



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



Mark Newton
Principal, Heartland QA, USA
(ex Eli Lilly)

Lab Data Integrity Master Class



Live Online Training from 12 – 14 October 2021



*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.

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: 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: 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: 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: 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: 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: 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: 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: 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 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 Limited, UK
Member of the ECA IT Compliance Interest
Group

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.



Mark Newton
Heartland QA, USA
Co-leader of the GAMP Data Integrity
Special Interest Group

Mark has 30+ years of GMP lab experience first as a lab scientist, then as a Lab Informatics, analytical equipment qualification and data integrity expert. He co-developed a data integrity remediation effort for QC labs and was an author of the GAMP Records and Data Integrity Guide (2017). He is currently Principal consultant of Heartland QA.

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Reservation Form (Please complete in full)



Lab Data Integrity Master Class, Live Online Training from 12 – 14 October 2021

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Date of the Live Online Training

Tuesday, 12 October 2021, 09.00 h – 17.30 h CEST

Wednesday, 13 October 2021, 09.00 h – 17.30 h CEST

Thursday, 14 October 2021, 09.00 h – 15.30 h CEST

Technical Requirements

For our Live Online Training Courses, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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