
  - Definition of responsibilities
  - Proposal for a network qualification strategy
  - Network operation management
- Yves Samson

### Server and Desktop Qualification and Management

- Pre-qualifying servers and desktops
  - Qualification process
  - Baseline control
  - Managing IT service
- Finn Andersen

### Qualification Requirements from Laboratory Systems to the IT Infrastructure

- Frequent problems caused by IT infrastructure
- On-line vs. off-line networks
- Specific requirements for laboratory networks: supporting high risk applications, compliance, uptime
- Initial and on-going testing
- On-line monitoring of connectivity and network traffic

Ludwig Huber

### Introduction to ISO 17799 and to NIST SP 800-30

- Applying ISO 17799 to IT infrastructure security
- Identifying security gaps in the IT infrastructure
- Establishing and maintaining security compliance
- Practical mitigation of security risks through the use of NIST SP 800-30

David Stokes

### Global Project

- Validation and qualification
- Definition of IT infrastructure platforms
- Principles of IT infrastructure management
- Global roll-out project

Jürgen Schmitz

### Regulatory expectations to IT Infrastructure in GMP Environments

- IT infrastructure in relation to GMP Chapter 4 and Annex 11
- Regulatory requirements to an IT infrastructure
- Distinguishing between requirements and desirabilities
- Deficiencies on IT infrastructure most often found

Jan Anton Norder

### GxP QA's Expectation to IT Infrastructure

- Quality management in an IT organisation
- Harnessing QA to IT
- Shared goals – disparate cultures
- QA and IT quality management liaison
- Deliverables and approvals – based on importance
- Audits and follow up – application of experts

Hasse Greiner

### Time Synchronisation/Time Management

- Definition
- Time services
- From time server to time service management
- Legal and regulatory requirements

Yves Samson

### Outsourcing

- Regulations, roles and responsibilities
- Contracts
- Service level agreements
- Audits of service providers

Wolfgang Schumacher

### Speakers

Finn Andersen,  
*NNIT, Denmark*

Hasse Greiner,  
*Novo Nordisk, Denmark*

Ludwig Huber,  
*Agilent Technologies, Germany*

Jan Anton Norder  
*Dutch Pharmaceutical Inspectorate, The Netherlands*

Yves Samson,  
*Kereon, Switzerland*

Jürgen Schmitz,  
*Novartis Pharma, Switzerland*

Wolfgang Schumacher,  
*F. Hoffmann-La Roche, Switzerland*

David Stokes,  
*Mi Services Group, UK*



# Maintaining the Validated State

7–8 March 2006

## Objectives

Today, the validation of computerised systems is a required and lived practice in the pharmaceutical industry. Even though the first validation only takes a short time in the life cycle of a system, the current regulations and industry guides deal above all with this phase. However, the greatest part of the life cycle is represented by daily operation.

How can the validated state be maintained during routine operation? What is required and how can these requirements be put into practice?

This event shows you in theory and practice

- How you can maintain the validated state of a computerised system
- How you should assign the responsibilities
- Which items have to be covered by an efficient change control system
- How you have to handle data and records in a GMP-compliant way
- Which safety requirements have to be observed

## Target Group

This Education Course is directed at employees from

- Production
- Quality control
- Quality assurance
- Engineering
- IT

who have to deal with the validation and operation of computerized Systems and how to maintain the validated state.



## Programme

### Introduction – What the Participants Expect

An open session capturing the expectations of the delegates

### Why Maintain the Validated State?

- Why is it necessary?
- What processes are involved?
- What are the roles and responsibilities?
- Managing the process
- Regulatory expectations
- Benefits of the process

*A review of the regulatory expectations and why it is good business practice to maintain the validated state. What are the elements of the process?*

### Ownership Responsibilities and Periodic Review

- What does ownership include?
- Who is the system owner?
- Who does the work?
- What is periodic review?
- The importance of a risk-based approach
- How can it be managed cost-effectively?

