



Speakers



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HPLC Data Integrity

Ensuring Control of Chromatographs, Integration
and Results



Live Online Training on 21/22 September 2022



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 Live Online Training are:

- To provide tools to enable GMP regulated analytical laboratories to map chromatographic 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 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 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 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?

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 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?
- 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?

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 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?
- 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?

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,
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, 21 September 2022, 08.30 - 17.00 h CEST
Thursday, 22 September 2022, 09.00 - 17.00 h CEST

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Fees (per delegate, plus VAT)

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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 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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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

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HPLC Data Integrity, Live Online Training on 21/22 September 2022

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