ECA Certified Quality Control Manager Course*

Participate in 6 Workshops!

Integrating Analytical Instrument Qualification and Computerised System Validation

An Integrated Approach to Analytical Instrument Qualification (AIQ) and Computerised System Validation (CSV) for the GMP Regulated Laboratory

28 February – 1 March 2011, Berlin, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- Analytical Equipment Qualification: Where Are We Now?
- Computerised System Validation: Where Are We Now?
- AIQ and CSV: A Risk-based Approach
- An Integrated Approach to AIQ and CSV:
  - Process Workflows
  - How to Minimise the Validation/ Qualification Effort
  - Key Documents to be Written
  - Component Installation
  - User Configuration
  - User Acceptance Testing
- Applying Integrated Approach Principles in Practice to
  - Analytical Balance
  - Stand Alone Spectrometer
  - HPLC with a Networked CDS Data System

ECA
European Compliance Academy

* This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager"

Integrating Analytical Instrument Qualification and Computerised System Validation

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Learning Goals

Analytical instrumentation used within GMP analytical laboratories is computerised either via firmware inside the instrument or via a workstation with software loaded on to a workstation that is situated next to the instrument. However, the **current situation** regarding the qualification of analytical instrumentation and validation of computerised systems **is unsatisfactory; qualification and validation are typically considered as separate activities** with little if any interaction between the two disciplines.

For example, the AAPS have produced guidance on analytical instrument qualification (AIQ) that has been incorporated as **General Chapter <1058>** within the United States Pharmacopoeia **(USP)**. This focuses on the instrument with little emphasis on computerised system validation.

In contrast, the **GAMP Good Practice Guide for Validation of Laboratory Computerised Systems** looks exclusively on the computerised system and ignores the instrument qualification aspects entirely.

The major problem is that you cannot validate the computer system without qualifying the instrument and vice versa.

This workshop will address these concerns and present an integrated approach to analytical instrument qualification (AIQ) and computerised system validation (CSV) for laboratory systems. This will be achieved by presentations coupled with workshops and discussions to reinforce the presentation principles. The number of participants is limited.

Note: This workshop will not discuss directly user training and the writing of SOPs for operating the instruments or systems.

Target Group

Analytical scientists, laboratory managers, validation personnel working with laboratory equipment and systems, quality assurance personnel and any IT personnel involved with systems such as chromatography data systems and LIMS.

Moderator

Dr Bob McDowall, McDowall Consulting, UK

Programme

Introduction to the Course

- Aims and objectives of the course
- Course process (presentations / workshops)
- Road map for the course

A Risk-based Approach - Working Smarter not Harder

- Quality Management Systems in the analytical laboratory; implications of ICH Q10
- Traditional approaches to calibration, qualification & validation
- Impact of new technology changes on instruments & systems
- New and novel regulatory expectations
- Instrument, equipment or system?
- Establishing 'fitness for purpose' and 'suitability for intended use'
- Terms and definitions; the role of a technical glossary

Analytical Equipment Qualification: Where Are We Now?

- Calibration or Qualification?; Modular & holistic approaches
- USP <1058> Analytical Instrument Qualification
- Establishing risk-based criteria based on user ways of working
- Software linking in USP <1058>
- Applying the principles of USP <1058> in practice to an
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

WORKSHOP I

Risk Categorisation of a Laboratory Inventory – Application of the Principles of <1058>
Attendees will be given an inventory based on a real laboratory and asked to classify the equipment and systems presented.

Computerised System Validation: Where Are We Now?

- Regulators
  - FDA; Part 11, Predicate Rules & 2002 software validation guidelines
  - EU; Existing and New Draft of Annex 11
  - PIC/S Good practices for computerised systems in regulated "GXP" environments
- Industry
  - GAMP 4 & 5
  - GAMP Good Practice Guides
- Applying CSV principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

An Integrated Approach to AIQ and CSV for Analytical Systems – Part 1

- Do I have to qualify or validate?
  - Risk assessment processes
  - System impact
  - System categorisation
- If I do how much do I do?

WORKSHOP II

Process Workflows – Exploring the Possibilities for an Integrated Approach to AIQ and CSV

An integrated approach for qualifying instruments and validating software will be developed using examples from Workshop I.

An Integrated Approach to AIQ and CSV for Analytical Systems – Part 2

- How can I minimise the validation/qualification effort?
- Phase integration of AIQ & CSV
- Applying integrated approach principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

WORKSHOP III

Turning the Principles of the Integrated Approach into Practice

Attendees will be given three examples and asked to adapt the integrated AIQ – CSV process for each one:

- Analytical Balance
- Stand alone spectrometer
- HPLC with a networked CDS data system

Documenting the Qualification and Validation Effort

- How much do I really need to do?
- Key documents to be produced
- "Validation Lite" a simplified approach for low risk systems
- Paper or electronic documentation
- Traceability of the validation/qualification effort
- Supporting documentary evidence
- Managing sign off and operational release
- Linking with a Quality Management System (QMS)

Component Installation and Integration

- Nomenclature & mapping; the USP <1058> 4 Qs & GAMP
- Factory acceptance testing; strengths and weaknesses
- Vendor documentation; pros & cons
- Vendor installation & commissioning
- Leveraging vendor activities to reduce user testing
- Configuration management and the change control baseline
- Managing the IT interface
- Applying the principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

WORKSHOP IV

Risk Assessment of Vendor IQ and OQ Documentation

Attendees will review examples of vendor qualification documentation from the examples below to identify where time can be saved or where there is little value add from the vendor approach:

- Analytical balance
- NIR spectrometer
- Networked CDS

Configuring the Application to Meet User Needs

- Establishing laboratory work flows & SOPs
- How good is the fit with vendor materials?
- Prototyping to determine/ensure the fit to the business process
- Defining mandatory user requirements as a consequence of the workflow
- Operational ranges & conditions
- Calibration procedures and reference standards
- Do you need a configuration document for
  - Analytical balance,
  - Stand alone spectrometer,
  - HPLC with a networked CDS data system?
- What are the implications for change control?

