



Participate in 4 Workshops!

HPLC in Analytical GMP Laboratories

New USP Approaches for Method Validation
and Instrument Qualification

7 - 9 May 2014, Barcelona, Spain

SPEAKERS:

Dr Joachim Ermer
Sanofi, Germany

Dr Manfred Fischer
SkyePharma AG, Switzerland

Dr Bob McDowall
McDowall Consulting, UK

Dr Christine Mladek
Boehringer Ingelheim, Germany

LEARNING GOALS:

- How to Avoid Compliance Mistakes
- Integrated Approach for HPLC Instrument Qualification and Validation
- Quality by Design
- Efficient and Robust HPLC Methods
 - Analytical Target Profile as Focal Point of the Lifecycle Approach
 - USP Analytical Procedure Lifecycle – New Approaches
 - Validation of HPLC Procedures
 - Successful Method Transfer
- Efficient and FDA-conform Investigation of OOS-Results
- 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
- Documentation for GMP compliance



HPLC in Analytical GMP Laboratories

7 – 9 May 2014, Barcelona, Spain

Learning Goals

The purpose of this course is to provide attendees with practical information to perform and manage HPLC analyses within GMP-/FDA-regulated environments of the pharmaceutical industry. We want to ensure that participants can work compliantly as well as being able to improve productivity by using good science and business practices. With the changes in the Food Drug and Cosmetic Act in 2012, if a company delays, refuses, limits or obstructs an FDA inspection their drugs are now adulterated. Can you retrieve your HPLC data rapidly enough to comply? It's cheaper to be compliant than not.

Quality by Design in pharmaceutical analytics is gaining increasing attention, and will facilitate development and maintenance of robust and reliable analytical procedures, as discussed in the USP Stimuli article "Lifecycle Management of Analytical Procedures" [Pharmacopoeial Forum 39(5) 2013].

Background

High performance liquid chromatography is a key analytical technique used in nearly all analytical laboratories in the pharmaceutical industry. 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. However, HPLC and the associated CDS applications are also the source of some major non-compliances involving falsification and fraud. Therefore attendees will be given practical advice on ways to ensure chromatographic data integrity.

This HPLC course will deal with all aspects for successful application of HPLC in a regulated GMP laboratory. The emphasis will be on the following issues:

- QbD Method development and validation including understanding and trouble shooting problems
- Analytical Target Profile as focal point of the lifecycle approach
- Sampling practices and pitfalls
- Sample preparation for HPLC
- Latest enforcement issues and lessons for CDS
- Science driven HPLC qualification
- Transitioning from HPLC to UPLC
- USP and EP system suitability tests
- Practical chromatographic integration
- Better working to avoid OOS investigations
- Fast and efficient validation of a CDS
- Defining and protecting CDS electronic records
- Ensuring the integrity of chromatographic data and records

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 Audience

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: Overview of HPLC in a GMP Laboratory

- Overview of the conference
- Role of HPLC in a regulated laboratory
- FDA issues with HPLC data integrity
- Quality by Design for HPLC analytical procedures - the proposed USP updates
- The proposed USP changes for <1058> on Analytical Instrument Qualification

Dr Bob McDowall

HPLC Instrument Qualification: Good Science and Compliance

- Proposed changes to USP <1058>
- Qualification, calibration and validation
- Modular and holistic testing
- 'Fitness for purpose' and traceability
- Qualification and validation challenge – an integrated approach

Dr Bob McDowall

WORKSHOP I

Identifying Problems with HPLC Instrument Qualification.

Topics to be covered in the workshop are:

- Solvent Mixing
- Pumps
- Auto injector
- Column thermostating
- UV detector
- Holistic testing and PQ

Moderator: Dr Bob McDowall

Quality by Design and Lifecycle Approach to Pharmaceutical Analysis

- Alignment with process terminology: QbD in analytics
- Defining the measurement requirements: Analytical Target Profile (ATP)
- 3-Stage concept of the analytical lifecycle
 - Method Design and Understanding
 - Method Performance Qualification
 - Continued Method Performance Verification

Dr Joachim Ermer

Exercise: From Analytical Target Profile (ATP) to HPLC Assay Performance Criteria

- Measurement requirements for the Quality Attribute Assay
- Precision and Accuracy of the reportable result
- Method selection to meet the ATP
- "Translation" into HPLC Assay performance criteria

Moderator: Dr Joachim Ermer

Method Design and Understanding

- ATP as the starting point for QbD-method development
- Identification of critical method parameters to establish the Method Design Space
- Understanding the components that make a robust assay

Dr Joachim Ermer

Translating from Traditional Chromatography to Fast Chromatography

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

Dr Manfred Fischer

Efficient and FDA-conform Investigation of Out of Specification HPLC Results

- Requirements of the FDA Guidance
- Efficient laboratory investigations
- Reanalysing, retesting, resampling
- Proactive strategies to prevent OOS results
- Controls of equipment and method, data trending

Dr Joachim Ermer

Sampling Practices and Pitfalls for HPLC Analysis

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

Dr Christine Mladek

Supporting Documentation for HPLC

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

Dr Bob McDowall

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 and Verification 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>
- Lifecycle approach to validation

Dr Joachim Ermer

WORKSHOP II

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: Ensuring Data Integrity and Quality of Results

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

Dr Bob McDowall

Ensuring HPLC and CDS Data Integrity

- 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, Ranbaxy, Fresenius Kabi, Wockhardt and many other worthy organisations

Dr Bob McDowall

Reference Standards for HPLC

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

Dr Christine Mladek

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
- Paper or electronic records are our raw data?

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 Christine Mladek

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

WORKSHOP IV

Validation of a Chromatography Data System

Moderator: Dr Bob McDowall



Speakers



Dr JOACHIM ERMER

Sanofi, Germany

Head of Quality Control Services Chemistry at Sanofi in Frankfurt, Germany. Global Reference Standards Coordinator. More than 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), Al-tana 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 BOB McDOWALL

McDowall Consulting, UK

Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK.



Dr CHRISTINE MLADEK

Boehringer Ingelheim, Germany

Head of quality control starting materials, including excipients, microbiology and packaging at Boehringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, Germany. Over 20 years experience in analytics, including method development and validations in HPLC and GC.

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 are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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



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Germany



Reservation Form:
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e-mail:
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Internet:
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Reservation Form (Please complete in full)

HPLC in Analytical GMP Laboratories
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Mr. Ms.

Title, first name, surname

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Department

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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 week 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, 7 May 2014, 09.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 8 May 2014, 08.30 - 18.00 h
Friday, 9 May 2014, 08.30 - 15.30 h

Venue

Nh Constanza
Deu i mata, 69 - 99
08029 Barcelona, Spain
Phone + 34 - 93281-1500
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Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form / POG when you have registered for the course. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation and Contact

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