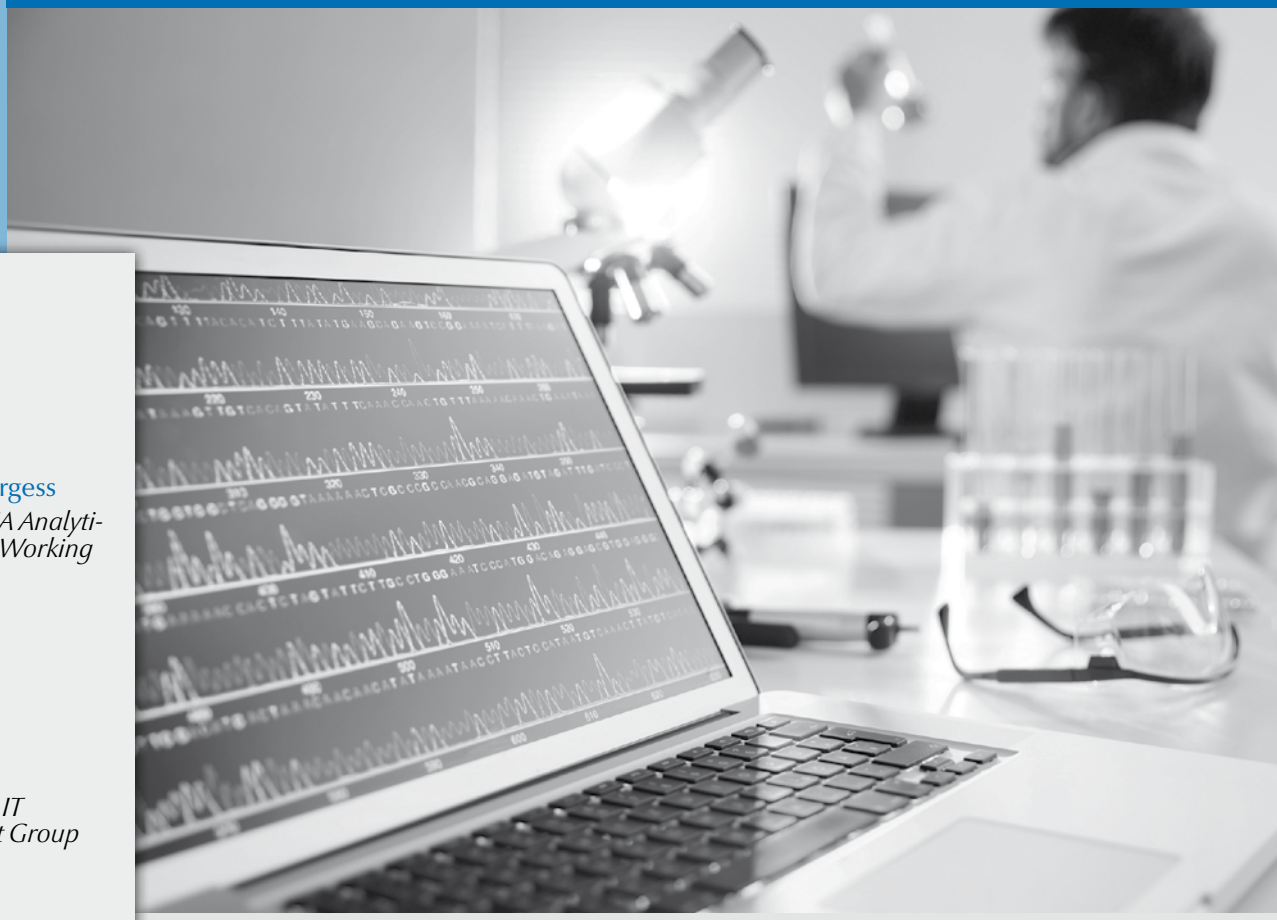
ECA Academy
Your GMP/GDP Information Source

Lab Data Integrity

Meeting FDA & EU Concerns



SPEAKERS:

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

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Dr Franz Schönfeld
GMP Inspector, German

Part 1: **Establishing the Controls for Ensuring Laboratory Data Integrity,**
7-8 June 2017, Vienna, Austria

Part 2: **Self Inspections and Audits to Confirm Effective Data Integrity Controls,**
8-9 June 2017, Vienna, Austria

PROGRAMME:

- Laboratory Data & Results
  - EU and US GMP Requirements
  - MHRA and WHO Data Integrity Documents
  - FDA Guidance Documents
  - Inspection Findings: 483 and Warning Letters
- Dealing with Mistakes before they become Falsification or Fraud
- 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

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu

Lab Data Integrity (Part 1 & Part 2)

7 - 9 June 2017, Vienna, Austria

Objectives

These two new courses have the following objectives:

Course 1:
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.

Course 2:
The auditing course will develop the understanding of what is required for a data integrity audit of a laboratory computerized system and then develop the principles, based on workshops and discussions, of how to audit hybrid and electronic laboratory systems The scope of auditing a system for data integrity will be developed during the course along with a risk based prioritisation of the key areas to focus audit attention on. The attendees will audit one computerized system and then feedback the audit findings to the laboratory manager and business process owner.

A checklist will be provided to all attendees for the auditing of computerised systems for data integrity.

Note that this course will focus only on hybrid and electronic systems and will not consider paper-based data integrity.

Background

Data Integrity is currently a 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 Europe, the UK's MHRA in December 2013 gave notice to regulated users to begin conducting data integrity audits of their own systems and those of their suppliers from the beginning of 2014.

In March 2015, 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. Follwoed in July 2016 buy a more general guidance for GXP data integrity. In June 2016, the World Heath 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 are expected to issue guidance on the subject as is the GAMP Forum and European Compliance Academy.

