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 Working Group

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Laboratory Data Integrity and Data Quality

Data Governance and Auditing the Analytical Process from Sampling to Reportable Value

Part 1: 12/13 November 2024, Barcelona, Spain
Part 2: 13/14 November 2024, Barcelona, Spain

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

Highlights

Part 1

- Data Governance, Integrity & Quality
- Regulations & Guidance
- Analytical Process Flows: where are the vulnerabilities?
- Role of Sampling in Ensuring Data Integrity
- Principles for Generation of Data
- Processing and Reporting Data
- Collation and Reporting of Results
- Second Person Review of Data
- 6 Workshops

Part 2

- Data Integrity Self Inspections and On-Site and Remote Audits of Hybrid and Electronic Systems
- Risk Assessment and Prioritisation for an Audit
- 8 Workshops covering various Aspects of Auditing Laboratory Data and Systems

Objective

These two courses have the following objectives:

Part 1:
The learning objectives are firstly, understand the data integrity requirements of a GMP regulated laboratory in Pharmaceutical organisations and contract labs from sampling to reporting. Secondly, how laboratory personnel can ensure compliance and be able to defend their positions. Records generated by three processes will be taken through the presentations and workshops: paper only with records maintained in a laboratory notebook or controlled sheets, hybrid system with signed paper records with underlying electronic records and an electronic system using electronic signatures. Second person review is a critical process that needs to be thorough and effective to ensure that data issues are picked up and resolved.

Part 2:
The auditing course will develop the understanding of what is required for a data integrity audit of a laboratory computerized system and then develop the principles, based mainly on workshops and discussions, of how to audit hybrid and electronic laboratory systems. The scope of auditing a system for data integrity will be developed during the course along with a risk based prioritisation of the key areas to focus audit attention on. In preparation for the final sessions there will be workshops dealing with specific data integrity topics. At the end, attendees will read the laboratory audit report, determine if there are any findings and classify them. Then feedback selected audit findings to the Quality Control manager and head of Quality Assurance.

A checklist will be provided to all attendees for the auditing of computerised systems for data integrity.

Background

Data Integrity continues to be the major concern with both FDA and European Regulatory Agencies. Many FDA warning letters and EU GMP inspections have highlighted major data integrity failures at companies globally. The regulatory concern has been responded by FDA issuing three versions of Compliance Program Guide (CPG) 7346.832 that covers Pre-Approval Inspections in 2010, 2019 and 2022. The latest version extends the objectives to include Quality in Pharmaceutical Development. Since 2015, various regulatory authorities have published data integrity guidance documents e.g.

- MHRA: 2 versions of a GMP guidance in 2015 and a GXP guidance in 2018
- WHO: two guidance documents in 2016 and 2021. The 2016 version is more comprehensive and contains the best description of ALCOA criteria in any regulatory guidance.
- FDA: issued an interpretation of CGMP about data integrity in a Q&A format in 2018
- PIC/S: published their final version of PI-041 guidance in 2021 and FDA: issued a draft guidance for Remote Interactive Investigations in 2023

Moreover, EU GMP Annex 11 for computerised systems and Chapter 4 on documentation are being updated to enhance the requirements for data integrity.

Industry bodies have also been active with the GAMP Forum publishing a Records and Data Integrity Guide in 2017 and three Good Practice Guides. APIC and PDA have issued guidance documents on the subject.

Finally, ECA have issued the 3rd Edition of a Data Governance and Data Integrity Guide that delegates will get a free electronic copy of.

The emphasis of all regulators is on the ALCOA++ principles to outline regulatory expectations for ways to ensure the integrity of data over the life cycle. This is reflected in the way the two courses will be presented.

Part 1 focuses on three types of record that can be found in analytical laboratories working to GMP: paper, hybrid computerized system and electronic workflows with electronic signatures. Through presentations, work- shops and discussions attendees are taken through the process from sampling to generation of the reportable value to understand data integrity issues.

Part 2 takes the principles from the earlier course and develops them to enable attendees to be able to conduct effective internal audits or self-inspections of either hybrid or electronic systems in compliance with EU GMP Chapter 9. This is achieved mainly via a series of interlinked workshops with a few presentations.

Target Audience

These courses will be of significant value to:

- Managers and scientists from quality control and analytical development laboratories wanting to understand the data integrity and audit process
- Quality assurance personnel
- Contract research organisation and contract manufacturing organisation, laboratory and QA personnel
- Auditors (internal and external) responsible for assessing laboratory quality and data integrity

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.

Programme Part 1:

Data Governance, Integrity & Quality, Regulations and Guidance

- Summary of EU and FDA GMP requirements
- MHRA, PIC/S and WHO Data Integrity Guidances
- FDA Guidance documents OOS, Inspection of QC labs
- Inspection findings 483 and warning letters
- Defining data integrity, "complete data" and „raw data"

Analytical Process Mapping and Where Are the Vulnerabilities

- Essential to map the process and identify all steps for traceability
- SOPs, analytical procedures & training of staff
- Internal and external auditing support
- Identifying data and the controls to ensure integrity

WORKSHOP I:
Assessment of an Analytical Process for Data Integrity Vulnerabilities of a Pharmacopoeial Loss on Drying Assay

Presented with a pharmacopoeial Loss on Drying (LOD) analysis attendees identify any data vulnerabilities in the process

Role of Sampling in Ensuring Data Integrity

- Why is proper sampling the key to ensuring the integrity and reliability of analysis?
- What are the key features of sampling?

