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

- Meeting FDA & EU Concerns -

Live Online Training on 22-23 September 2020

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
- Audit 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.

Programme

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.

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

Establishing the Controls for Ensuring Laboratory Data Integrity

EU and FDA 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

Second Person Review of Data

- 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 III:
Second Person Review of Data

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

WORKSHOP IV:
Investigating Out of Specification Results

Key Learning Points and Final Q & A Session

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 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 and a member of the European QP Association advisory board. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and re-elected 2015 to 2020 for and 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 Executive committee of European Compliance Academy. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>.

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; Bob has been a consultant for over 25 years. He has been involved with the validation of computerised systems for over 25 years and is the author of the second edition of a book on the validation of chromatography data systems published in December 2016. 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.

In order to prepare the workshops, you will receive the questions upfront the Live Online Training.

Approaches and results will be presented and explained live online.

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Reservation Form (Please complete in full)

Lab Data Integrity - Meeting FDA & EU Concerns | Live Online Training on 22-23 September 2020

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)

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Date of the Live Online Training

Tuesday, 22 September 2020,
09.00 h - 17.00 h CEST
Wednesday, 23 September 2020,
09.00 h - 15.15 h CEST

Technical Requirements

For our 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 € 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.

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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