ECA Certified Quality Control Manager Course*

A Two Day Introductory Course to HPLC Compliance (EU & US)

An Introduction to HPLC in Analytical GMP Laboratories

How to Operate and Document HPLC Analysis in a GMP Regulated Laboratory

12 – 13 October 2011, Amsterdam, The Netherlands

SPEAKER:

Dr Bob McDowall
McDowall Consulting, UK

LEARNING OBJECTIVES:

- Regulatory Requirements
  - US and EU
  - Pharmacopoeias (Ph.Eur and USP)
- Preparing and Handling of Reagents and Reference Standards
- Sample Preparation
- System Suitability Tests
  - Relevant Parameters
  - What to Do if SST Criteria are not Met?
- Sample Analysis
- Integrating and Interpreting the Chromatograms
  - When to (Re-) Integrate and When not to (Re-) Integrate?
  - Impact of the Decision
- How to Calculate and Report Results?
  - Individual Results versus Reportable Results
  - What to Do if the Reportable Results are not within the Specification?
- cGMP Compliant Working Practices

ECA
EUROPEAN COMPLIANCE ACADEMY

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

An Introduction to HPLC in Analytical GMP Laboratories

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Objectives

The learning objectives of this new course are three fold:

- First, what are the GMP regulations as they apply to the analytical laboratory and specifically to HPLC analysis?
- Second, what are the pharmacopoeias and how do they interact with GMP and the HPLC analysis of samples?
- Third, what documentation must I generate when I undertake a GMP analysis?

Background

This educational course is intended for liquid chromatographers who have started to work in a GMP analytical laboratory and want to understand the regulatory requirements for pharmaceutical companies, contract research organisations and active pharmaceutical ingredient suppliers. The programme assumes the attendee has a working knowledge of how to operate a liquid chromatograph e.g. set up an instrument and carry out an analysis. However the aim of the course is to provide the regulatory framework, information and advice so that a chromatographer can operate in a practical, scientific and compliant way within a GMP laboratory.

The layout of the course starts with an overview of the pharmaceutical R&D and manufacturing process and how regulated HPLC analysis fits in with this. Going into specific detail the course starts with sample preparation and follows the HPLC analysis through the logical stages from getting the instrument prepared for the method, running the samples, interpreting the chromatograms and calculation of the final results. The last stage is handling the paper or electronic data package to your supervisor to check what you have done and handling any queries that may arise.

The course consists of presentations, workshops and discussions and follows the process of analysis of samples from preparation of reagents, checking the LC system, analysis of the samples, interpretation of the data and reporting the results.

A major feature of this course is the inclusion, at the start of every presentation, of the EU and FDA regulatory requirements in both the GMP regulations but also the applicable sections of chapters of the pharmacopoeias applicable to the topic. This is intended to provide the regulatory and compliance framework within which the science of HPLC can be applied to the compliant GMP analysis of samples. Furthermore, it will enable the course manual to be a practical guidance document for each attendee after completion.

Note that this course provides a practical regulatory framework to the analysis samples in a GMP laboratory by HPLC and therefore will not include topics such as instrument qualification, method development or method validation. These can be found in our ECA advanced education course on Maximising HPLC Productivity.

To reinforce the principles of the course there is a facilitated discussion and four workshops. There is sufficient time to discus any issues with your fellow delegates or the course tutor during the meeting.

Target Audience

Chromatographers who have experience to set up and run an analytical procedure and prepare the results for review but are new to working in a GMP laboratory, these individuals need a comprehensive knowledge of the applicable regulations and chapters of the pharmacopoeias and how to apply them in their work. GMP covers laboratories in the pharmaceutical industry, contract research and manufacturing organisations and active pharmaceutical ingredient (API) manufacturers.

Speaker/Moderator

Dr. BOB MCDOWALL, *McDowall Consulting*

Programme

Introduction

- Aims of the course and mechanism to achieving them
- Scope of LC analysis in GMP:
  - Excipients and raw materials
  - In process control (IPC) analysis
  - Active pharmaceutical ingredients based on pharmacopoeial methods
  - APIs based on in-house methods
  - Finished product: assay, stability, dissolution, related substances (impurities)
- Different types of assay possible by HPLC
- GMP requirements for HPLC analysis: a combination of education, training and experience
- Overview of the topics to be covered during the course

