ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

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

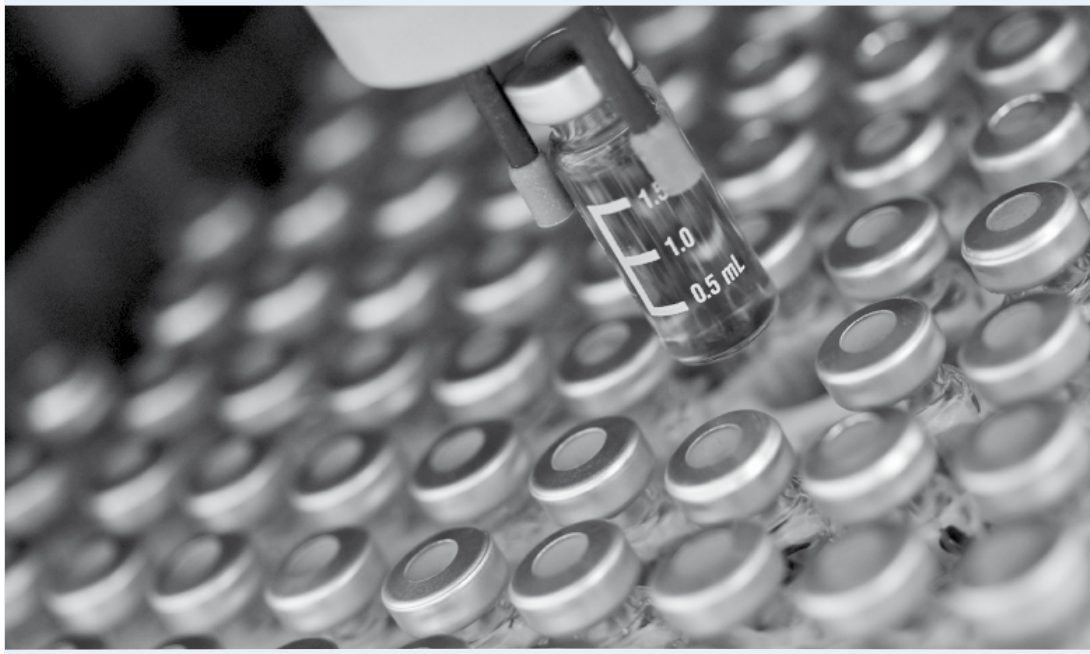
Dr Bob McDowall
R D McDowall Ltd, UK

Dr Christine Mladek
Boehringer Ingelheim, Germany

HPLC Data Integrity

Ensuring Control of Chromatographs, Integration and Results

21/22 September 2022 | Heidelberg, Germany



Highlights

- Data Process Mapping to Identify Risks and Vulnerabilities
- Understanding the current version of USP <1058> and its 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 and Data Processing
- Second Person Review of Chromatographic Analysis
- Metrics for HPLC Data Integrity

Participate in 4 Workshops!

Objective

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 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 latest version of 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.

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.

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.

The Current Version of USP <1058> for AIQ and its Impact on Data Integrity – Part 1 URS to OQ

- The updated USP <1058> has major changes that impact data integrity.
- The 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.

Controlling Chromatographic Integration and Data Processing

- 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?

The current version of USP <1058> for AIQ and its Impact on Data Integrity – Part 2 What Does PQ Really Mean?

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

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 is the scope of the 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?

Testimonial

"The two days were very informative, educational and interesting. The design of the workshops was very well executed, and it was even fun."
Sebastian Hahn, Sanofi-Aventis Deutschland GmbH
Live Online Training: HPLC Data Integrity
February 2021

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 Systems Coordinator in the Synthetic 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 GmbH & Co. KG, Ingelheim, Germany

Food Chemist with the main focus of analytical science and more than 30 years' experience in analytics, including practical experience in method development, validations and training. Since 1999, she is working for Boehringer Ingelheim in several positions in quality management. Since 2018, she is responsible for global standardization of laboratory processes and a QC Network. This includes data integrity, data management, equipment standardization and stability study management.

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.

Date
Wednesday, 21 September 2022, 09.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 22 September 2022, 08.30 - 16.00 h

Venue
Qube Hotel Bahnstadt
Grüne Meile 21
69115 Heidelberg, Germany
Phone +49(0)6221 18799 0
Email bahnstadt@qube-heidelberg.de

Fees (per delegate, plus VAT)
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 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/POG when you have registered for the course. 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

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guenster@concept-heidelberg.de

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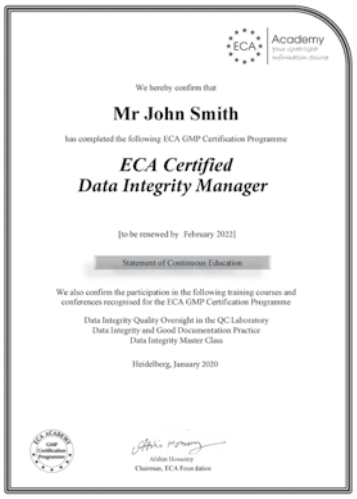
GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.


ECA Academy

We hereby confirm that

Mr John Smith

has completed the following ECA GMP Certification Programme

ECA Certified Data Integrity Manager

[to be renewed by February 2022]

Statement of Continuous Education

We also confirm the participation in the following training courses and conferences recognised for the ECA GMP Certification Programme

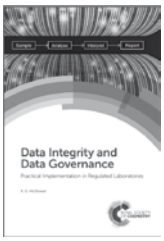
Data Integrity Quality Oversight in the QC Laboratory
Data Integrity and Good Documentation Practice
Data Integrity Master Class

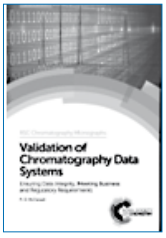
Heidelberg, January 2020

Alisha Hennessy
Chairman, ECA Foundation

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.





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D-69007 Heidelberg
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Reservation Form (Please complete in full)

HPLC Data Integrity, 21/22 September 2022, Heidelberg, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). 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.