ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Dr Christopher Burgess
Chairman of the ECA Analytical Quality Control Group

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

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Data Integrity Quality Oversight in the QC Laboratory

Ensuring Data Integrity

11/12 October 2022 | Heidelberg, Germany

Post-Conference Workshop **Audit Trail Review for CDS / Laboratory Systems** on 13 October 2022, Heidelberg, Germany

Highlights

- Regulatory Guidance for Data Integrity Quality Oversight
- Knowing and Managing Data Integrity Risks
- Role of Quality Assurance in Control of Master Templates and Blank Forms
- Case Study: Handling Data Integrity Concerns
- Data Integrity Audits:
  - Priority and Frequency
  - Coverage
- Data Integrity Investigation:
  - Determining the Scope
  - Findings, Root Causes and CAPAs
- Data Process Mapping
- Raising Data Integrity Concerns
- PLUS 6 Workshops

All participants get free access to the current version of the ECA „Data Governance and Data Integrity“ Guidance

Programme

Objective

The involvement of Quality Assurance in ensuring data integrity in GMP regulated laboratories is discussed in both the PIC/S and WHO guidance documents. However, turning guidance document recommendations into practice can be difficult, especially if members of QA are not familiar with the topics covered in these guides. This two-day, interactive workshop-based course is intended to fill this gap in the training spectrum. After an introduction covering the scope and regulatory requirements of quality oversight for GMP regulated laboratories there are presentations, discussions and workshops on the main topics of the course:

- Understanding process and record risk by using data process mapping
- Controlling master templates and blank forms
- Raising and handling data integrity concerns
- Data integrity audits
- Data integrity investigations

The workshop material is based on case studies so that attendees can work with real world examples and gain experience that they can take back to their own organisations.

Background

Data integrity is a major topic in the pharmaceutical industry and organisations supporting it such as contrast research and manufacturing organisations. The regulatory focus has been in Quality Control and Analytical Development laboratories working to GMP especially since 2012 with the updated FDA Compliance Programme Guide 7346.832 for Pre-Approval Inspections. This guide has as objective 3 the data integrity audit. Therefore, it is important that Quality Assurance be aware of the FDA approach as well as ensuring that laboratory activities are under control, compliant and ensure data integrity.

Target Audience

- Managers and staff from Quality Control and Analytical Development Laboratories of pharmaceutical companies
- Contract Research Organisation and Contract Manufacturing Organisation laboratory personnel
- Quality Assurance staff involved in reviewing laboratory data or performing data integrity audits
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity

Programme

Introduction to the Course

- What will be covered in the course
- Introduction to the teaching team
- Roles of Quality Assurance and Quality Control defined and discussed

Regulatory Guidance for Data Integrity Quality Oversight

- Review of data integrity guidances: PIC/S, WHO, EMA, MHRA, GAMP Guide for quality assurance role in data integrity and data governance
- Building a framework for quality oversight for Data Integrity (DI) in a GMP analytical laboratory within the QMS
- How culture can impact data integrity
- Identifying key QA roles in the Data Integrity programme

Knowing and Managing Data Integrity Risk

- Data Process Mapping for Paper and Computerised Processes in the laboratory
- Identifying risk to records and mitigating them

Workshop 1: Data Process Mapping

- Review of data process maps for paper and hybrid process
- Identification of record and data integrity risks
- Proposals for risk mitigation
- Course feedback and discussion

Role of Quality Assurance in Control of Master Templates and Blank Forms

- Overview of regulatory guidance for blank forms – 1993 to date
- Process flows for master templates and blank form use
- Identifying the QA role in the process
- Look at alternative options from paper

Raising Data Integrity Concerns

- Process for handling concerns outlined
- Confidentiality of the people and process
- How to handle whistle blowers

Workshop 2: Handling Data Integrity Concerns; a Case Study

- How should a concern be raised and to whom?
- How will the matter be kept confidential?
- Generating a high-level scope and action plan

Overview of Data Integrity Audits and Investigations

- Regulatory guidance
- Approaches for DI audits – computer system inventories, paper processes and critical data identified
- Preventing overlap with computer system periodic reviews
- Dealing with data integrity violations: the DI investigation

Workshop 3: Identifying Data Integrity Audit Priority and Frequency

- From a list of processes and systems attendees will identify the priority order of processes and systems to be audited
- From the priority, the audit schedule will be developed
- Frequency of DI audit of critical systems and paper processes

Workshop 4: Developing the Data Integrity Audit Coverage

- Scope of the data integrity audit
- What will you audit?
- How will you audit a computerised system vs. a paper process?

Workshop 5: Data Integrity Investigation – Determining the Scope

- A data integrity violation has been found during a data integrity audit and an investigation is to be launched
- In a facilitated discussion, the course will define the scope and boundaries of the investigation

Workshop 6: Data Integrity Investigation – Findings, Root Cause and CAPAs

- A list of findings from the investigation will be given and attendees must determine if they are poor data management errors or falsification
- Identification of the root cause
- What are the CAPAs: immediate fixes and long-term remediation actions?

Post-Conference Workshop **Audit Trail Review for CDS/Laboratory Systems** on 13 October 2022

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?

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK - Chairman of the ECA Analytical Quality Control Working Group

He is a Chartered Chemist and has more than 46 years experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 26 years in international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2020 and re-elected for the 2020 to 2025 cycle. He is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Extended board of the European Compliance Academy Foundation. He is also a member of the USP Joint Sub Committees entrusted to produce a new General Chapter <1220> on Analytical Procedure Lifecycle and revised General Chapter <1058> on Analytical Instrument Qualification.

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 and QMS.

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

Analytical chemist with nearly 50 years' experience including 15 years working in the pharmaceutical industry. Bob has been a consultant for nearly 30 years and has been involved with computer validation for 35 years. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several journals. He was a contributor to the GAMP Good Practice Guide for Validation of Laboratory Computerised Systems and a contributor and reviewer of the GAMP Guide on Records and Data Integrity and two associated Data Integrity Good Practice Guides. He is the author of Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories.

Dates

Data Integrity Quality Oversight in the QC Laboratory
Tuesday, 11 October 2022, 09.00 – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 12 October 2022, 08.30 h – 16.00 h

Post Conference Workshop Audit Trail Review for CDS / Laboratory Systems
Thursday, 13 October 2022, 09.00 h – 16.00 h
(Registration and coffee 08.30 h – 09.00 h)

Venue of both events

NH Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49(0)6221 / 1327 0
Email nhheidelberg@nh-hotels.com

Fees (per delegate, plus VAT)

Data Integrity Quality Oversight in the QC Laboratory
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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.

Data Integrity Quality Oversight in the QC Laboratory + Audit Trail Review for CDS/Laboratory Systems
ECA Members € 2,190
APIC Members € 2,290
Non-ECA Members € 2,390
EU GMP Inspectorates € 1,340
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on three days and all refreshments. VAT is reclaimable.

Post-Conference Workshop Audit Trail Review for CDS/ Laboratory Systems
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference 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 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.
CONCEPT HEIDELBERG
P.O.Box 10 17 64 | 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0 | Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.de

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or per e-mail at
guenster@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.

Social Event

In the evening of the first couse 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.

Your Benefit

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

WA/04052021

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Data Integrity Quality Oversight in the QC Laboratory, 11/12 October 2022, Heidelberg, Germany
☐ Post-Conference Workshop Audit Trail Review for CDS/Laboratory Systems, 13 October 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.