*A detailed look at what system ownership means, who is responsible for what, and who actually does it. A practical way to approach periodic review will be described.*

### Workshop 1: Prioritisation for Periodic Review

- Assess the need for periodic review
- Identify the highest risk systems
- Outline a plan for review
- Justify the choice of system

*In a given scenario, delegates will identify the priorities for review and justify why some systems are low priority whilst others are relatively urgent. The output forms the basis of a review plan.*

### Operational Change Control and Configuration Management

- Regulatory requirements
- Configuration management
- Responsibilities
- Planned/unplanned changes
- Classification
- Sources of changes

*The session will provide practical guidance on the set-up of an operational change control procedure covering computerised systems.*

### Workshop 2: Change Control

- What is the impact of the change?
- What are the risks?
- What tests will be necessary?

*The participants will work on a real-life change control activity arising from a test failure. They will assess the impact of the failure and devise a list of appropriate tests.*

## Security and Training

- Scope of security measures
- Roles and responsibilities
- Security measures available
- System security requirements
- Training for everyone!
- Training records

*A review of the importance of security when creating, managing and maintaining GxP records and a discussion of the different requirements. A brief look at the need for training and the importance of training records.*

## Workshop 3: Security Hierarchy

- What is a security hierarchy?
- What security controls are available?
- What are the risks?
- How should they be applied?

*The participants will choose a list of appropriate controls for different types of e-records and justify their selection.*

## Infrastructure Management

- Validation or qualification?
- Configuration items and management
- Data center
- Network
- Outsourcing issues

*IT infrastructure can have a considerable influence on the validated state of computerised systems. Changes have to be documented, their consequences for GMP compliance, evaluated.*

## Workshop 4: Infrastructure Management

- Planning – what is necessary?
- System description – do we need it really?
- Testing – how much witnessing is required?
- Reporting – what is enough?

*The participants will develop the documentation needed (entire registry) for an IT infrastructure upgrade project and identify the business involvement in the process.*

## System/Data Migration, Back-up and Restore

- Regulatory expectations for record retention
- What are the considerations for migration?
- It will not be perfect process!
- Which techniques are most appropriate?
- The importance of back-up and its management
- The difficulties encountered

*The value of e-records generally decreases with age. The issues surrounding data or system migration will be discussed. Then the process of back-up and restore will be reviewed. It is a key area of regulatory interest.*

## Record Archiving and Retrieval

- When is archiving necessary?
- It will not be a perfect process!
- How should it be indexed?
- What are the security issues?
- Periodic electronic regeneration

*Archiving is appropriate once data volumes are high or the records need to be consulted infrequently. The process needs to be controlled so that the records can still be located and still need to be accessible sometimes at quite short notice in case of emergency.*

## Workshop 5: Data Migration

- What are the issues with data mapping?
- What is the sequence of a migration?
- Must all the data be migrated?
- Impact of data migration on interfaces

## Legacy Systems Validation

- Legacy systems need validating and maintaining
- How do you create a specification retrospectively?
- What information is available to help?
- How can the system be brought under control
- How should the results be reported?

*Legacy systems – those in use but not yet qualified to current standards – are a focus for regulatory attention. The process for restoring control is not easy but there are approaches which allow control to be established satisfactorily in most cases.*

## Business Continuity Planning

- How do you survive a business interruption?
- What should you plan for?
- What options are available?
- Managing the short and long term
- Maintaining regulatory credibility

*Every business is dependent, many almost totally, on the availability of their system to operate. There needs to be plan in place to manage this situation which takes account of both short and long term interruptions to the business and to key suppliers.*



## Quality Assurance and Document Management

- Who makes it happens?
- Who ensures it is to the appropriate standard and regulatory expectation?
- What documentation?
- Where is it?

*As well as maintaining the systems, the supporting documentation must be maintained. This session looks at the documentation supporting the maintenance of the validated state.*

## Speakers

Dr David Selby, Selby Hope International, UK  
Kate Samways, KAS Associates, UK  
Dr Wolfgang Schumacher,  
F. Hoffmann-La Roche, Switzerland

# Computer Validation for Suppliers

9–10 March 2006

## Objectives

The validation of computerised systems requires the active participation of the suppliers. Orders often include the specification 'GMP-compliant' or 'GAMP-compliant'. What does this mean in detail?

