ECA Certified Quality Control Manager Course*

Participate in 4 Workshops!

Maximising HPLC Productivity

Combining Science and Compliance in a GMP Laboratory

18 - 20 April 2012, Prague, Czech Republic

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Joachim Ermer
Sanofi, Germany

Dr Manfred Fischer
SkyePharma AG, Switzerland

Dr Howard Hill
NDA Analytics, UK

Dr Bob McDowall
McDowall Consulting, UK

Dr Christine Mladek
Boehringer Ingelheim, Germany

LEARNING GOALS:

- HPLC Laboratory Effectiveness and Productivity
- How to Avoid Compliance Mistakes
- Integrated Approach for HPLC Instrument Qualification
- Proactive Strategies to Prevent OOS Results
- Efficient HPLC Methods
  - Method Development
  - New and Emerging HPLC Trends
  - Validation of HPLC Procedures
  - Successful Method Transfer
- Quality by Design in the HPLC Laboratory
- Sampling Practices and Sample Preparation
- EP and USP System Suitability Requirements
- How to Interpret HPLC Chromatograms
- Effective Electronic Records' Protection to Meet Regulatory Expectations
- Risk-based Validation of a CDS

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Maximising HPLC Productivity

18 - 20 April 2012, Prague, Czech Republic

Learning Goals

The purpose of this course is to provide attendees with practical information to manage HPLC within GMP-/FDA-regulated environments of the pharmaceutical industry by combining science and compliance. We want to ensure that participants can work compliantly as well as being able to improving productivity by using good science and business practices. This is particularly so in light of the FDA's new approach to compliance as 483 observations must be answered in full within 15 days. It's cheaper to be compliant than not.

Background

High performance liquid chromatography is a key analytical technique used in nearly all analytical laboratories in the pharmaceutical industries. As such it is regulated with sections in all of the major pharmacopoeias (Ph.Eur., USP, etc.) as well as the subject of an FDA reviewer guidance document published in 1994.

This HPLC course will deal with all aspects for successful merging of science and compliance of HPLC to maximise productivity. The emphasis will be on the following science and compliance issues:

- Emerging Technologies for HPLC
- Sampling practices and pitfalls
- Sample preparation for HPLC
- Latest enforcement issues and lessons for CDS
- Science driven HPLC qualification
- Method development and validation including understanding and trouble shooting problems
- USP and EP system suitability tests
- HPLC column selection
- Practical chromatographic integration
- Better working to avoid OOS investigations
- Generating productivity gains through the validation of a CDS
- Defining and protecting CDS electronic records
- Documentation for HPLC

It is the aim of this course to provide guidance on ways of attaining best regulatory practice (GMP, FDA, pharmacopoeias, etc.) and to address tools to increase analytical HPLC labs' efficiency and effectiveness.

Target Group

This course is intended for experienced chromatographers, HPLC Laboratory supervisors, QC Laboratory Managers and employees in Quality Assurance.

Moderator

Dr Bob McDowall, McDowall Consulting, Kent, UK

Programme

Introduction: Balancing Science and Compliance in the HPLC Laboratory for Effectiveness and Productivity

- Overview of the conference and introduction of the teaching team members
- Review of the science themes of the conference
- Quality by Design in the HPLC laboratory
- Impact of the revised versions of GMP Annex 11 and Chapter 4 on HPLC analysis
- Review of the compliance themes of the conference
- Compliance is better and cheaper: the new FDA approach to 483 Observations and Warning Letters

Dr Bob McDowall

Strategies for Efficient HPLC Method Development

- Fit for Purpose method development
- Don't re-invent the wheel
- Using tips and tricks to shorten the process
- Maximizing method robustness – simple is best
- Understanding the components that make a robust assay

Dr Howard Hill

New and Developing Technologies in HPLC

- Miniaturisation of HPLC - pros and cons
- Increasing the speed of analysis
- Reducing solvent volumes, i.e. cost of solvent and cost of disposal
- Reduced sample volumes - pros and cons
- Other emerging technologies - hot off the press

Dr Howard Hill

Translating from Traditional Chromatography to Fast Chromatography

- Minimizing the changes
- Maximising the advantages
- Improving efficiency and productivity

Dr Howard Hill

HPLC Equipment Qualification: Good Science and Compliance

- Qualification, calibration and validation
- Modular and holistic testing
- 'Fitness for purpose' and traceability
- Qualification challenge – an integrated approach

Dr Christopher Burgess

WORKSHOP I

HPLC Equipment Qualification

Topics to be covered in the workshop are:

- Solvent Mixing
- Pumps
- Auto injector
- Column thermostating
- UV detector
- A/D converters
- Holistic testing and PQ

Moderator: Dr Christopher Burgess

Ten Compliance Commandments for CDS Systems

- Hear and understand the ten compliance requirements for chromatography data systems and the benefits they will bring to your laboratory
- Learn from the mistakes of others: Able Laboratories , Ohm Laboratories, Sunrise Pharma, Concord Laboratories and many other worthy organisations

Dr Bob McDowall

Out of Specification HPLC Results: Prevention Is Better than Investigation

- Proactive and reactive strategies
- Equipment control and maintenance
- Sample control
- Method control
- Data trending and failure prediction

Dr Christopher Burgess

Sampling Practices and Pitfalls for HPLC Analysis

- Sampling and sampling equipment
- Consequences for the analysis
- Examples for sampling plans, etc

Dr Christine Mladek

Reference Standards for HPLC

- Different types of reference standards
- How to quality a reference standard

Dr Christine Mladek

Sample Preparation for HPLC / Robotic HPLC

- Sample preparation techniques for HPLC
- Consequences for the analysis
- Validation and robustness of sample preparation
- Coupling and automation of sample preparation

Dr Christine Mladek

Validation of HPLC Procedures

- Validation according to ICH and FDA Guidelines
- Identification of relevant performance parameters
- Evaluation of validation results
- Sensible use of statistics and validation software
- Verification of compendial procedures, USP Chapter <1226>
- Quality by Design approach to validation

Dr Joachim Ermer

WORKSHOP II

Validation Quiz: Common Method Validation Problems and How to Troubleshoot Them

- Examples from published papers
- Discussion in groups:
- What are the mistakes?
- What are possible improvements?