Overview of the Analytical Process

- To set the scene for the remaining talks we will look briefly at the analytical process that we will use in the remainder of the course and how the pieces of the jigsaw puzzle fit together:
  - Regulated processes in pharmaceutical R&D and manufacturing and the analytical sub-process
  - Samples for analysis
  - Analytical Procedures
  - Standard Operating Procedures
  - Liquid Chromatographs
  - Spreadsheets
  - Chromatography Data System and LIMS

A Concise Guide to Understanding the GMP Regulations and the Role of Pharmacopoeias

- Regulators and regulations: FDA and EU regulators and Good Manufacturing Practice regulations for finished products and active pharmaceutical ingredients (APIs)
- Key requirements of the GMP regulations for chemical analysis for finished products and APIs including the role of specifications
- Role of the pharmacopoeias for more detailed requirements for chromatographic analysis
- Interpreting the regulations: company SOPs and analytical procedures
- Documentation: How to record the analysis: proforma sheets and laboratory notebooks?

Workshop 1 Regulations and Pharmacopoeias

How do the GMP regulations and the pharmacopoeias interact? Teams will identify the relevant sections in the GMP regulations and compare them to pharmacopeial general chapters for discussion with the course and tutor.

Preparing Reagents and Reference Standards

- Pharmacopoeial and GMP requirements
- Handling reference standards and chemicals: what to look for and what to do
- Documenting and labelling reference solutions and reagents
- What should you do if you have problems?

Preparing the Samples for Analysis

- GMP and Pharmacopoeial requirements
- Follow the procedure, recording data and noting any issues
- Weighing samples and USP <41>
- Sample continuity from sample to LC vial

Workshop II: Reagent and Standard Solution Preparation

Descriptions of the preparations of reagents and standards will be given to the attendees working in teams to discuss and debate if they are compliant or not. The consensus of the groups will be discussed with the rest of the course.

Setting up the Liquid Chromatograph

- Pharmacopoeial and GMP requirements
- Understanding the phrase is my chromatograph qualified?
- Instrument and column use log books
- Inputting sample information into the chromatography data system (CDS) e.g. the sample sequence
- Checking that the overall system works

Workshop III: Setting up the HPLC

Working in groups, attendees will review how a chromatograph is set up before an analysis and then checked to see if it is working acceptably. In the descriptions provided, participants will identify and correct non-compliant working practices for discussion with the rest of the course.

System Suitability Tests

- Pharmacopoeial and GMP requirements
- The what, why and when of system suitability tests (SSTs) and parameters
- What happens if your SST criteria do not meet acceptance criteria?
- Troubleshooting and resolving problems
- Maintenance of the liquid chromatograph and instrument requalification

LC Sample Analysis

- GMP requirements from the US and EU
- Instrument log update
- Input of additional data from the preparation into the CDS: dilutions, factors and weights
- Monitoring the analysis
- Completing the analysis and things NOT to do before the results are calculated

Workshop IV: Documenting any Changes or Problems with the Analysis

Based in groups the attendees will review changes that could occur during an analysis as well as changes that might be made by the operator. What will the team do and, if required, how will they document their actions? The outputs will be discussed with the whole course.

Integrating the Chromatograms

- GMP requirements from the US and EU
- Interpreting the chromatograms – exercising scientific judgement
- When can I integrate and when can I not integrate my chromatograms?
- Integration issues – what is the impact of my decisions?
- Review by a supervisor or peer of your work: resolving and documenting any issues

Calculating and Reporting the Results

- GMP requirements from the US and EU
- What are individual results and reportable values?
- What happens if the Reportable Results are not within Specification?
- Working with your supervisor and documenting the investigation: Solutions, samples, chromatograms and calculated results
- Collating the records of your analysis

Workshop V: A Regulated HPLC Analysis

Working in groups the attendees will read and discuss a description of a regulated HPLC analysis to try to identify non-compliant working practices. For the non-compliant working practices identified, the teams will devise alternative compliant ways of working for discussion with the whole course.

Key Learning Points and Review of the Course

- Summary of the key learning points from the course
- Final discussion and close

Speaker

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 12 October 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.

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

Date

Wednesday, 12 October 2011, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 13 October 2011, 08.30 – 16.30 h

Venue

Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
The Netherlands
Phone + 31 20 519 12 00
Fax + 31 20 519 12 49

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members (does not include ECA membership) € 1,590.- per delegate plus VAT
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 6946 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 31 August 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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

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.

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 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.

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

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GERMANY

Reservation Form (Please complete in full)

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☐ Mr ☐ Ms

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Title, first name, surname

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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 %.

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)!