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

**Dr Bob McDowall**
Member of the ECA IT Compliance Interest Group

# Lab Data Integrity Master Class

## Live Online Training from 19–21 September 2023

*Case Studies, Best Practices, Practical Solutions for GMP Laboratories*

## Highlights

- Regulatory Citations – What would you do?
- How poor is your Process? Data Process Mapping and Analysis
- Sampling and Data Integrity
- Instrumental Analysis
- Data Interpretation
- Calculation of the reportable Result
- Quality Metrics for Laboratory Analysis
- Second Person Review
- Developing and maintaining an open Culture in a regulated Laboratory
- How to implement your short-term and long-term Solutions?

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

# Programme

## Objective

The objectives of this Laboratory Data Integrity Master Class are:

- Identify areas where Data Integrity can be compromised
- Provide a methodology to assess your current processes and identify Data Integrity risks that attendees can use in their own laboratories
- To take attendees on a journey through the analytical process to identify area of Data Integrity risk and to develop both short-term remediation and, more importantly, long-term solutions
- Move from principles and requirements into Data Integrity best practice scenarios

Note, this Live Online Training assumes that attendees already understand the principles for Laboratory Data Integrity and the contents of regulatory guidance documents as these aspects will not be covered.

## Background

Data Integrity has become the major regulatory concern with Regulatory Agencies who have issued several guidances that focus on computerised systems, data governance and Data Integrity audits and investigations. Manual processes are discussed but focus on uncontrolled blank forms and the control measures. The analytical process is not covered in any Data Integrity guidance. This is surprising as sample management and sample preparation are primarily manual, paper based and error prone.

The WHO regulatory guidance document notes:

*The use of hybrid systems is discouraged*
*Replacement of hybrid systems should be a priority*

PIC/S Guidance PI-041, section 5.3.2 states:

*Manufacturers and analytical laboratories should design and operate a [quality management] system which provides an acceptable state of control based on the data integrity risk, and which is fully documented with supporting rationale.*

These guidance documents push laboratories and pharmaceutical companies towards implementing automated systems as technical controls are superior to procedural controls for ensuring Data Integrity.

This Live Online Training will provide attendees with tools for:

- Understanding your process
- Identifying process risks
- Assessing Data Integrity criticality
- Developing practical mitigation strategies

## Target Audience

This Laboratory Data Integrity Master Class is directed at

- Managers and scientists from QC and Analytical Development Laboratories
- Quality Assurance personnel responsible for Data Integrity
- CRO and CMO laboratory and QA personnel
- Auditors responsible for laboratory quality and Data Integrity

## Programme

### Introduction to the Master Class

- Course objectives
- Introduction to the teaching team
- Structure of the course: presentation / workshop combinations

### Workshop 1: Regulatory Citations – What Would You Do?

- Inspection findings can hit everybody – be prepared for Data Integrity
- What do the agencies expect: Case Studies from recent citations and appropriate reaction?
- What helps, what not?
- How to prevent that specific finding? How to fix the issue?

### How Poor is your Process? Data Process Mapping and Analysis

- More than Data Integrity: the benefits of mapping
- Process flow and data flow: strengths and weaknesses
- Tools for mapping and the best time to use them
- Parts of a complete flowchart (sample process)
- Shortcuts to get to the finish more quickly
- Priority of risks - create your “quick wins”

### Analytical Process 1: Sampling

- Importance of sampling in the analytical process
- Regulatory requirements for sampling
- Sample management procedures and flows to ensure traceability
- Is the laboratory sample representative of the batch or lot?
- Tools and techniques for sampling

## Workshop 2: Sampling and Data Integrity

- Case study scenarios for a variety of sampling and sample management activities will be presented for evaluation and critique by groups
- The objective of the evaluation is to ensure that scientifically sound methodologies are employed and Data Integrity maintained throughout the sample management procedure

## Analytical Process 2: Sample Preparation

- Scope of sample preparation in the analytical process
- How is sample preparation typically documented?
- Data Integrity issues with sample preparation
- Ways of improving sample preparation data integrity

## Workshop 3: Sample Preparation

- Attendees are presented with a sample preparation scenario where Data Integrity issues have been identified during an internal audit
- Identify what, if any, short term remediation is required and what would be options for long term solution
- How would the long term solutions be justified?

