ECA Academy
Your GMP/GDP Information Source

New USP & FDA Approaches for HPLC Ensuring HPLC Data Integrity

With Post-Conference Workshop
CDS Audit Trail Review
18 May 2018

Participate in 4 Workshops!

15 – 17 May 2018, Prague, Czech Republic

SPEAKERS:

Dr Markus Dathe
F.Hoffmann-La Roche AG, Basel, Switzerland

Dr Joachim Ermer
Sanofi, Germany

Dr Manfred Fischer
Skyepharma (member of Vectura group), Switzerland

Dr Bob McDowall
R D McDowall Ltd., UK

Dr Christine Mladek
Boehringer Ingelheim, Germany

LEARNING GOALS:

- How to Ensure Data Integrity of HPLC and CDS Data
- Integrated Approach for HPLC Instrument Qualification and Validation: understanding the New USP <1058>
- Quality by Design
- Efficient and Robust HPLC Methods
  - Analytical Target Profile as Focal Point of the Lifecycle Approach
  - USP Analytical Procedure Life cycle – New Approaches
  - Validation of HPLC Procedures
  - Successful Method Transfer
- Efficient and FDA-conform Investigation of OOS Results
- Sampling Practices and Sample Preparation
- Reference Standards and their Requirements
- EP and USP System Suitability Requirements
- Practical Integration and Interpretation of HPLC chromatograms
- Effective Electronic Records' Protection to Meet Regulatory Expectations
- Risk-based Validation of a CDS
- Second Person Review of HPLC Data and Audit Trail Entries
- Data Integrity Metrics for HPLC

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

New USP & FDA Approaches for HPLC

15 – 17 May 2018, Prague, Czech Republic

Objectives

The purpose of this course is to provide attendees with practical information to perform and manage HPLC analyses within GMP-/FDA-regulated environments as well as ensure the integrity of the data generated. The course content includes the latest information on USP with proposed approaches on HPLC method development, validation and continued verification and new version of USP <1058> on Analytical Instrument Qualification (AIQ). This is reinforced by outlining the requirements for ensuring data integrity.

Quality by Design throughout the life of an analytical procedure is the new approach to method development and validation. The USP will be writing <1220> to complement <1224>, <1225> and <1226>. ICH Q2(R1) is also due to be updated as a consequence. The FDA method validation guidance issued in 2015 includes a section on lifecycle management, as well as the amendment of USP <1225>.

Data falsification and fraud as a result of poor data management practices and manipulation of chromatography data system (CDS) files continues to be a major regulatory topic. It is not confined to India and China but a global issue. Data management includes generating "complete data" to comply with 21 CFR 211 but also good chromatographic integration practices – when can manual integration be performed and when can't it? What measures should GMP regulated analytical laboratories have in place to ensure the integrity of their chromatographic data? What should a second person reviewer do to ensure that procedures are complied with, data meet the ALCOA+ requirements and that audit trails are reviewed. The course will include the latest FDA, WHO, MHRA, PIC/S and GAMP guidance on the subject and other guidance documents due to be published or updated.

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 and carry out effective second person reviews.

This HPLC course will deal with helping attendees understand the latest USP and FDA requirements for the 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 (ATP) as focal point of the lifecycle approach
- Sampling practices and pitfalls
- Sample preparation for HPLC
- Documentation and Review
- Latest enforcement issues and lessons for CDS
- Understanding the new USP <1058>
- Transitioning from HPLC to UPLC
- USP and EP system suitability tests
- Monitoring and trending of HPLC performance parameters
- Chromatographic integration in an GMP context
- Better working to avoid OOS investigations
- Fast and efficient validation of a CDS
- Defining and protecting CDS electronic records
- Understanding the requirements for complete data, raw data and primary analytical record

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, R D McDowall Ltd., Kent, UK

Programme

Introduction: Overview of HPLC in a GMP Laboratory

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

Sampling and Sample Preparation Practices and Pitfalls for HPLC Analysis

- Sampling and sampling equipment
- Sampling plans and rationals
- Possible pitfalls during sample preparation incl. some examples for automation
- Consequences for the analysis
- Data Integrity for samples and sample preparation

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

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

Method Design and Understanding

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

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

Translating from Traditional Chromatography to Fast Chromatography

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

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

Risk-based HPLC Instrument Qualification: Good Science and Compliance

- Changes to USP <1058> for AIQ in 2017
- Difference between the new and old versions of USP <1058>
- 'Fitness for purpose' and traceability
- Qualification and validation challenge – an integrated approach

WORKSHOP I

Risk Assessment for Analytical Instruments and Computerised Systems

Topics to be covered in the workshop are:

- Understanding the risk assessment methodology
- Facilitated discussion for a simple instrument
- Workshop and discussion for more complex systems

Moderator: Dr Bob McDowall

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>

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
- Continued method performance verification – Monitoring of SST data

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?

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, Wockhardt and many other worthy organisations

Reference Standards for HPLC

- Different types of reference standards
- Requirements and how to quality a reference standard

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?

