ECA Certified Computer Validation Manager Course*

New EU Annex 11 and Chapter 4 Requirements will be covered

Computerised Systems in Analytical Laboratories

Foto: DRK

The Electronic Analytical GMP Laboratory: Integrating Computerised Systems to Ensure Compliance and Maximise Productivity

2-4 May 2011, Heidelberg, Germany

SPEAKERS:

Eberhard Kwiatkowski
Bayer Schering Pharma, Germany

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- Developing a Strategy for an Electronic Laboratory
- How to Design Electronic Regulatory Compliance
- Involving the IT Department in the Strategy
- How to Manage Electronic Records
- Protecting Electronic Records
- Streamlining Working Practices for Electronic Signatures
- Integrating LIMS, ELNs and Instrument Data Systems
- Computerised System Validation
  - Effective Risk-Based Validation
  - Options for Streamlining and Automation
- Changing a System – What to Do with the Old Data?

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager". Please find details at www.gmp-certification.eu

Computerised Systems in Analytical Laboratories

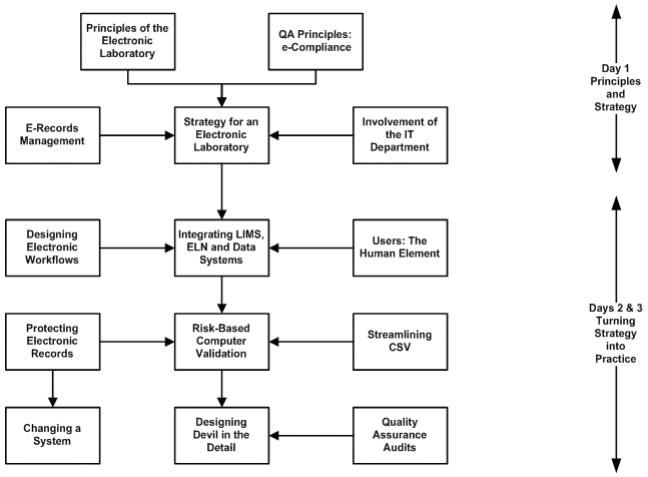
2-4 May 2011, Heidelberg, Germany

Background

Pharmaceutical companies, API manufacturers and contract research organisations are under increasing cost containment pressures. Consequently GMP regulated analytical laboratories working within these organisations must now implement and integrate computerised systems under budget restrictions, but yet maintain regulatory compliance whilst increasing productivity.

Productivity can be increased relatively easily when 21 CFR 11 (electronic records and electronic signatures regulation) technically compliant applications are implemented together with the use of electronic working and e-signatures for review and approval of records. However, recent fraud cases indicate that electronic systems and records integrity and data falsification can be under increased scrutiny during FDA inspections. This increases the importance of designing regulatory compliance into specific applications as well as when applications are integrated together. Furthermore computerised systems must be implemented, validated and operated to ensure that questions of data integrity can be easily answered.

This educational course will provide course participants with the strategies to implement and integrate computerised systems in a regulated analytical laboratory. It is divided into two parts. On the first day we will present the principles and strategy for planning the regulated electronic analytical laboratory and the second part on days two and three will be focussed on turning the strategy and principles into practice as outlined in the diagram below.



The overall strategy for implementing individual computerised systems, together with any instruments that it controlled, must provide business benefits coupled with the automation of regulatory compliance. Therefore the operating principles and practice for any computerised system within an analytical GMP laboratory must be:

- Capture data at the point of origin
- Never transcribe data, always transfer data electronically
- Know where you will store / archive the data to ensure it's easy restoration and reuse as necessary

The benefits of individual systems can be leveraged when they are interfaced with other ones. For example interfacing a laboratory information management system (LIMS) with a chromatography data system (CDS) will provide the benefits of the CDS plus the elimination of manual data entry into the LIMS when the two are interfaced to provide more benefit than if the two were not connected.

Increasing emphasis on computerised systems means increased computer validation requirements for the laboratory. However, it should not be the case of one size fits all to validate each computerised application but a risk based approach to focussed effort depending on the risk posed by a specific system. In addition the role of IT in developing the electronic laboratory is often omitted and this needs to be reflected in the overall strategy for the laboratory.

