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

Lab Data Integrity

A Practical Approach for Generating and Auditing Laboratory Records

Live Online Training on 14 - 16 September 2021

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. In April 2016 a draft Data Integrity guidance was issued for industry comment.

In March 2015, also MHRA issued an updated Data Integrity Guidance containing an expansion of the expectations of Data Integrity governance together with a list of 19 definitions and expectations for each one. Followed in July 2016 by a more general guidance for GXP data integrity.

In June 2016, the World Health Organisation issued a final version of a guidance document which provides a more encompassing explanation of Data Integrity and also data governance expectations for regulated healthcare companies. EMA and PIC/S both issued draft Data Integrity guidance documents in August 2016. ECA have published two versions of Data Governance and Data Integrity guidance in 2016 and 2018. The GAMP Forum has published a Guide on Records and Data Integrity in 2017 and the first of three Good Practice Guides on Data Integrity - Key Concepts. Lastly, PDA has also issued a guidance document for pharmaceutical laboratories in August 2018.

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

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

- 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

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

Reviewing Data

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

WORKSHOP III: Data Review – Paper Records

- Application of ALCOA+ principles for the review of paper records

Collation and Reporting Results

- 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

- Discussion of the strengths and weaknesses of reporting processes

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

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

WORKSHOP V: 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 VI: 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 from the teaching team

WORKSHOP VII: 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 VIII: 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 IX: 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 X: Preparing for the Data Integrity Audit

- 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

- 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

- 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 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.

Date of the Live Online Training

Tuesday, 14 September 2021, 09.00 h – 17.00 h CEST
Wednesday, 15 September 2021, 09.00 h – 16.45 h CEST
Thursday, 16 September 2021, 09.00 – 17.15 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, 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 € 2,380
APIC Members € 2,480
Non-ECA Members € 2,580
EU GMP Inspectorates € 1,290
The 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.

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.

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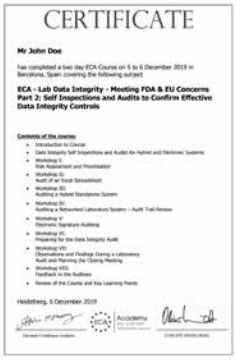
Internationally Acknowledged Certificate from ECA Academy

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.

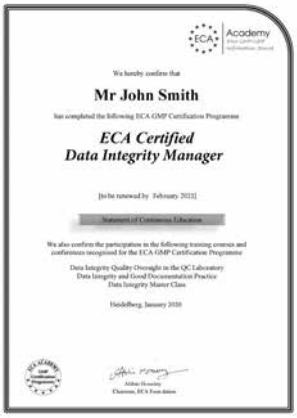

CERTIFICATE

Mr John Doe

ECA - Lab Data Integrity - Meeting FDA & EU Concerns
Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

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


Academy

Mr John Smith

ECA Certified
Data Integrity Manager

WA/24032021

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Reservation Form (Please complete in full)

Lab Data Integrity - A Practical Approach for Generating and Auditing Laboratory Records
Live Online Training on 14 - 16 September 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation until 1 weeks prior to the conference 50 %
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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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