Principles for the Generation of Data

- Qualified analytical instruments and validated software
- Recording observational tests and instrument/system tests
- Identification of key vunerabilities
- Application of ALCOA++ principles

WORKSHOP II:
Generation of Data

- What are the requirements for raw data integrity?
- Three scenarios covering:
  - a paper system
  - a hybrid system
  - a networked electronic system

Processing and Reporting of Data

- Paper / hybrid based systems
- Networked systems with electronic records and signatures
- Calculations and transformation of data manually and by computer applications
- Application of ALCOA++ principles to the process
- Calculating the reportable value and comparison with the specification
- Paper processes versus electronic processes
- Linkage with out of specification investigations (OOS)

WORKSHOP III:
Processing and Reporting of Data

- Reviewing an analytical record
- Scenario covering paper based record and an electronic system

Reviewing Data and Collating Records

- Identification and correction of errors for paper and electronic systems
- Do you have complete data?

WORKSHOP IV
and facilitated Discussion:Reviewing analytical records; Do we have to check everything?

Using technical controls to aid the reviewer

WORKSHOP V:
Data Review of an Excel Template

Application of ALCOA+ principles for the review of paper records

Second Person Review including Audit Trail Review

- Role of the second person review
- Determination that the reportable result is correctly calculated
- Identification and correction of errors for paper and electronic systems
- Facilitated Discussion: Reviewing audit trails by exception

WORKSHOP VI:
Facilitated Discussion
Paper, Hybrid and Electronic Reporting Processes

Discussion of the strengths and weaknesses of reporting processes

Key Learning Points and Final Discussion
End of Part 1 / Registration for Part 2

Programme Part 2:

Introduction to the Course

Data Integrity Self Inspections and On-Site and Remote Audits of Hybrid and Electronic Systems

- Observations and findings
- Remote audits: practicalities, limitations and problems
- Overview of the FDA Draft Guidance on Remote Interactive Evaluations 2023

WORKSHOP VII:
Risk Assessment and Prioritisation

- So much to do but so little time – risk management in practice
- When conducting a data integrity audit which areas within a pharmaceutical quality system will be the focus?
- Feedback and discussion with the teaching team

WORKSHOP VIII:
Audit of an Excel Spreadsheet

- Attendees will be given an example of a spreadsheet
- What questions need to be asked to determine if there is sufficient Data Integrity and control?
- Feedback from the teaching team

WORKSHOP IX:
Auditing a Hybrid Standalone System

- A laboratory system is used in hybrid mode
- What questions should the auditor ask to determine if there are any data integrity problems?
- Feedback and discussion with the teaching team

WORKSHOP X:
Auditing a Networked Laboratory System – Audit Trail Review

- Review of audit trail entries is a key data integrity requirement of Annex 11
- Attendees will review the printout of an audit trail to determine if there any data integrity issues to be raised?
- Can the attendees find what those issues are?
- Feedback and discussion with the teaching team

WORKSHOP XI:
Electronic Signature Auditing

- Use of electronic signatures can mask some Data Integrity issues
- Can the attendees find what those issues are?
- Feedback from the teaching team

WORKSHOP XII:
Preparing for the Data Integrity Audit

In the first of three linked workshops, attendees will be given a laboratory scenario to answer the following questions:

- What will be the composition of the audit team?
- What will be their skills?
- What will be the duration of the audit?

WORKSHOP XIII:
Observations and Findings During a Laboratory Audit and Planning the Closing Meeting

- Each team will be provided with an audit of a laboratory with observations
- Teams will determine if there are any data integrity non-compliances with the regulations and laboratory procedures
- Teams will determine if any observations are findings (non-compliances) and grade the severity of each one
- Prepare for the closing meeting with the Head of the Laboratory and the business process owner of the systems

WORKSHOP XIV:
Feedback to the Auditees

- Teams will present the audit conclusions and the findings to the Head of the QC Laboratory and the business process owner of the systems
- Discussion with the auditees of the findings

Review of the Course and Key Learning Points

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 50 years experience in the pharmaceutical industry initially with Glaxo in Analytical R&D, Quality Control and Quality Assurance and then 30 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 at 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 Committee (JSC) entrusted to produce the new General Chapter <1220> on Analytical Procedure Lifecycle and chair of the JSC for revising General Chapter <1058> on Analytical Instrument Qualification.

Dr Bob McDowall
R D McDowall Limited, UK
Member of the ECA IT Compliance Interest Group

Analytical chemist with 50 years' experience including 15 years working in the pharmaceutical industry. Bob has been a consultant for over 30 years and has been involved with computer validation for over 35 years. Bob is the writer of the Questions of Quality (LC-GC International) 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.

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Laboratory Data Integrity and Data Quality - Part 1, 12/13 November 2024, Barcelona, Spain
☐ Laboratory Data Integrity and Data Quality - Part 2, 13/14 November 2024, Barcelona, Spain
☐ Laboratory Data Integrity and Data Quality - Part 1 AND Part 2, 12 - 14 November 2024, Barcelona, Spain

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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.

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Date Part 1

Tuesday, 12 November 2024, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 13 November 2024, 08.30 h - 12.30 h

Date Part 2

Wednesday, 13 November 2024, 13.30 h - 17.30 h
(Registration and coffee 13.00 h - 13.30 h)
Thursday, 14 November 2024, 08.30 h – 15.30 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n | 08014 Barcelona, Spain
Phone: +34 93 503 53 00 | Email: sants@barcelo.com

Fees (per delegate, plus VAT)

Part 1: ECA Members € 1,290 | APIC Members € 1,390
Non-ECA Members € 1,490 | EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Part 2: ECA Members € 1,290 | APIC Members € 1,390
Non-ECA Members € 1,490 | EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice and includes lunch on the second day and all refreshments. VAT is reclaimable.

If you book both parts simultaneously, the fee for **each part** reduces as follows:
ECA Members € 1,090 |APIC Members € 1,190
Non-ECA Members € 1,290 | EU GMP Inspectorates € 645

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 conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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 21481.

Conference language

The official conference language will be English.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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