Learning Goals

This education course has the following objectives:

- To present ways of developing strategies to automate a GMP analytical laboratory to reduce overall analytical turnaround time
- To integrate existing or newly purchased software applications and leverage the business benefits of them for greater efficiencies
- To maintain or improve the integrity of data generated within a GMP analytical laboratory
- To ensure compliance with GMP regulations

The requirements of the final version of EU GMP Annex 11 and Chapter 4 which were issued in January 2011 and which will become effective on 30th June 2011 will also be covered.

Target Audience

Laboratory managers, Quality Assurance professionals, computerised system owners and project managers are encouraged to attend. IT staff working with laboratory systems will also benefit from attendance.

Moderator

Dr. Bob McDowall, McDowall Consulting, UK

Programme

Principles and Strategies

Principles of the Electronic Analytical GMP Laboratory
- Integration of laboratory software applications
- Design of electronic workflows
- Data capture at point of origin
- Never transcribe data
- Effective data and information management

e-Compliance in Regulated Laboratories: Quality Assurance Principles for an Electronic Analytical Laboratory
- Responsibilities
- Validation of Computerised Systems
- Documentation
- Maintenance and Disaster Recovery
- Reproduction Accuracy
- Record Review
- Security
- Archives
- Training

Developing a Strategy for the Electronic Analytical Laboratory
- Where are we now and where do we want to be?
- Inventory of current systems and applications: can they be integrated or do we need new ones?
- Implementing software one application at a time
- Leveraging the benefits from interfacing to existing applications
- Justification of individual systems
- Roles and responsibilities of senior management, laboratory management and users

Workshop I:
Devising a Electronic Laboratory Strategy

Participants will be presented with a description of an existing laboratory and will be asked to develop a strategy to integrate applications and work electronically.

What is Your Strategy for Managing the Electronic Records Produced by the Laboratory
- Regulatory requirements for records retention of laboratory data
- Central or local data storage?
- Store in the proprietary file format or convert the file?

Involving the Information Technology Department in Developing the Laboratory Strategy
- Know the corporate IT standards and directions
- Planning network access, network bandwidth and data storage requirements for the laboratory
- Planning network resilience including computer rooms

Turning Strategy into Practice

Designing Electronic Working Practices and Incorporating Electronic Signatures
- Mapping your current process and identifying the bottlenecks
- Identifying improvement ideas for the laboratory
- Know the regulations for electronic signatures
- Improve the process including electronic signatures and then automate using software

Workshop II:
Designing Electronic Working Practices in an Analytical GMP Laboratory

Working in groups, participants will be presented with the current workflows from a laboratory and will be asked to streamline them prior to implementing a common laboratory application.

Integrating LIMS, Electronic Laboratory Notebooks and Instrument Data Systems
- Functions automated by the three types of software application
- Areas of specialism versus areas of overlap for each application
- Deciding which application will automate a specific function

Workshop III:
Designing Integrated Systems for a Laboratory

Working in groups, participants will take a laboratory description and determine which application will be used to automate a specific function. Results will be presented to the course for discussion.

Understanding and Applying Risk-Based Computerised Systems Validation to Laboratory Systems
- Overview of current regulations for computerised system validation
- GAMP 5 software categories and life cycle models
- Developing a flexible risk based approach to computer validation for the laboratory

Users: The Human Element of the Electronic Laboratory
- Role of senior management
- Role of laboratory management
- Role of users
- Ensuring users are involved in the projects

Protection of Electronic Records in the Electronic Laboratory
- The paper analogy applied to electronic records
- Long versus short term protection in the records life cycle
- Short term protection controls: technical and procedural
- Long term protection controls: technical and procedural

Quality Assurance Audit of the Electronic Laboratory

- Audit Intervals
- Risk Management
- Installation and Operation
- Verification
- Raw Data Audit
- Training
- Change Management
- Deviations

Changing a System – What to Do with the Old Data?

- Data migration: system upgrades and system to system
- Regulatory requirements: US and EU GMP
- Impact of the Part 11 scope and application guidance on data migration
- Options to consider when changing a system

Facilitated Discussion: Options for Retention and Archiving of CDS Records

Based on a case study the records retention options for a laboratory will be explored in a facilitated discussion. We will also explore the same scenario if the type of organisation changes.

