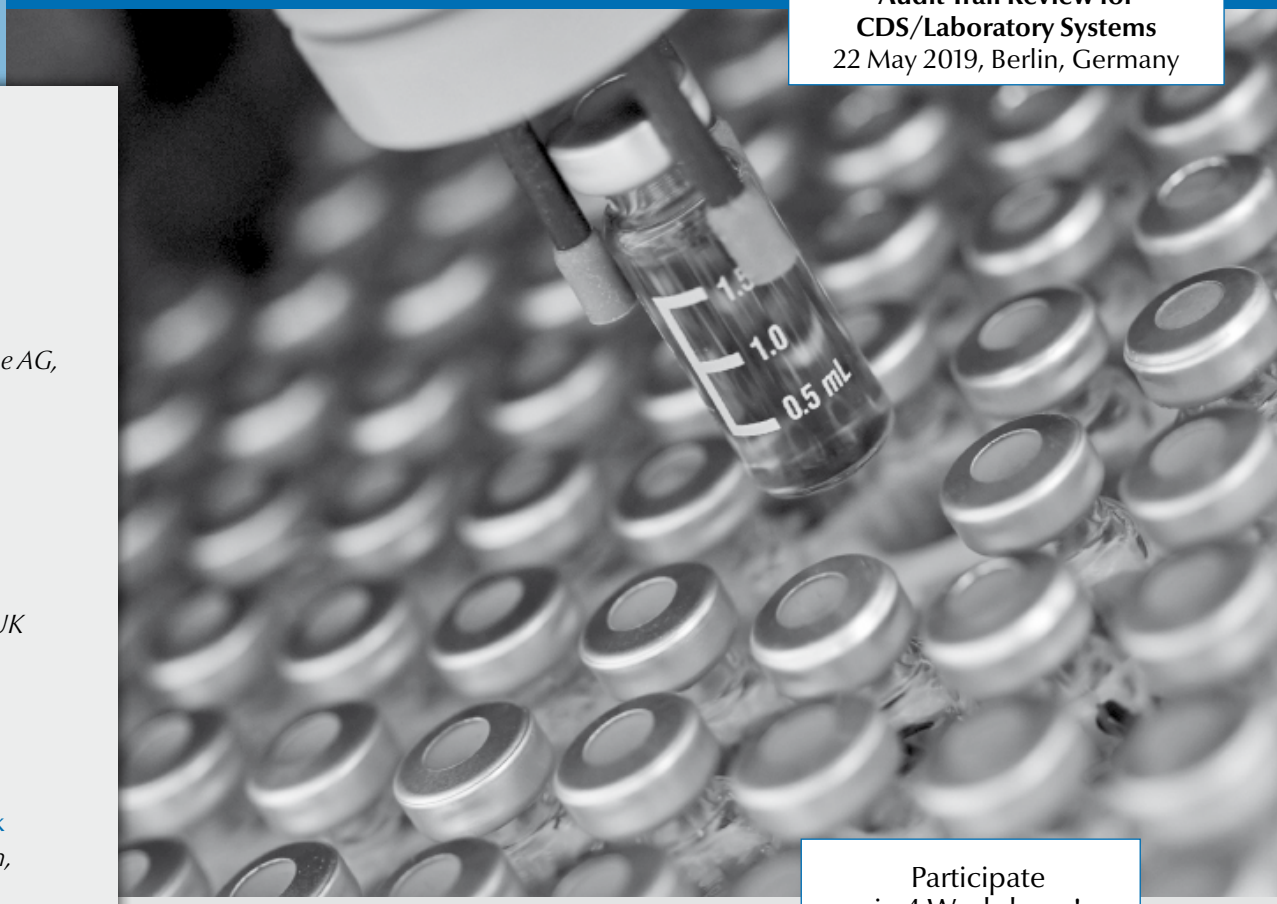
20 YEARS ECA Academy Your GMP/GDP Information Source

HPLC Data Integrity

Ensuring Control of Chromatographs, Integration and Results

With pre-conference Workshop
Audit Trail Review for CDS/Laboratory Systems
22 May 2019, Berlin, Germany



SPEAKERS:

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

Dr Bob McDowall
R D McDowall Ltd., UK

Dr Christine Mladek
Boehringer Ingelheim, Germany

Participate in 4 Workshops!

