ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Dr Markus Dathe
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Dr Bob McDowall
R D McDowall Ltd, UK

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HPLC Data Integrity

Ensuring Control of Chromatographs, Integration and Results

Live Online Training on 22/23 January 2025

Highlights

- Data Process Mapping to Identify Risks and Vulnerabilities
- The Current Version of USP <1058> > - A Critical Review
- The 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
- Ways to Identify Data Manipulation and Falsification in HPLC Analysis

Participate in 4 Workshops!

Objective

The objectives of this Live Online Training are:

- To provide tools to enable GMP regulated analytical laboratories to map chromatographic processes and identify risks and vulnerabilities in their records
- To understand pros and cons of USP <1058> for analytical instrument qualification and data integrity
- Take the attendees through key stages of chromatographic processes highlighting the areas where control is required
- How to identify falsification and data manipulation in HPLC analyses

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.) and is 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 Live Online Training 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 to ensure 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 Live Online Training 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 Process Mapping help you to ensure protection of HPLC records and data integrity?
- How can Data Process mapping help to identify potential risks?

A Critical Review of the Current State of USP<1058>

- USP <1058> on Analytical Instrument Qualification and Computerised System Validation
- Principles of the USP chapter with its advantages and disadvantages for Data Integrity
- Typical pitfalls and deficiencies in practical context for standalone and computerized systems

Workshop II
Specifying Data Integrity Requirements for HPLC Instruments and CDS Software

- Based on the Workshop I: What critical parameters must be specified for HPLC instruments and the accompanying CDS application software to ensure data integrity?
- The workshop familiarises you with the concept of standard requirements for 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?
- Paper or electronic - the right tool and how it should be used

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?
- How can I evaluate integration and data integrity errors in my chromatogram?

An Introduction to the ECA Guide on Analytical Instrument Qualification and System Validation (AIQSV)

- Background to the ECA Guide on AIQSV
- Risk assessment to determine the USP <1058> group and sub-type based on intended use
- Lifecycle of analytical instruments and systems
- Practical qualification and validation examples

Second Person Review and its Importance in Ensuring Data Integrity

- Second person review 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-correlations?
- How are consistency checks to be performed?
- What is review by exception and how should it be conducted?
- How can/should a CDS support the review?

WORKSHOP IV
Second Person Review of a CDS Audit Trail

- How will a second person review an HPLC audit trail?
- What is the scope of the procedure?
- How will you structure reporting and use the CDS to reduce review work?
- How will your procedure define review by exception?

Ways to Identify Data Manipulation and Falsification in HPLC Analyses

- Regulatory expectations for identification of falsification – an integral part of second person review and DI audits and investigations
- What to look out for from sample receipt to sample preparation
- From volumetric flask to loading the autosampler
- Data manipulation and falsification in the chromatography data system

Speakers

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

Analytical and Process Chemist with more than 25 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 50 years experience including 15 years working in the pharmaceutical industry and over 30 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, 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.

Date Live Online Training

Wednesday, 22 January 2025, 08.30 - 17.00 h CET
Thursday, 23 January 2025, 09.00 - 17.00 h CET

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21534.

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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Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. 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. Please find more information at www.gmp-certification.org

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GERMANY

Reservation Form (Please complete in full)

HPLC Data Integrity, Live Online Training on 22/23 January 2025

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:
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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.

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