The first versions of the GAMP Guide were actually developed by representatives of the British pharmaceutical industry in order to familiarise suppliers with the requirements of the pharmaceutical industry. In GAMP 3, there was a special part exclusively written for suppliers. Customer and supplier have to co-operate in order to develop quality-assured computerised systems. In this task, the supplier has to understand and implement the specific requirements of the pharmaceutical industry. Which knowledge and skills does a supplier need to be able to fulfil these requirements?

This event will show you in theory and practice

- What the requirements of the pharmaceutical industry are
- How you can identify the critical points at the customer-supplier interface
- Which tasks have to be fulfilled by the customer, which ones, by the supplier
- Which documents have to be created by you as the supplier
- How you as a supplier can implement the requirements laid down in the GAMP Guide

## Target Group

This Education Course is directed at employees from suppliers who have to deal with the validation of computerized Systems.



## Programme

### Introduction – What the Participants Expect

An open session capturing the expectations of the delegates

### Laws, Regulations and Guidelines for Computer Validation

- The historical perspective
- Current regulations and regulatory guidelines from Europe and US
- New regulatory guidance
- New industry guidance
- Regulatory training
- Harmonisation

*A review of the laws, regulations and guidelines from both the regulators and industry, right up to the present day, and anticipating new developments.*

### The GAMP 4 Approach/The Computer Validation Life Cycle

- Validation needs structure
- The GAMP 4 approach
- General validation activities
- The GAMP categorisation system
- Life cycle cost reduction

*An overview of all the processes in the computer validation lifecycle, including how the approach to validation can be modified to fit in with the GxP criticality of the application.*

### Workshop 1: Evaluating User Requirements Specifications

- What is a URS?
- Why is it important?
- Contents of a URS
- Poor specification/good specification
- Testable specification

*A short review of the URS and how to write specifications, as a prelude to a workshop in which delegates will evaluate a real requirements specification.*

### The Evolving Role of the Supplier

- An introduction to the ISPE White paper
- A risk-based approach to qualification
- The impact on qualification and commissioning
- The changed roles of the supplier and customer

*A look at the proposed changes in the approach of the pharmaceutical industry to qualification using a risk-based approach. This will involve a significant change in the expectations of the supplier by the industry and should result in better working relationships.*

### Risk Management (including ICH Q9a)

- Definition of 'Quality Risk Management'
- Application of the principles in validation
- Methods of assessing risk
- Risk in a regulatory context

*Methods of identifying and assessing risk will be explained based on ICH Q9a and the principles will then be applied to the validation lifecycle. The regulatory expectations for risk assessment will be discussed.*

## Risk Management: The GAMP Way

- Introduction to FMEA
  - Risk in the pharmaceutical industry
  - Where to apply risk management in validation
  - The GAMP Risk Management methodology
- The FMEA process will be explained and the adaptation used in GAMP. The application of the process in validation will be discussed as a preliminary to a practical application.*

## Workshop 2: Risk Management in Validation

- Identifying risks
  - Classification of risks
  - Controls to mitigate unacceptable risks
  - Links to the validation plan and protocols
- The participants will work on a case study in which the risks associated with a computer system are assessed and managed to reduce the testing workload in validation.*

## Quality and Validation Planning

- What is quality planning?
  - Why validation planning?
  - The key sections of the process
  - Interaction between supplier and customer
  - Regulatory and industry expectations
- The importance of the planning process will be highlighted and the parts which are of the most importance. The interactions between the quality plan and the validation plan will be highlighted.*

## Specifications, Design Review and Traceability

- What goes into specifications
  - How should they be reviewed
  - How do you know they are complete?
  - How do you link specifications and protocols?
  - Where does risk management fit in?
- The link between the specifications, design review and traceability will be explained. The design review process will be described and the importance of creating a traceability matrix to help maintain a coherent systems supported by relevant documentation.*

## Workshop 3: Design Review

- Planning a Design Review
  - What are the steps?
  - What is the output?
  - How is it documented?
- The participants will work through a design review exercise based on a real-life case study.*

## Protocols and Testing

- What constitutes a good protocol?
  - Who should write it?
  - How should it be written?
  - How should the results be recorded?
  - How do you manage test failures?
- The characteristics of a good protocol will be discussed and how it should be completed. Roles and responsibilities for approval, execution and review will be discussed.*

## Workshop 4: Writing Test Scripts

- What tests should be included?
  - How should the tests be described?
  - What other information is necessary?
- The participants will develop a section of a protocol for a high-risk function.*