## Analytical Process 3: Instrumental Analysis

- Scope of instrumental analysis in the analytical process
- Risk based strategies for classification for Data Integrity
- Criticality and lifecycle of instruments
- Role of Audit Trail Review (ATR) in the Instrumental Analysis
- What do we expect from the suppliers?

## Workshop 4: Instrumental Analysis

- Develop risk-based strategies on case studies
- Participants are encouraged to present their own examples
- Risk identification on examples and ATR implementation

## Analytical Process 4: Data Interpretation

- Scope of data evaluation in the analytical process
- 'Fitness for purpose' of analytical data
- Acceptance criteria and procedure mapping
- Statistical tools for the detection of imprecision and bias

## Quality Metrics for Laboratory Analysis

- Regulatory expectation for Data Integrity metrics
- Benefits and limitations in Data Integrity metrics
- Example metrics for governance
- Example metrics for operations
- Finding ideas for new metrics

## Forensic Auditing of Laboratory Data

- Uncovering file deletions - what is forensic auditing?
- When do you use forensic auditing?
- Tools for forensic auditing
- Pros and cons of forensic auditing

## Workshop 5: Data Interpretation

- Case study scenarios
- The objective of the evaluation is to determine if scientifically sound methodologies are employed and Data Integrity maintained throughout the data evaluation procedure

## Analytical Process 5: Calculation of the Reportable Result

- Scope of calculating the reportable result in the analytical process
- Automation vs manual intervention in calculations
- Benefits of converting to auto-integration
- Importing factors from other systems: benefits and risks

## Workshop 6: Calculation of the Reportable Result

- Procedural controls for calculations (chromatography SOP)
- Testing into compliance and other practices to avoid
- Use of metrics to provide quality oversight of calculations

## Analytical Process 6: Second Person Review

- Scope of a second person review in the analytical process
- Electronic, hybrid and paper-based processes
- Options for Second Person Review
- What do the inspectors expect?
- Role of data and records definition

## Workshop 7:
## Second Person Review

- Data are not records - find the difference. Explain it! Defend it!
- Falsification detection and prevention
- Where and how is Audit Trail Review performed
- Short term remediation and long term solutions for paper-based and hybrid systems

## Developing and Maintaining an Open Culture in a Regulated Laboratory

- Defining “culture” in a practical way
- Opportunity, means and motive in the lab
- Getting People to cheat is easy!
- What you said versus what they heard
- Changing your Organization’s Perspective

## Workshop 8:
## Pulling it all Together

- Attendees will be presented with a laboratory scenario containing Data Integrity issues.
- Using the principles learnt in the course, participants must identify the Data Integrity issues and propose long term solutions
- What would be the order of implementing your options and why?

# Speakers

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

He has more than 40 years‘ experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 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 2015 and re-elected 2015 to 2020. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>. In addition, he is a member of the Executive committee of European Compliance Academy.

Dr Markus Dathe
F. Hoffmann-La Roche AG, Switzerland
GMP/ CSV- Coordinator

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 and QMS.

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

Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant for 25 years.  Bob has been involved with the validation of computerised systems for over 30 years and is the author of a book on the validation of chromatography data systems. His latest book is Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories. He is a member of the GAMP Data Integrity SIG, contributing to the publications.

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Reservation Form (Please complete in full)

## Lab Data Integrity Master Class, Live Online Training from 19 – 21 September 2023

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German law shall apply. Court of jurisdiction is Heidelberg.

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## Date of the Live Online Training

Tuesday, 19 September 2023, 09.00 h – 17.30 h
Wednesday, 20 September 2023, 09.00 h – 17.30 h
Thursday, 21 September 2023, 09.00 h – 15.30 h
All times mentioned are CEST.

## 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 € 2,190
APIC Members € 2,290
Non-ECA Members € 2,390
EU GMP Inspectorates € 1,195
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 message.
Or you register online at www.gmp-compliance.org.

## Conference language

The official conference language will be English.

## You cannot attend the live event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

## Organisation and Contact

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

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