Moderator: Dr Joachim Ermer

System Suitability Requirements for HPLC according to Ph.Eur. and USP

- Ph.Eur and USP monographs for chromatographic techniques
- Chromatographic parameters
- System suitability requirements
- Adjustments of chromatographic conditions
- System suitability vs. Robustness

Dr Manfred Fischer

WORKSHOP III

HPLC System Suitability Tests

Moderator: Dr Manfred Fischer

Practical Interpretation of HPLC Chromatograms

- Basics of integration
- How do you judge if the chromatogram is OK?
- Setting the integration parameters
- System suitability for integration?

Dr Christopher Burgess

HPLC Column Selection

- Understanding the scope of HPLC columns available to use
- Approaches to effective HPLC column selection
- Is there a "best" column to use or should the selection be made on the basis of the analyte?
- Good practices in column selection

Dr Howard Hill

Supporting Documentation for HPLC

- Minimizing documentation – maintaining clarity – keep it simple
- Use of "e" recording systems
- Standardizing processes and procedures
- Operator responsibilities and training
- Servicing – internal and external provider responsibilities

Dr Howard Hill

Practical Interpretation of Electronic Records for a CDS

- Defining the main electronic records for a CDS to comply with 21 CFR 11 and EU GMP Chapter 4
- Additional e-records that can be created depending on your ways of working
- Further e-records created depending on your HPLC equipment
- Effective protection of the electronic records to meet regulatory expectations

Dr Bob McDowall

Effective Analytical Method Technology Transfer

- Determining requirements
- Assigning responsibilities
- Secrets of successful method transfer
- Standardising and harmonising the process
- Regulatory issues

Dr Howard Hill

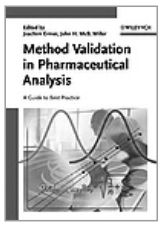
WORKSHOP IV
Validation of a Chromatography Data System
Moderator: Dr Bob McDowall

Risk-based Validation of a CDS including Implementing Electronic Signatures for Productivity

- Understanding your working practices
- Eliminating Excel from the process
- Plan for electronic working including electronic signatures
- Understanding the regulatory requirements for electronic signatures
- Validation of the CDS: expected documentation
- Case study examples of productivity gains

Dr Bob McDowall

Literature



Participants of this course can purchase Dr Joachim Ermer's book „Method Validation in Pharmaceutical Analysis" (Wiley VCH, Weinheim 2005, ISBN: 3-527-31255-2) at a 15% reduced price! You will receive the order form for this book at the course.

ECA Education Course
Integrating Analytical Instrument Qualification and Computerised System Validation
16 – 17 April 2012, Prague

On 16 – 17 April 2012, i.e. on Monday and Tuesday of the same week, there will be another ECA GMP Education Course in Prague about an **Integrated Approach to Analytical Instrument Qualification (AIQ) and Computerised System Validation (CSV).** This course is an ideal precursor to the Education Course **Maximising HPLC Productivity** (18-20 April 2012). Further information about this course 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).

Speakers

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy, UK
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board and he has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015.

Dr JOACHIM ERMER
Sanofi, Germany
Head of Quality Control Services Chemistry at Sanofi in Frankfurt, Germany. Global Referece Standards Coordinator. 20 years of experience in pharmaceutical analytics, including drug development and a global function as Director of Analytical Processes and Technology.

Dr MANFRED FISCHER
SkyePharma AG, Switzerland
Dr. Manfred Fischer worked for AstraZeneca (former ASTRA Chemicals GmbH), Altana Pharma (former Byk Gulden) and Lilly Forschung GmbH. Since March 2007, Dr. Fischer is the Head of the Analytical Department & Quality Control at SkyePharma AG in Muttenz (Switzerland).

Dr HOWARD HILL
NDA Analytics, UK
Director of NDA Analytics, Alconbury, UK
Howard Hill spent over 30 years in the pharmaceutical industry, 29 of those in contract research in the UK, Germany, Spain and Canada.

Dr BOB McDOWALL
McDowall Consulting, UK
Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK.

Dr CHRISTINE MLADEK
Boehringer Ingelheim, Germany
Christine Mladek has over 20 years experience in analytics, including method development and validations in HPLC and GC. She is now responsible for the quality control of starting materials and packaging at Boehringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, Germany.

Conference language

The official conference language will be English.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at 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.

Social Event

On Wednesday evening, 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.

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 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**

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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Maximising HPLC Productivity,** 18 - 20 April 2012, Prague, Czech Republic
☐ **Integrating Analytical Instrument Qualification and Computerised System Validation,**
16-17 April 2012, Prague, Czech Republic

☐ Mr. ☐ Ms.

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Company Department

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

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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

Wednesday, 18 April 2012, 09.00 - 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 19 April 2012, 08.30 - 18. 30 h
Friday, 20 April 2012, 08.30 – 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069, Praha 4
Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

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 three days and all refreshments. VAT is reclaimable.

If you register for the ECA Education Course "Integrating Analytical Equipment Qualification and Computerised System Validation" from 16-17 April 2012 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 course. Please use this form for your room reservation or be sure to mention booking code "CON180412" to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 18 March 2012. Early reservation is recommended.

Organisation and Contact

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