## Project Change Control and Configuration Management

- Regulatory requirements
  - Configuration management
  - Responsibilities
  - Planned/unplanned changes
  - Classification
  - Sources of changes
- The session will provide practical guidance on the set-up of a project change control procedure covering computerised systems.*

## Workshop 5: Change Control

- What is the impact of the change?
  - What are the risks?
  - What tests will be necessary?
- The participants will work on a real-life change control activity arising from a test failure. They will assess the impact of the failure and devise a list of appropriate tests.*



## Validation Reporting & Presentation to Inspectors

- The link between the plan and the report
  - Key documents
  - Validation summary reports
  - Style and emphasis
  - Managing the inspection
- The relative importance of different validation documents will be discussed from the point of view of presenting a validation study to an inspector. The presentation and the key communication issues will be discussed.*

## What the Regulators Say! – 483s and Warning Letters

- Recent general trends
  - Highlights from Warning Letters and 483s
  - Lessons we must learn
- We will give you the necessary overview and update of national and international regulations. Beside others you will hear about the 'Hot Buttons' of computer validation and frequent misconceptions.*

## Speakers

Dr David Selby, Selby Hope International, UK  
Kate Samways, KAS Associates, UK

# Recent FDA/EU Requirements on Laboratory Computers and Records

9–10 March 2006, Copenhagen

## Objectives

Computers are used in laboratories for instruments control, data acquisition, data evaluation, data management and archiving. Pharmaceutical laboratory computers and records have to comply with regulations such as GLP, GMP and GCP. In the last couple of years the focus of laboratory inspections went from equipment and stand alone computers to networked systems and electronic records authenticity, integrity and security. Inspection practices have been heavily influenced by FDA's 21 CFR part 11 and relevant industry guidance but also by FDA's new initiative on risk based inspection practices for systems. This conference will help you to interpret and implement the current FDA and EU requirements. Experts from international pharmaceutical companies will share their experience on how they prepared the lab and successfully passed FDA and EU audits with minimum efforts. Example documents with checklists and SOPs will be discussed during the conference and will be available in electronic format for easy and trouble-free customization and implementation.

The interactive workshops and discussion sessions are designed to give attendees the guidance and help on the validation and auditing of computerized systems for compliance with GMP and GLP from FDA and EU and the opportunity to discuss their experiences with experts from the pharmaceutical industry and the authorities.

## WORKSHOP ON THE NEW GAMP LABORATORY GUIDE:

GAMP recently has introduced a new guide: Validation of Laboratory Computerized Systems. This will become the reference document for laboratory system validation. Attendees will get a good understanding of the new guide and learn how to implement it in the most effective way.

## Target Group

Everybody who is either directly or indirectly involved in the preparation or the conduct of FDA inspections in laboratories. These are lab scientists, QC managers, QA managers, IT personnel, validation specialists, internal auditors, industry consultants and inspectors.



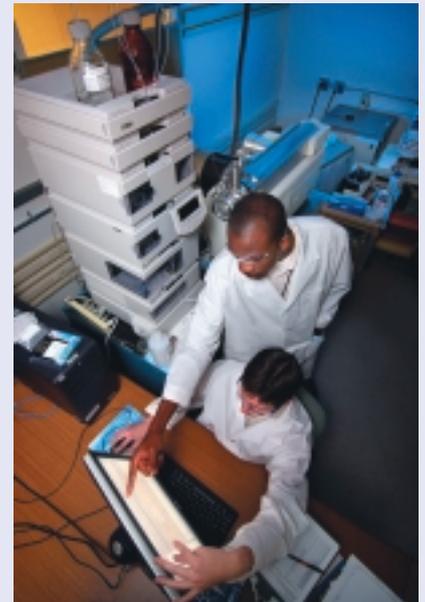
## Programme

### Update on FDA Requirements

- New directions for part 11
- New guide: Using computers in clinical trials
- Impact of FDA's new quality system guide on laboratories
- Risk based validation
- Recent inspection practices, 483s and warning letters related to laboratory computers

### A European Inspector's Perspective on Computerised Systems Validation (CSV) for Laboratory Computers

- The need for CSV in relation to lab activities and product release
- Inspecting CSV and ERS
- Deficiencies most often found
- EU/FDA differences
- European view on ERS



