



## Speakers



Dr Christopher Burgess  
Chairman of the ECA Analytical  
Quality Control Working Group



Dr Bob McDowall  
Member of the ECA IT Compliance  
Interest Group

# Lab Data Integrity

## A Practical Approach for Generating and Auditing Laboratory Records



Live Online Training on 05 - 07 December 2023



### *Meeting Global Regulatory Concerns*

## Highlights

- Laboratory Data & Results
  - EU and US GMP Requirements
  - MHRA and WHO Data Integrity Documents
  - FDA Guidance Documents
  - Inspection Findings: 483 and Warning Letters
- Principles of Data Management
  - Understanding and Applying ALCOA+ Principles to Laboratory Data
  - Second Person Review of Analytical records
- Requirements for Raw Data Integrity for
  - Paper Records
  - Hybrid Systems
  - Electronic Systems incl. ELNs
- On-site and Remote Audits of Analytical Records
- Data Transformation: How to Identify and Handle Transcription Errors
- Collation and Reporting of Results

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

## Objective

The learning objectives are firstly, understand the data integrity requirements of a GMP regulated laboratory in Pharmaceutical organisations and contract labs and 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.

The auditing part of the Live Online Training will develop the understanding of what is required for a data integrity on-site or remote audit of a laboratory computerized system and then develop the principles, based mainly on workshops and Q&A session, of how to audit hybrid and electronic laboratory systems. The scope of auditing (on-site and remote) a system for data integrity will be developed during the training 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.

## Background

Data Integrity is currently the major concern with both the 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 the FDA issuing Compliance Program Guide (CPG) 7346.832 that covers Pre-Approval Inspections. This document became effective in May 2012 after Agency inspectors received training in Data Integrity where they focus on computer systems and not the paper output. The CPG objective 3 covers the laboratory data integrity audit.

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 and
- PIC/S: published their final version of PI-041 guidance in 2021.

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 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.

The **Live Online Training** focuses on three types of records that can be found in analytical laboratories working to GMP: paper, hybrid computerized system and electronic workflows with electronic signatures. Through presentations, workshops and Q&A sessions attendees are taken through the process from analysis to generation of results to understand Data Integrity issues.

## Target Audience

This Live Online Training 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

Programme Part 1, 05/06 December 2023

### Establishing the Controls for Laboratory Data Integrity

#### GMP Regulations Impacting Laboratory Data and Results

- EU GMP requirements
- MHRA and WHO Data Integrity Guidances
- FDA GMP requirements
- FDA Guidance documents OOS, Inspection of QC labs
- Inspection findings 483 and warning letters
- Defining Data Integrity, “complete data” and „raw data“

#### Principles for the Generation of Data

- Observational tests and instrument tests
- Training of staff
- Qualified analytical instruments and validated software
- Integrity issues
- Application of ALCOA+ principles



#### WORKSHOP I: Generation of Data

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

## Processing and Reporting of Data

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- 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 II: Processing and Reporting of Data

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

## Reviewing Data

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- Role of the second person review
- Determination that the reportable result is correctly calculated



### WORKSHOP III: Data Review of an Excel Template

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## Collation and Reporting Results

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- Role of the second person review
- Determination that the reportable result is correctly calculated
- Identification and correction of errors for paper and electronic systems
- Do you have complete data?



### WORKSHOP IV: Paper, Hybrid and Electronic Reporting Processes

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- Discussion of the strengths and weaknesses of reporting processes

## Programme Part 2, 06/07 December 2023 Self Inspections and Audits to confirm Effective Data Integrity Controls

## Data Integrity Self Inspections and On-site and Remote Audits for Hybrid and Electronic Systems

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- Observations and findings
- Remote audits: practicalities, limitations and problems



### WORKSHOP V: Electronic Signature Auditing

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



### WORKSHOP VI: Risk Assessment and Prioritisation

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- 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 from the teaching team



### WORKSHOP VII: Audit of an Excel Spreadsheet

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- 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 VIII: Auditing a Hybrid Standalone System

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- 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 IX: Auditing a Networked Laboratory System – Audit Trail Review

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- 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 X: Preparing for the Data Integrity Audit

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- Preparation for a remote audit - what can you read?
- Requesting the Site Master File
- Requesting documents
- Handling time zone differences
- What video conferencing system will you use?



## WORKSHOP XI: Conducting a Remote Data Integrity Audit

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- Remote laboratory tour - what are you allowed to see?
- On-line access to networked computer systems
- Access to standalone systems?
- Viewing documents on-line
- Screens for the remote audit and taking notes



## WORKSHOP XII: Reviewing the Follow up Responses from a Remote Data Integrity Audit

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- Access to documents after the audit
- Reviewing responses to audit findings
- Resolution of audit findings with evidence

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 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 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 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 of the Live Online Training

### Part 1: Establishing the Controls for Laboratory Data Integrity

Tuesday, 05 December 2023, 09.00 h - 16.15 h CET  
Wednesday, 06 December 2023, 09.00 h - 12.30 h CET

### Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Wednesday, 06 December 2023, 13.30 h - 16.30 h CET  
Thursday, 07 December 2023, 09.00 h - 16.30 h CET

### Part 1 & Part 2:

Tuesday, 05 December 2023, 09.00 h - 16.15 h CET  
Wednesday, 06 December 2023, 09.00 h - 16.30 h CET  
Thursday, 07 December 2023, 09.00 h - 16.30 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)

### Part 1: Establishing the Controls for Laboratory Data Integrity

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.

### Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

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.



### Save up to 400 € by booking Part 1 & Part 2 simultaneously:

ECA Members € 2,380  
APIC Members € 2,480  
Non-ECA Members € 2,580  
EU GMP Inspectorates € 1,290

The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## 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.

## 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](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

### For questions regarding content please contact:

Ms Anne Günster (Operations Director) at  
+49(0)62 21/84 44 50, or at  
[guenster@concept-heidelberg.de](mailto:guenster@concept-heidelberg.de).

### For questions regarding organisation please contact:

Ms Marion Grimm (Organisation Manager) at  
+49(0)62 21/84 44 18, or at  
[grimm@concept-heidelberg.de](mailto:grimm@concept-heidelberg.de).

## 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](http://www.gmp-certification.org).



If the bill-to-address deviates from the specifications on the right, please fill out here:

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CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34  
  
D-69007 Heidelberg  
GERMANY

### Reservation Form (Please complete in full)



#### Lab Data Integrity - Live Online Training

- Part 1: 05/06 December 2023
  - Part 2: 06/07 December 2023
  - Part 1 & Part 2: 05 - 07 December 2023
- (Please mark your choice)

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 %.

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 HEIDELBERG will 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 can-

cellation 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 <https://www.gmp-compliance.org/privacy-policy>). 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.