23 – 24 May 2019, Berlin, Germany

LEARNING GOALS:

- Data Process Mapping to Identify Integrity Risk and Vulnerabilities
- Understanding the Major Changes to USP <1058> and their Impact on Data Integrity
- Role of Log Books for Ensuring Data Integrity
- The Role of Suppliers in Data Integrity
- Understanding Complete Data and Raw Data
- Controlling Chromatographic Integration
- Second Person Review of Chromatographic Analysis
- Metrics for HPLC Data Integrity

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

HPLC Data Integrity

23 – 24 May 2019, Berlin, Germany

Objectives

The objectives of this ECA educational course are:

- To provide tools to enable GMP regulated analytical laboratories to map their processes and identify risks and vulnerabilities to their records
- To understand the role of the new version of USP <1058> for analytical instrument qualification and the role in data integrity
- Take the attendees through key stages of chromatographic processes highlighting the areas where control is required
- Outline quality metrics for data integrity that could be used to monitor chromatographic analysis

Note that this course will not present or discuss basic data integrity topics such as the applicable regulations, regulatory guidance documents or the ALCOA principles

Background

High performance liquid chromatography is a key analytical technique used in nearly all analytical laboratories in the pharmaceutical industry from analytical development to quality control. 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 have been the source of major non-compliances involving data falsification and fraud since the Able Laboratories fraud case in 2005. 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 DI requirements for the successful application of HPLC in a regulated GMP laboratory. The emphasis will be on the following:

- Data process mapping as a technique to identify risks and vulnerabilities to data and records
- Understanding the changes in the new USP <1058> for Analytical Instrument Qualification (AIQ)
- The use of log books in ensuring data integrity in the chromatography laboratory
- The role of suppliers in ensuring data integrity for chromatographs and CDS application software
- Controlling chromatographic integration in a GMP context: when can integration parameters and manual integration be performed?
- Understanding the requirements for complete data and raw data
- Second person review for ensuring chromatographic data integrity
- Metrics for monitoring data integrity in HPLC laboratories

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 to the Course

The background and content of the course will be presented to set the scene for the two days.

- Description of a data integrity model for data governance and data integrity in an organisation
- An analytical data life cycle
- Regulatory issues with HPLC and CDS
- Compliance requirements for a CDS

Data Process Mapping: Why and How?

- What is data process mapping?
- Why is it important?
- Emphasis on process, manual and computerised system assessment.
- Don't forget the whole analytical and data life cycles. Many labs focus on quick fixes and not long-term solutions: get rid of paper! Simple example of HPLC to spreadsheet to LIMS what are record vulnerabilities – lead into workshop. Risk management as further steps (e.g. to CAPA or not to CAPA?).

WORKSHOP I

Data Process Mapping in Practice

- How should Data Mapping help you ensure protection of HPLC records and data integrity?
- Development of short-term remediation as quick fixes and long-term solutions to move away from paper

Major Changes in the new Version of USP <1058> for AIQ and Their Impact on Data Integrity – Part 1 URS to OQ

- The updated USP <1058> has major changes that impact data integrity.
- The new version of USP <1058> requires a user requirements specification, risk assessment to determine the Group based on intended use
- A separate DQ phase followed by OQ testing against URS requirements.
- The requirements should cover both the chromatograph as well as the CDS application.
- Harmonisation of USP <1058> with Annex 15 clauses 2.5, 3.2 and 3.3.

WORKSHOP II

Specifying Data Integrity Requirements for HPLC Instruments and CDS Software

- What critical parameters must be specified for HPLC instruments and the accompanying CDS application software to ensure data integrity?
- Aim of the workshop is to get attendees to outline requirements e.g. instrument control, audit trail functionality, security and access control, etc.

Ensuring HPLC Data Integrity: What Records Should Log Books Contain?

- Instrument and column log books are essential records for ensuring data integrity.
- What records should a log book contain?
- How often should these log books be reviewed?
- Must a log book be paper or can a log be electronic?

Role of Suppliers in Data Integrity

- What is the role of a supplier in data integrity for specifications of liquid chromatographs?
- USP <1058> calls for suppliers to publish meaningful specifications.
- CDS software needs an architecture where data are acquired directly to the network, has a database and adequate technical controls for data integrity.
- IQ and OQ qualification protocols executed by a supplier's engineer need to be reviewed before and after execution and ensure that records are complete, consistent and accurate.

Complete Data and Raw Data for HPLC Analysis

- FDA 21 CFR 211 regulations require complete data
- EU GMP Chapter 4 mentions raw data.
- What do these terms mean and what is their impact on HPLC records from regulated analyses?
- What about hybrid systems are paper or electronic records the main records?
- Definition of e-records for an HPLC analysis.

Processing and Controlling Chromatographic Integration and Data

- Process methods and data integration
- Training in process methods with the focus on integration
- Automatically processing versus manual intervention: when can I manually integrate a peak?
- Process requirements for reporting data – audit trail, integration, calculation e.g. custom fields etc.
- Training in chromatographic integration in a regulated environment.
- Manual intervention versus manual intervention: when can I manually integrate a peak?

WORKSHOP III

Controlling Chromatographic Integration

- What should be included in an SOP for chromatographic integration?
- How can this be enforced by the CDS where possible?

Major Changes in the new Version of USP <1058> for AIQ and their Impact on Data Integrity – Part 2 What Does PQ Really Mean?