### Implementing FDA's Narrow Scope for Part 11 in Laboratories

- Interpretation of FDA's narrow scope for part 11 records
- Strategies to identify electronic records and controls – What is in/out of scope
- The impact of applying these principles to real systems and laboratory records
- Recommendations how to handle method parameters, raw data, and reports

### Interactive Workshop I Implementing System and Data Security in Laboratories

- Physical and logical security
- Working with user IDs and passwords
- Approaches to testing
- Contingency planning
- Backup and recovery
- Disaster recovery

## **Interactive Workshop II Implementing the New GAMP Guide for Validation of Laboratory Computer Systems**

- Difference to GAMP 4
- Seven categories of the new GAMP guide
- Validation and documentation requirements for each category
- The concept of risk-based validation
- Documenting planning, specifications, installation, testing and changes
- Case studies

## **Interactive Discussion Session I Inspection of Laboratory Systems**

## **Interactive Discussion Session II Writing Test Scripts for Validation of Computerised Laboratory Systems**

- Defining scope of testing – specifications and DQ
- Test documentation hierarchy and traceability matrix
- Developing test cases (IQ, OQ, PQ)
- Testing activities and collection of evidence

## **Interactive Discussion Session III Description of Computerised Systems and Required Records**

- FDA/EU Regulatory expectations for documented system and record descriptions, and for control over system documentation
- Identification and documentation of GXP-related records created by the system
- Challenges of controlling system documentation
- Example procedures and templates

## **Interactive Discussion Session IV Using Excel in Regulated Environments**

- FDA/EU requirements and expectations for Excel applications
- Developing a procedure for design, development and use of Excel spreadsheets
- Design for lowest errors, highest data integrity and security
- Validation of spreadsheet applications
- Case studies

## **Scaleability of Equipment Qualification**

- Unify the Qualification approach for laboratory equipments
- Systematize the Qualification, limit the effort and increase the working efficiency with the categorisation of equipment
- Standardize document templates for a consistent approach
- Customize the specific qualification work based on Risk assessments

## **Decommissioning and Record Maintenance**

- Understanding the relationship between system lifecycle and record lifecycle
- Requirements for record maintenance
- Strategies for long term record maintenance
- Drivers and challenges for decommissioning of computerized systems
- Cost effective and compliant decommissioning of computerised systems

## **Toolbox for Easy Implementation**

All attendees will get reference material that will help to easily implement what they have learned during the seminar. It includes SOPs, templates, examples and checklists, all related to computers. Material will be supplied by [www.labcompliance.com/solutions](http://www.labcompliance.com/solutions) and will include:

## **Standard Operating Procedures**

- Validation of laboratory computer systems
- Validation of spreadsheets and other computer applications
- Development and use of spreadsheets in regulated environments
- Change control of software and computer systems
- Risk based validation of computer systems
- FDA Inspections – Preparation, conduct, follow-up

## **Examples/Templates**

- Requirement specification for chromatographic data systems
- Testing of Excel applications (incl. traceability matrix)
- Computer system identification
- Test protocol: Authorized system access

## **Speakers**

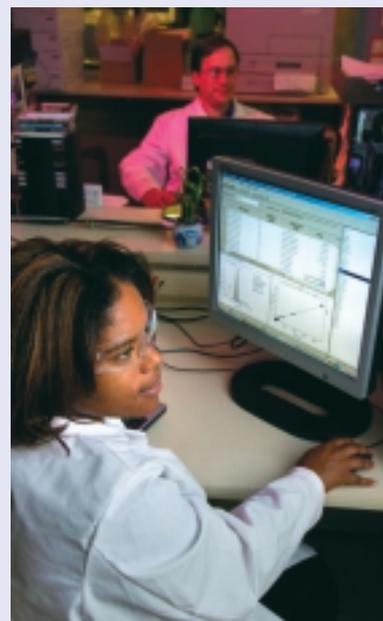
Dr Akos Bartha,  
*AstraZeneca Sweden  
Operations, Sweden*

