ECA Certified QA Manager Course*

With several Case Studies:

- LIMS
- Complaint Management
- Quality Management System
- Document Management System
- SOP-System

Principles and Practice of Electronic Solutions for GMP and Documentation Systems

How to achieve the benefits promised and stay compliant

24 – 25 November 2011, Heidelberg, Germany

SPEAKERS:

Dr Susanne Dommasch
Nextpharma

Kai Kiefer
Gambro

Dr Bob McDowall
McDowall Consulting

Holger Schwendemann
BASF

LEARNING OBJECTIVES:

- Impact of the updated legislation and guidance
- How to identify the best system
- Management of costs and risks
- Efficient and compliant implementation
- How to achieve the benefits promised
- Business Benefits with GMP Compliance
- Auditing Electronic Systems

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

24 – 25 November 2011, Heidelberg, 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.**

In June 2011, the new versions of EU GMP Annex 11 and Chapter 4 will become effective and the course will look at some of the key aspects of the new legislation and how it impacts electronic solutions.

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 Use Electronic Systems 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
- Effort required to maintain state-of-the-art electronic process support

Developing a Strategic Design of Electronic Solutions

- How to establish a strategic vision and build a roadmap
- How to develop an enterprise information architecture
- What to do with the already existing systems? (Decision Guidelines)
- Review Benefits / Risks

Impact of the new GMP Regulations including Annex 11 on Electronic Systems Design and Validation

- 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

Part 2: Moving from Theory to Practice with Case Study Examples

Case study: Pros and Cons of implementing an electronic SOP Management System

- How to identify the best system
- What needs to be considered when implementing and running the system
- How to achieve the benefits promised
- How does it work in the daily business

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
- Roles of management for a successful implementation
- Roles of users for a successful implementation

Managing Complaints and Sending Adverse Event Reports Electronically to Authorities

- New Policies from FDA and EU on reporting Adverse Events
- Requirements on Process, Trending and Reporting
- Planning an Implementation
- Review Benefits / Risks and Lessons Learned

Online Documentation and Content Management at BASF

- Requirements of documents
- Implementation of a new online documentation together with the employees
- Workflow of documents
- Role of doc manager, creator, reviewer and approver

Options for Retention and Archiving of Electronic Records

- EU GMP Chapter 4 requirements for retention of records
- Impact of the new regulation on electronic systems

Case study: Implementation of a LIMS system

- Planning the system
- Implementation and Validation of the system
- Benefits, efforts, challenges and possible pitfalls

Part 3: Compliance Aspects

Current Validation Challenges (Part 1)

- Risk-based Computer Validation
- Benefits using tools to support risk-based Computer Validation activities
- Validation of interfaces and data migrations
- Review Benefits / Risks

Interpreting the New EU GMP Chapter 4 Requirement for Raw Data Definition

The new GMP Chapter 4 brings a new requirement for the definition of raw data used for releasing a batch.

- Understanding the requirement for defining raw data for electronic systems
- Interpreting this for different electronic GMP systems

Current Validation Challenges (Part 2)

- Change Control and Risked-based Computer Validation
- Maintaining a system using GAMP5 and ITIL
- Experiences implementing tools using GAMP5 and ITIL for System Maintenance
- Review Benefits / Risks

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?

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

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.

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.

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

Social Event

On 24 November, you are cordially invited to a social event in Heidelberg. 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

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**
24 – 25 November 2011, Heidelberg, 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
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 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 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

Thursday, 24 November 2011, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 25 November 2011, 8.30 – 16.00 h

Venue

nh-Hotel Heidelberg
Bergheimer Str. 91
69115 Heidelberg
Germany
Phone +49 (0)6221 1327 0
Fax +49 (0)6221 1327 100

Fees

ECA Members € 1.590.- per delegate plus VAT
APIC Members € 1.690.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1.790.- per delegate plus VAT
EU GMP Inspectorates € 895.- 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 6916" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 26 October 2011. 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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