- PQ is perhaps the most misunderstood part of the 4Qs model.
- The updated USP <1058> states that PQ consists of calibration, service, maintenance and monitoring of instrument performance.
- The new USP <1058> links PQ back to the instrument URS. How will you comply with this?

Second Person Review and its Importance in Ensuring Data Integrity

- Second person review (3rd and 4th eyes of the 4 eyes principle) is key to ensuring data integrity.
- Who should perform this task and what training and experience should they have?
- How to review HPLC analysis records and cross-correlation and consistency checks to be performed.
- What is review by exception and how should it be conducted?
- Differences to a normal GMP review?
- How can CDS support the review?

WORKSHOP IV

Second Person Review Procedure

- How will a second person review of any HPLC analysis be controlled and documented?
- What ist he scope oft he procedure?
- How will you use the CDS to reduce review work?
- How will your procedure define review by exception?

Metrics for HPLC Data Integrity

- To monitor and review chromatographic analysis and data integrity, regulatory guidance documents from WHO, MHRA and PIC/S require metrics to be generated.
- However, the PIC/S guidance contains a warning about metrics influencing analyst working and impacting DI.
- What metrics could be generated and reviewed for HPLC analysis?
- Why should metrics be generated automatically?

Speakers

Dr MARKUS DATHE

F. Hoffmann-La Roche AG, Basel, Switzerland

Analytical and Process Chemist with more than 20 years of practical 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 Roche since 2011. He had been successfully leading global projects in the area of CDS, LIMS, QMS and is acting as Data Integrity Steward.

Dr BOB McDOWALL

R D McDowall Ltd., Bromley, Kent, UK

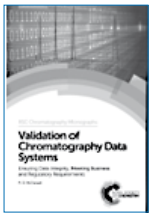
Analytical chemist with over 45 years experience including 15 years working in the pharmaceutical industry and over 25 years as a consultant; Director of R D McDowall Ltd., UK. He has written and taught extensively on compliance within analytical laboratories including qualification of instruments and validation of informatics solutions. He is the recipient of the 1997 LIMS Award.

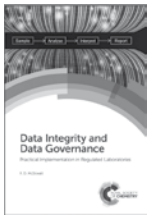
Dr CHRISTINE MLADEK

Boehringer Ingelheim, Germany

Analytical chemist with more than 25 years experience in analytical laboratories (HPLC, GC etc.) for development, quality control and other quality management functions. Now responsible for data integrity, stability management and divisional analytics network for QC as a management system owner for QC lab processes at Boehringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, Germany.

Literature





Participants of this Course can also purchase the 2nd Edition of Dr Bob McDowall's books "Validation of Chromatography Data Systems" or Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories (Royal Society of Chemistry) each with a discount of 20%!

You will receive the order form for both books at the course.

Pre-conference Workshop "Audit Trail Review for CDS/Laboratory Systems"

22 May 2019

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?
- Static data and dynamic data impacts on audit trail functionality

When is an Audit Trail not an Audit Trail?

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

Workshop 1: Which Audit Trail to Review?

Attendees will be presented with an overview of the audit trails within an application and the content of each one. Which audit trails should be reviewed and when in the context of the work performed by the laboratory data system?

What are GMP-Relevant Data?

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

Workshop 2: Identifying GMP Relevant Data

Attendees will be presented with a list of 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 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 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?

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

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
D-69007 Heidelberg
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Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:

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. please contact:

Mr Rouwen Schopka (Organisation Manager) at +49-62 21/84 44 13, or per e-mail at schopka@concept-heidelberg.de

Social Event

On 23 May, 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.

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As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

GMP/GDP 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:

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- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity 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

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

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☐ **HPLC Data Integrity**, 23 – 24 May 2019, Berlin, Germany
☐ **Pre-conference Workshop Audit Trail Review for CDS/Laboratory Systems**, 22 May 2019, Berlin, Germany

☐ Mr. ☐ Ms.

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I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

HPLC Data Integrity
Thursday 23 May 2019, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Friday 24 May 2019, 08.30 - 16. 00 h

Pre-conference Workshop Audit Trail Review for CDS/Laboratory Systems
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 22 May 2019, 09.00 h – 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0) 030 2120 - 0
Email berlin@steigenberger.de

Fees (per delegate plus VAT)

HPLC Data Integrity
ECA Members € 1,790
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 23 May, lunch on all days and all refreshments. VAT is reclaimable.

HPLC Data Integrity + pre-conference Workshop Audit Trail Review for CDS/Laboratory Systems
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 23 May, lunch on all days and all refreshments. VAT is reclaimable.

Pre-conference Workshop Audit Trail Review for CDS/Laboratory Systems
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/POG when you have registered for the event. Reservation should be made directly with the hotel.
Early reservation is recommended.