Dr Ludwig Huber,  
*Agilent Technologies,  
Germany*

Jan Anton Norder,  
*Dutch Pharmaceutical  
Inspectorate,  
The Netherlands*

Yves Samson,  
*Kereon, Switzerland*

Michael Wegmann,  
*F. Hoffmann-La Roche,  
Switzerland*



## 4 Parallel Pre-conference Workshops on 6 March

### Workshop: IT Security

#### Objectives

IT security is of basic importance for the GMP-compliant operation of IT systems. It forms the basis for maintaining the validated status of quality-relevant IT systems. Section 8 of Annex 11 to the EU GMP Guide requires that:

*'Data should only be entered or amended by persons authorised to do so. Suitable methods of deterring unauthorized entry of data include the use of keys, pass cards, personal codes and restricted access to computer terminals. There should be a defined procedure for the issue, cancellation, and alteration of authorisation to enter and amend data, including the changing of personal passwords. Consideration should be given to systems allowing for recording of attempts to access by unauthorized persons'*

In this workshop you will learn how the regulatory requirements can be translated into practice and what the current 'Good Industry Practice' looks like.

#### Programme

##### IT-Security From the CSV Perspective

- Security assessments
- IT-Security checklists
- What the inspector asks

##### Comparison of IT Security Standards

- ISO 17799 / BS 7799
- NIST
- GAMP IT-Infrastructure Guide
- FDA Guidance for Industry – Cybersecurity for Networked Medical Devices containing Off-the-Shelf (OTS) software

##### IT-Security Risk Management in Controlled Environments

- Security vulnerabilities in information systems
- Typical attack scenarios and attack vectors
- Malicious code: Viruses, worms, trojans
- Security risk assessment
- CVSS – Common Vulnerability Scoring System
- How to minimize exposure
- Incident handling: How to stay compliant

##### Patch Management

- What are patches?
- Patching risk assessment
- Security patch management
- Alternatives to patching

#### Speakers:

Dr Wolfgang Schumacher, F. Hoffmann-La Roche, Switzerland  
Michael Wegmann, F. Hoffmann-La Roche, Switzerland

### Workshop: Qualification of Network Infrastructure

#### Objectives

Well characterised, controlled and qualified network infrastructure is a prerequisite for reliable operation of systems running on the network. Networks are quite dynamic and typically can not be taken out of operation for qualification. This interactive workshop will help to balance cost, risk, and available technology to meet business and regulatory requirements related to network infrastructure qualification.

#### Programme

##### FDA Compliance and Business Requirements

- Learn what GMPs, GLPs, GCPs and 21 CFR Part 11 require
- Learn how to interpret network related statements in FDA's guidance documents
- Gain insight in inspectional observations and FDA expectations
- Importance of networks for business continuity
- Recommendations from industry task forces: GAMP, IVT

##### Planning, Installing and Testing Network Infrastructure

- Developing a network qualification plan
- Developing design specifications
- What to do during installation and testing
- How much and what to test
- Qualification of data centers, servers and PC clients

##### Configuration Management and Change Control

- The IEEE model for configuration management
- Developing procedures for change control
- Managing planned changes
- Managing unplanned changes
- Case studies

##### Risk Assessment and Management

- Learn why risk management is must
- Understand the concepts of risk management
- Understand network Infrastructure related risk factors
- Learn how to evaluate and prioritize risk factors for infrastructure
- Online monitoring for high risk systems

##### Developing Documents

- Define what types of documents should be developed
- Design of qualification plan and summary report
- Review security procedures
- Review qualification procedures and protocols
- Review other SOPs that you must have and what they should address

#### Speaker:

Dr Ludwig Huber, Agilent Technologies, Germany

## Workshop:

# Sarbanes Oxley Act and GxP in the IT Environment

## Objectives

More and more companies in the pharmaceutical and medical device market have no more only to comply one area of regulations. Especially the GxP regulations and the Sarbanes Oxley Act have a reasonable impact on the IT environment. Usually each regulation is handled separately in the company without evaluating interrelationships and redundancies. This workshop will show managers and QA in IT how to develop an integrated compliance framework that helps you to manage, implement and maintain these regulations most efficiently.