Streamlining and Automating Computerised System Validation (CSV) in the Electronic Laboratory

- Risk-based approaches fit the validation to the system not the system to single validation model
- Automating the validation: document management and validation management systems
- Reusing requirements – but intelligently!
- Working smarter and not harder in validation: getting more out of a single test
- Screen dumps for each test step: true or false?
- Speeding the writing of the validation summary report

Workshop IV:

Designing Electronic Working Practices – The Devil is in the Detail

Attendees will be presented with the part of a laboratory workflow and will be asked how they will automate the process to meet certain criteria. The team outcomes will be discussed with the course.

Speakers

EBERHARD KWIATKOWSKI,

Bayer Schering Pharma AG, Elberfeld, Germany

Eberhard Kwiatkowski started his apprenticeship as Biological Laboratory Technician at Bayer AG in 1976. After different functions in the biochemical process development and the biological monitoring within the medical department, Eberhard was engaged in the qualification of analytical systems and the validation of computerised systems in the QC unit. Since 2000 he has been in charge of the computerised system validation for the entire Bayer Schering Pharma plant in the "GMP-Referat" for the API production in Wuppertal. He is a co-author of the ISPE Good Practice Guide for the Audit of external suppliers and he is a member of the GAMP-DACh Forum and he is also a member of APV's expert group on computerised systems.

DR BOB MCDOWALL

McDowall Consulting, Bromley, Kent, UK

Analytical chemist with over 35 years experience including 15 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and 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. Bob is also the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

Social Event

On Monday, 2 May 2011, 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.

For questions regarding content:
Dr Günter Brendelberger (Operations Director) at +49-62 21/84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at +49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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 € 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software 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.

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 certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager

On the internet at 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 or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

ECA Education Course
New EU GMP Annex 11 Regulations for Computerised Systems
5-6 May 2011, Heidelberg, Germany

On 5 – 6 May 2011, i.e. from Thursday to Friday of the same week, ECA offers an GMP Education Course in Heidelberg about New EU GMP Annex 11 Regulations for Computerised Systems. The objectives of this new course are

- to review and understand the changes that have been made in the new version of EU GMP Annex 11 before it becomes effective
- to review and understand the impact of the changes to EU GMP Chapter 4 (Documentation) and their impact on the definition of raw data and generation and maintenance of electronic records
- to understand how the requirements of Annex 11 and Chapter 4 interact

These three objectives will allow organisations to plan for the changes to policies and procedures for the validation of computerised systems and management of electronic raw data that the new regulations bring.

Speakers:
Dr Bob McDowall, McDowall Consulting, UK
Karl-Heinz Menges (European GMP Inspector), Regierungspräsidium Darmstadt, Germany

The course on New EU GMP Annex 11 Regulations (5-6 May 2011) is an excellent extension to the course Computerised Systems in Analytical Laboratories (2-4 May 2011).

Further information about the course **New EU GMP Annex 11 Regulations** can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive a 350€ discount (not valid for EU GMP Inspectorates).

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

☐ **Computerised Systems in Analytical Laboratories**, 2-4 May 2011, Heidelberg, Germany
☐ I would also like to register for the Course **New EU GMP Annex 11 Regulations for Computerised Systems**, 5-6 May 2011, Heidelberg, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No, if applicable**

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City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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P.O. Box 101764
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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

Monday, 2 May 2011, 09.00 – 18.15 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 3 May 2011, 08.30 – 18.15 h
Wednesday, 4 May 2011, 08.30 – 16.00 h

Venue

Crowne Plaza Hotel Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone + 49 / (0) 6221 917 0
Fax + 49 / (0) 6221 917 100

Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890,- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- 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 all days and all refreshments. VAT is reclaimable.

Would you like to save money?
If you register for the ECA Education Course "New EU GMP Annex 11 Regulations for Computerised Systems" from 5 to 6 May 2011 at the same time, you will receive a **350 EUR discount**. This is not valid for EU GMP Inspectorates.

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 6885 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 April 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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