ECA Certified QA Manager Course*

With several Case Studies:

- LIMS
- SAP
- Quality Management System
- Document Management System
- Training Administration
- SOP System

Principles and Practice of

Electronic Solutions for GMP and Documentation Systems

How to achieve the benefits promised and stay compliant

19 – 20 October 2010, Berlin, Germany

SPEAKERS:

Konstantin Clevermann
IDS Scheer

Dr Susanne Dommasch
Nextpharma

Kai Kiefer
Gambro

Sandrine Lauvergne
Actelion Pharmaceuticals

Dr Bob McDowall
McDowall Consulting

Bernard Przybylski
Actelion Pharmaceuticals

Holger Schwendemann
BASF

LEARNING OBJECTIVES:

- How to identify the best system
- Strategic project management
- Relevant legislation and guidance
- Efficient and compliant implementation
- How to achieve the benefits promised

ECA
EUROPEAN COMPLIANCE ACADEMY

*This master class is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Principles and Practice of Electronic Solutions for GMP and Documentation Systems

19 – 20 October 2010, Berlin, Germany

Objectives

During this Master Class you will get to know **benefits and risks** using electronic solutions for GMP and Quality Assurance systems. You will learn how they work and interact, and **what needs to be considered** when implementing and running them.
Experts will show you possibilities to **improve your systems** and how to **use them efficiently and (c)GMP-compliant**. Based on **case studies and examples** you will learn how different electronic systems have been successfully implemented in a pharmaceutical environment.

Background

Computerised systems have been used for many years in pharmaceutical industry. Their use increases product safety and saves time and costs in manufacturing. And over the last years, electronic solutions for GMP and QA Systems have been getting more and more sophisticated and popular for the same reasons. And they are able to remove much of the paper work that is still used in quality assurance, manufacturing and quality control.

But while implementing those systems, a lot of facts have to be considered and questions to be answered both from a technical and compliance point of view:

- How to identify the best system
- Strategic design of electronic solutions
- Management of costs and risks
- Complex computer validation requirements
- Efficient and compliant implementation
- How to achieve the benefits promised

Increasing cost pressures on pharmaceutical companies mean that internal efficiencies are essential to ensure profitability from manufacturing operations but also in R&D. And implementing electronic systems first of all needs a lot of resources: people, money, time. Therefore it is of utmost importance to do the right things: **chose the right systems, implement them quickly and efficiently and get the most out of them.**

Target Audience

This Education Course is designed for all persons in pharmaceutical, biopharmaceutical and API industry who are involved in projects establishing, implementing and improving electronic solutions for GMP Systems:

- Quality Assurance
- Project Management
- Business Development
- IT
- Production
- Quality Control

Moderator

Dr Bob McDowall

Programme

Part 1: Principles

Why Electronic Systems and not Paper?

- Business and regulatory drivers for working electronically
- Benefits of electronic working locally and globally
- Ensuring product quality and supply chain integrity through end-to-end traceability
- The human element of electronic systems
- Agility in responding to changed product and production requirements
- Ensuring product quality through end-to-end traceability
- Cost transparency
- Effort required to maintain state-of-the-art electronic process support
- Effort required securing data and applications – do we need a separate talk on data preservation and archiving?

Recent Updates of relevant Legislation and their Consequences

- EU GMP Annex 11 proposed update
- Impact of the new clause of US GMP: 21 CFR 211.68(c)
- Part 11 – what's new?
- Impact of the FDA's new Post Inspection Response programme
- GAMP®5: flexibility not constraint?
- Traps and challenges of the new regulations and guidance on electronic systems

Developing a strategic Design of Electronic Solutions

- How to establish a strategic vision and build a roadmap
- How to develop an enterprise information architecture
- Managing your „Forces and Sources"
- What to do with the already existing systems? (Decision Guidelines)

Part 2: Moving from Theory to Practice

Consolidating electronic QA Systems in one single System: yes or no?

- Pros and cons
- What small companies can do

Effective and efficient Implementation and Use of Electronic GMP Systems

- Process mapping and redesign as an essential part of understanding the business process and an essential pre-requisite for implementation of an electronic solution
- Using risk management effectively
- Validation of interfaces

Part 3: Examples from the real World

Managing electronic Documents

- Management of Documents
- XML as a possibility
- Control of bi- and multilingual documents
- Electronic and digital signatures
- Electronic Archiving & Retention Management

Case Studies:

- Electronic Solutions in the Analytical Laboratory
- Using SAP for electronic documentation in a regulated environment
  - Overview of concepts and components SAP
  - Using SAP for storage of validation documentation (incl. electronic signatures)
- Managing a Roll-out of a Global QMS

User Experiences:

- Online Documentation and Content Management at BASF
- QUATRO: Quality And Training Management System Optimized - Planning, Implementation and Roll-out of a Global eQMS
- Implemtentation of an electronic SOP Management System

and other examples

Part 4: Compliance Aspects

Auditing Electronic Systems

- The impact of working electronically will change the way that we audit and inspect manufacturing facilities, laboratories and computerised systems
- What do we need from the systems?
- What do we need from the auditors / inspectors?
- The future of audits and inspections? Remote access and video conference discussion?

The Issues with Validation

- Risk-based Computer Validation and CASE/CAST/CMM Tools
- Good Practises using tools to support risk-based Computer Validation activities
- Maintaining Validate State of Electronic Solutions (GAMP®5 and ITIL Tools)
- Experiences implementing processes and using tools to support validated systems

Part 5: Exhibition

Suppliers of electronic GMP Systems are invited to exhibit their systems and products. Delegates can get first hand information on the products offered and will be able to address questions directly to the suppliers.
If you are interested to exhibit at this conference, you will details and a registration form on our website www.gmp-compliance.org under link Conferences.

Speakers

Konstantin Clevermann,
IDS Scheer AG
Konstantin Clevermann is responsible for IT-Compliance, IT-Infrastructur-Qualification, SAP-Validation and implementation of the SAP Solution Manager at IDS Scheer's Pharma/Life Sciences Business

Dr Susanne Dommasch,
Nextpharma
Dr Susanne Dommasch is Head of Quality Assurance at the allphamed Pharbil Arzneimittel GmbH and PenCef Pharma GmbH, Göttingen (Subsidary of Nextpharma Technologies Holding Ltd). She was responsible to establish a computerised training system and an electronic SOP management system.

Kai Kiefer,
Gambro Renal Products
Manager Center-of-Excellence ECM & Quality Solutions. Before Kai Kiefer started working for Gambro, he was IT Manager Document Management & Quality Systems Solutions at Sanofi-Aventis.

Sandrine Lauvergne
Actelion Pharmaceuticals Ltd

Dr Bob McDowall, *McDowall Consulting*
Principal of McDowall Consulting, UK. He has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems.

Bernard Przybylski
Actelion Pharmaceuticals Ltd

Holger Schwendemann,
BASF
Supervisor Quality Management, Panton Plant at BASF in Ludwigshafen, Germany.

Social Event

On 19 October, you are cordially invited to a social event in Berlin. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GAMP® is a trademark of ISPE - http://www.ispe.org/gamp5

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Principles and Practice of **Electronic Solutions for GMP and Documentation Systems**
19 – 20 October 2010, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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

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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)!

Date

Tuesday, 19 October 2010, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 20 October 2010, 8.30 – 15.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-799

Fees

ECA Members € 1.521.- per delegate plus VAT
APIC Members € 1.605.- 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.

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 ECA 6401" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 10 September 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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