### Sarbanes Oxley Act (SOA) Compared to GMP for IT

- Sarbanes Oxley Act 302 and 404
- COSO guidelines with PCAOB
- IT Control objectives for SOA
- 21 CFR Part 11 & Annex 11: Comparison

### How to Build an Integrated IT Compliance Framework Based on CobiT

- The idea of an integrated compliance framework
- What is CobiT?
- CobiT content (in a nutshell)
- CobiT and Sarbanes Oxley Act
- CobiT and GxP
- Integrated approach for an internal control system

### Workshop: Mapping of GMP Regulations and PCOAB/COSO Guidelines to CobiT

### How to Relate Best Practices to the IT Compliance Framework?

- Why link to best practices?
- Best practices: ITIL, GAMP, BS7799, CMMI
- Control objectives and control activities
- Examples

### How to Implement IT Compliance in your Organisation

- Guideline for the ICS and scoping of controls
- The concept of general computer controls (end user and IT-hosted)
- General SOPS for documentation and testing
- SOP design and implementation of control and rollout

## Speakers:

Christian Baumgartner, *Arcondis, Switzerland*  
Valery Cottet, *Arcondis, Switzerland*

## Workshop:

# Elaborating Good Requirements

## Objectives

Well elaborated requirements are the first key-factor for the project success. Well formulated requirements make possible a correct and efficient definition of processes. Nevertheless the reality shows how many difficulties customers, system owners and users have to write good requirements.

After a refresh regarding life cycle, methodology and quality properties of requirements, this interactive workshop will give a large place for exercises. Based on proposed business needs, the participants will have the opportunity to develop specifications – User Requirements Specifications and Functional Specifications – and to acquire or improve methodology for elaborating good requirements.

### Requirements and Life Cycle

- Requirement management & quality awareness
- What should be specified? When?
- Scope of URS, FS and DS

### Guideline for Preparing Specifications

- Requirements traps to avoid
- Recommendations to the project team
- Quality requirements
- Requirement traceability

### Case Study 1: Requirement Review

- Identify good (and bad) requirement
- Improve requirement formulation

### Elaboration Process

- The 7 steps approach

### Case Study 2: Elaborating Requirement

- Requirement capture
- Structuring requirement
- Developing requirement

## Speaker:

Yves Samson, *Kereon, Switzerland*



## What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

## What Are the Benefits of ECA?

### First benefit:

During the membership, you enjoy a 10% discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

### Second benefit:

A CD ROM with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

## How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.

More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>

## GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following qualification levels:

- ECA Certified Quality Assurance Manager – Pharmaceutical Production
- ECA Certified Quality Assurance Manager – API Production
- ECA Certified Quality Control Manager
- ECA Certified Pharmaceutical Engineering Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager



On the internet at [www.gmp-compliance.org](http://www.gmp-compliance.org) you will find a text explaining which seminars are recognised for which certificates.

Or you send an e-mail to [info@gmp-compliance.org](mailto:info@gmp-compliance.org) or a fax to +49(0)62 21 / 84 44 64 with the request for information about the Professional Certification Programme. We will then send you our brochure on the topic.

## About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Germany, Austria and Switzerland. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

## Venue of the Conferences and Pre-conference

### Workshops

Radisson SAS Scandinavia Hotel  
Amager Boulevard 70  
2300 Copenhagen S  
Denmark  
Phone + 45 33 96 50 00  
Fax + 45 33 96 55 00



## Accommodation

CONCEPT has reserved a limited number of rooms in the Radisson SAS Scandinavia Hotel. Reservation should be made directly with the hotel not later than 5 February 2006. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention ECA/CONCEPT and the password A0803A to receive the specially negotiated rate for the duration of your stay. 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

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

Dr Andreas Mangel (Phone + 49 (0) 62 21 / 84 44 41, e-mail: [mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de)), the responsible project manager, will help you with any technical questions as regards content.

Ms Marion Grimm (Phone + 49 (0) 62 21 / 84 44 18, e-mail: [grimm@concept-heidelberg.de](mailto:grimm@concept-heidelberg.de)), the responsible organisation manager, is happy to help you with any questions concerning reservation, hotel, etc.