Effective Analytical Method Technology Transfer

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

Second Person Review of HPLC Analysis Records including Audit Trails

- The HPLC report and an approach to review
- CTQ – which parameter are important to check
- Audit trails – best case and worst case scenario

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

WORKSHOP IV

Identifying the Common Pitfalls in the Validation of a Chromatography Data System

Moderator: Dr Bob McDowall

Speakers

Dr MARKUS DATHE

F. Hoffmann-La Roche AG, Basel, Switzerland

Analytical and Process Chemist with more than 20 years of experience in laboratory, quality and informatics functions. Markus held several positions in life sciences and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP Coordinator in the Small Molecules Technical Development of Hoffmann-La Roche in Basel since 2011. He had been successfully leading global projects like CDS, LIMS and QMS.

Dr JOACHIM ERMER

Sanofi, Germany

Head of Quality Control Services Chemistry at Sanofi in Frankfurt, Germany. Global Reference Standards Coordinator. 25 years of experience in pharmaceutical analytics, including drug development and a global function as Director of Analytical Processes and Technology.

Dr MANFRED FISCHER

Skyepharma (member of Vectura group), Muttenz, 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 BOB McDOWALL

R D McDowall Ltd., Bromley, Kent, UK

Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Principal of R D McDowall Ltd., UK. He has written and taught extensively on compliance within analytical laboratories including qualification of instruments and validation of informatics solutions. He is the recipient of the 1997 LIMS Award.

Dr CHRISTINE MLADEK

Boehringer Ingelheim, Germany

Director of Quality Control Standards and Network, responsible for training, data management, stability management and divisional analytics network for QC, including the local system ownership for QC lab processes at Boehringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, Germany. Over 25 years experience in analytics, including method development and validations especially in HPLC and GC.

Easy Registration

Reservation Form:
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www.gmp-compliance.org

Date

New USP & FDA Approaches for HPLC
Tuesday 15 May 2018, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday 16 May 2018, 08.30 - 18. 00 h
Thursday, 17 May 2018, 08.30 – 15.30 h

Post Conference Workshop Audit Trail Review
Friday, 18 May 2018, 09.00 h - 16.00h
(Registration and coffee 08.30 h - 09.00h)

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone + 420 261 191 111
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prague@corinthia.com

Fees (per delegate plus VAT)

New USP & FDA Approaches for HPLC
ECA Members € 1,791
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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.

New USP & FDA Approaches for HPLC + CDS Audit Trail Review Post Conference Workshop
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all four days and all refreshments. VAT is reclaimable.

CDS Audit Trail Review Post Conference Workshop
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The fee is payable in advance after receipt of invoice and includes conference documentation, lunch 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. Reservation should be made directly with the hotel. 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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For questions regarding content please contact:

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at +49-62 21/84 44 40, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc., please contact:

Mr Niklaus Thiel (Organisation Manager)
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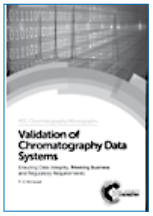
thiel@concept-heidelberg.de.

Social Event

In the evening of the first course day, 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.



Participants of this Course can purchase the 2nd Edition of Dr Bob McDowall's book "Validation of Chromatography Data Systems" (Royal Society of Chemistry) with a discount of 20%! You will receive the order form for the book at the course.

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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)! (As of January 2012)
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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 %.

Post Conference Workshop

CDS Audit Trail Review

on 18 May 2018

Programme

Why Is An Audit Trail and Its Review Important?

- Part 11 and Annex 11 / Chapter 4 requirements for audit trail
- Regulatory requirements for audit trail review
- Guidance documents for audit trail review
- Do I really need an audit trail?

When is an Audit Trail not an Audit Trail?

- What do we look for in an CDS for auditing?
- Pros and cons for event logs and audit logs?
- Audit trail(s)?
- Part 11 compliant CDS – does this help data integrity?

Workshop 1: Which CDS Audit Trail to Review?

Attendees will be presented with an overview of audit trails within some CDS applications and the contents of each one. Which audit trails should be reviewed and when in the context of the work performed by the CDS?

What are GMP-relevant Data?

- Annex 11 requires that audit trails monitor GMP-relevant data – what are GMP relevant data?
- Critical data?

Workshop 2: Identifying GMP-relevant Data

Attendees will be presented with a list of chromatographic records to identify if they are GMP records and how critical they are to help focus the second person review of audit trail data.

Review of CDS Audit Trail Entries

- What are we looking for in an audit trail review?
- Process versus system: avoiding missing data integrity issues
- Regulatory requirement is "frequent review" of audit trails
- What do we need to validate and what to check?
- Suspected data integrity violation - What do we need to do?

Workshop 3: Reviewing CDS Audit Trail Entries

Attendees will be provided with the output of an audit trail to review and see if any potential issues are identified for further investigation.

Controls to Aid Second Person Review of Audit Trails

- Procedural controls for data review
- Technical considerations for audit trail review e.g. identifying data that has been changed or modified – how the system can help
- Documenting the audit trail review has occurred
- Review by exception – how technical controls can help
- Have you specified and validated these functions?

Speakers:
Dr. Bob McDowall
R D McDowall Ltd., Bromley, Kent, UK

Dr Markus Dathe
F. Hoffmann-La Roche AG, Basel, Switzerland

Reservation Form (Please complete in full)

☐ ☐ **New USP & FDA Approaches for HPLC**, 15 – 17 May 2018, Prague, Czech Republic
☐ ☐ **Post Conference Workshop CDS Audit Trail Review,** 18 May 2018, Prague, Czech Republic

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