WORKSHOP V

Documenting the User Configuration

The attendees will identify where user configuration is required for a real life scenario of an implementation of an automated dissolution system connected to an automated HPLC and networked data system.

User Acceptance Testing – Instrument, Software and System

- What to test and what not to test
- What has the vendor to offer?
- Risk assessment and the URS
- Typical aspects to test
- Test plans and test scripts
- Assumptions exclusions and limitations of testing
- White box and black box testing
- Testing approaches
- Setting sound acceptance criteria
- Integrating calibration and qualification

WORKSHOP VI
How to Focus on Critical Areas for User Acceptance Testing
Based on the outputs from workshop 5, the attendees will decide how to focus on the critical areas of the system for user acceptance testing.

Speakers

Dr Christopher Burgess

Burgess Analytical Consultancy, Barnard Castle, UK

Dr Burgess has over 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He has MSc and PhD degrees from Loughborough University in Analytical Chemistry. He is a qualified ISO Guide 17025 assessor. Dr. Burgess has published over 70 papers and books in analytical science. He is also a Qualified Person and a member of the European QP Association Advisory Board.

Dr Bob McDowall

McDowall Consulting, Bromley, Kent, UK

Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry; 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. Bob is 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

At the evening of the first course day all participants and speakers are invited to a dinner in a nice restaurant in the city of Berlin, where the topics of the course can be further discussed in a relaxed atmosphere.

ECA Education Course

Maximising HPLC Productivity

2 – 4 March 2011, Berlin, Germany

On 2 – 4 March 2011, i.e. from Wednesday to Friday of the same week, there will be another ECA GMP Education Course in Berlin about **Maximising HPLC Productivity**. The objective of this course is to provide attendees with **practical information to efficiently and effectively manage HPLC within GMP-/FDA-regulated environments of the pharmaceutical industry by combining science and compliance.**

Topics that will be covered are:

- Balancing Science and Compliance in the HPLC Laboratory for Effectiveness and Productivity
- Sampling Practices and Pitfalls for HPLC Analysis
- Sample Preparation for HPLC Chromatography
- Advantages and Disadvantages of LC Miniaturisation
- HPLC Equipment Qualification
- CDS Compliance Lessons
- Prevention of OOS HPLC Results
- HPLC Method Validation
- System Suitability Testing: Ph.Eur and USP Requirements
- Efficient HPLC Method Development
- Practical Interpretation of HPLC Chromatograms
- CGMP-Compliant HPLC Documentation
- Electronic Records for a CDS
- Effective Analytical Method Technology Transfer
- Validation of CDS and Electronic Signatures for Productivity

In addition, **workshops** are offered about:

- HPLC Equipment Qualification
- Method Validation
- HPLC System Suitability Tests
- Validation of a Chromatography Data System (CDS)

Speakers:

Dr Christopher Burgess, Burgess Analytical Consultancy, UK
Dr Manfred Fischer, SkyePharma AG, Switzerland
Dr Joachim Ermer, Sanofi-Aventis, Germany
Dr Howard Hill, NDA Analytics, UK
Dr Bob McDowall, McDowall Consulting, UK
Dr Christine Mladek, Boehringer Ingelheim, Germany

The course on **Integrating Analytical Instrument Qualification and Computersised System Validation** (28 February – 1 March 2011) is an ideal precursor to the Education Course **Maximising HPLC Productivity** (2-4 March 2011). Further information about the course Maximising HPLC Productivity 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).

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: The GMP Guidelines 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**

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.

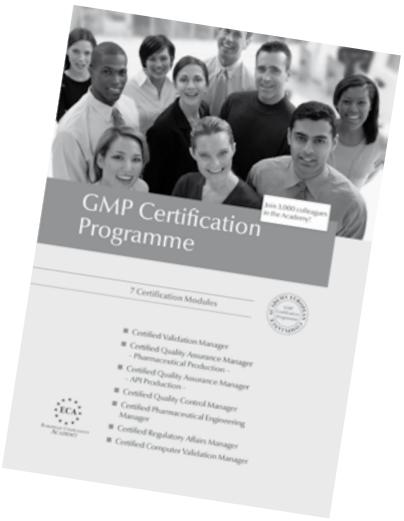
GMP Certification Programme

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.



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Reservation Form (Please complete in full)

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☐ **Integrating Analytical Instrument Qualification and Computerised System Validation,** 28 February – 1 March 2011, Berlin, Germany

☐ **Maximising HPLC Productivity,** 2-4 March 2011, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

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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)!

Easy Registration
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Internet:
www.gmp-compliance.org

Date

Monday, 28 February 2011, 09.00 - 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 1 March 2011, 08.30 - 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Phone + 49 / (0) 30 / 21 27 0
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Fees

ECA Members € 1,490,- per delegate plus VAT
APIC Members € 1,590,- 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 course 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.

If you register for the ECA Education Course "Maximising HPLC Productivity" from 2 to 4 March 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 booking code "VA 6938 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 17 January 2011 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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