## Parallel Pre-conference Workshops

---

### Date

Monday, 6 March 2006, 13.00 h – 18.30 h  
(Registration and coffee 12.30 h – 13.00 h)

### Fees

Non-ECA Members € 590.– per delegate plus VAT  
ECA Members € 531.– per delegate plus VAT  
EU GMP Inspectorates € 295.– per delegate plus VAT  
The fee is payable in advance after receipt of invoice and includes conference documentation and all refreshments. VAT is reclaimable.

## 2 Day Conference IT Infrastructure Compliance and Control

---

### Date

Tuesday, 7 March 2006, 10.00 h – 18.15 h  
(Registration and coffee 9.00 h – 10.00 h)  
Wednesday, 8 March 2006, 8.30 h – 18.00 h

### Fees

Non-ECA Members € 1,490.– per delegate plus VAT  
ECA Members € 1,341.– per delegate plus VAT  
EU GMP Inspectorates € 745.– per delegate plus VAT  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 7 March, lunch on both days and all refreshments. VAT is reclaimable.

## 2 Day Conference Maintaining the Validated State

---

### Date

Tuesday, 7 March 2006, 9.30 h – 18.30 h  
(Registration and coffee 9.00 h – 9.30 h)  
Wednesday, 8 March 2006, 8.30 h – 17.00 h

### Fees

Non-ECA Members € 1,490.– per delegate plus VAT  
ECA Members € 1,341.– per delegate plus VAT  
EU GMP Inspectorates € 745.– per delegate plus VAT  
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 7 March, lunch on both days and all refreshments. VAT is reclaimable.

## 2 Day Conference Computer Validation for Suppliers

---

### Date

Thursday, 9 March 2006, 9.30 h – 18.30 h  
(Registration and coffee 9.00 h – 9.30 h)  
Friday, 10 March 2006, 8.30 h – 16.00 h

### Fees

Non-ECA Members € 1,490.– per delegate plus VAT  
ECA Members € 1,341.– per delegate plus VAT  
EU GMP Inspectorates € 745.– per delegate plus VAT  
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 9 March, lunch on both days and all refreshments. VAT is reclaimable.

## 2 Day Conference Recent FDA/EU Requirements on Laboratory Computers and Records

---

### Date

Thursday, 9 March 2006, 9.00 h – 18.00 h  
(Registration and coffee 8.30 h – 9.00 h)  
Friday, 10 March 2006, 9.00 h – 16.45 h

### Fees

Non-ECA Members € 1,490.– per delegate plus VAT  
ECA Members € 1,341.– per delegate plus VAT  
EU GMP Inspectorates € 745.– per delegate plus VAT  
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 9 March, lunch on both days and all refreshments. VAT is reclaimable.

### Save Money!

**If you book 2 conferences you will get a 25% discount on the second conference.**

**If you book a pre-conference workshop and a conference you will get a 25% discount on the pre-conference workshop.**

### 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 weeks prior to the conference 50 %, within 1 week prior to the conference 100 %.

CONCEPT 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 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 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)!

Reservation Form (Please complete in full)

## Pharma IT Week 2006

6–10 March 2006, Copenhagen, Denmark

- Parallel Pre-conference Workshops on 6 March 2006** (Please tick only ONE workshop)
- IT Security
  - Qualification of Network Infrastructure
  - Sarbanes Oxley Act and GxP in the IT Environment
  - Elaborating Good Requirements

### Conferences on 7 and 8 March, 2006

- IT Infrastructure Compliance and Control**  
7–8 March 2006
- Maintaining the Validated State**  
7–8 March 2006

### Conferences on 9 and 10 March, 2006

- Computer Validation for Suppliers**  
9–10 March 2006
- Recent FDA/EU Requirements on Laboratory Computers and Records**  
9–10 March 2006

(Please indicate the conference(s) and the workshop you would like to participate in)

Mr    Ms

\_\_\_\_\_  
Title, first name, surname

\_\_\_\_\_  
Company

\_\_\_\_\_  
Department

\_\_\_\_\_  
Street / P.O. Box

\_\_\_\_\_  
City

\_\_\_\_\_  
Zip Code

\_\_\_\_\_  
Country

\_\_\_\_\_  
Phone / Fax

\_\_\_\_\_  
E-mail (Please fill in)

If the bill-to-address deviates from the specification above, please fill in here:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Please send this form to

CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax + 49(0)6221/844434  
69007 Heidelberg  
GERMANY