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. This is reflected in the way the two courses will be presented.

Course 1 focuses on three types of record that can be found in analytical laboratories working to GMP: paper, hybrid computerized system and electronic workflows with electronic signatures. Through presentations, workshops and discussions attendees are taken through the process from analysis to generation of results to understand data integrity issues.

Course 2 takes the principles from the earlier course and develops them to enable attendees to be able to conduct effective internal audits or self-inspections of either hybrid or electronic systems in compliance with EU GMP Chapter 9. This is achieved mainly via a series of interlinked workshops with a few presentations. **This course will focus only on hybrid and electronic systems.**

Target Audience

These courses 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 Course 1:
Establishing the Controls for Ensuring Laboratory Data Integrity
7 - 8 June 2017, Vienna, Asutria

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

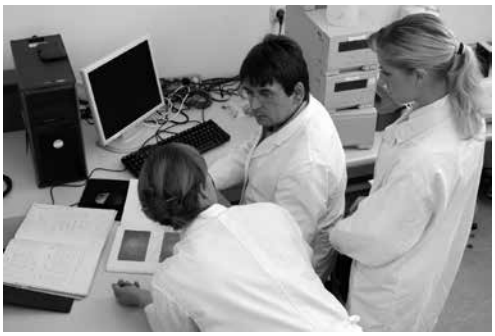
Reviewing Data
- Role of the second person review
- Determination that the reportable result is correctly calculated
- Identification and correction of errors for paper and electronic systems
- Do you have complete data?

WORKSHOP III:
Data Review – Paper Records
- Application of ALCOA+ principles for the review of paper records

WORKSHOP IV:
Data Review – Electronic Records
- Application of ALCOA+ principles for the review of electronic records

Key Learning Points and Final Discussion

End of Course 1 / Registration for Course 2



Programme Course 2:
Self Inspections and Audits to Confirm Effective Data Integrity Controls
8 - 9 June 2017, Vienna, Austria

Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Data integrity audits of computerised systems
- Understanding the data life cycle of the system to be audited
- Validated system can have data vulnerabilities
- Presentation and discussion of the data integrity audit checklist

WORKSHOP I:
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 and discussion with the teaching team

WORKSHOP II:
FDA Key Laboratory Data Integrity Concerns
- Working in teams, attendees will analyse FDA warning letters to understand the regulatory concerns.
- Discuss and feedback session

WORKSHOP III:
Sspreadsheet Auditing

- Working in groups attendees will be given a printout of a spreadsheet
- What questions need to be asked to determine if there is sufficient data integrity and control?
- Feedback and discussion with the teaching team

WORKSHOP IV:
Hybrid Systems Auditing

- 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 V:
Audit Trail of Electronic Systems and Electronic Signature Auditing

- 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?
- Use of electronic signatures can mask some data integrity issues
- Can the attendees find what those issues are?
- Feedback and discussion with the teaching team

WORKSHOP VI:
Preparing for the Data Integrity Audit

In the first of three linked workshops, attendees will be given a laboratory scenario to answer the following questions:

- What will be the composition of the audit team?
- What will be their skills?
- What will be the duration of the audit?

WORKSHOP VII:
Observations and Findings During a Laboratory Audit and Planning the Closing Meeting

- Each team will be provided with an audit of a laboratory with observations
- Teams will determine if there are any data integrity non-compliances with the regulations and laboratory procedures
- Teams will determine if any observations are findings (non-compliances) and grade the severity of each one
- Prepare for the closing meeting with the Head of the Laboratory and the business process owner of the systems

WORKSHOP VIII:
Feedback to the Auditees

- Teams will present the audit conclusions and the findings to the Head of the Laboratory and the business process owner of the systems
- Discussion with the auditees of the findings

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 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 20 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.

Dr Franz Schönfeld
Government of Upper Bavaria, Germany
Dr Franz Schönfeld is a GMP inspector at the centralised inspectorate for medicinal products of the government of Upper Bavaria. He is head of the expert working group for APIs and deputy head of the Radiopharmaceutical expert working group at the Central Authority of the Federal States for Health Protection.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

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.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

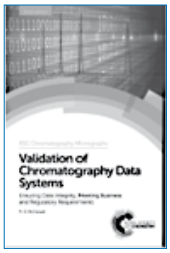
For questions regarding content:
Dr Günter Brendelberger (Operations Director) at +49-62 21 / 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager) at +49-62 21 / 84 44 44, or per e-mail at ludwig@concept-heidelberg.de

Social Event

On Wednesday, 7 June 2017, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Literature



Participants of this Course can purchase the 2nd Edition of Dr Bob McDowall's book "Validation of Chromatography Data Systems" (Royal Society of Chemistry) with a discount of 20%!

You will receive the order form for this book at the course.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager
ECA Certified Packaging Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates.
Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

wa/versl/10082016

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Lab Data Integrity (Part 1 AND Part 2), 7 - 9 June 2017, Vienna, Austria**
☐ **Lab Data Integrity (Part 1 only), 7 - 8 June 2017, Vienna, Austria**
☐ **Lab Data Integrity (Part 2 only), 8 - 9 June 2017, Vienna, Austria**

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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 cancellation 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)

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 http://www.gmp-compliance.org/eca_privacy.html). 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.

Date Course 1:
Establishing the Controls for Ensuring Laboratory Data Integrity

Wednesday, 7 June 2017, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 8 June 2017, 08.30 h - 12.30 h

Date Course 2:
Self Inspections and Audits to Confirm Effective Data Integrity Controls

Thursday, 8 June 2017, 13.30 h - 18.00 h (Registration and coffee 13.00 h - 13.30 h)
Friday, 9 June 2017, 08.30 h – 16.00 h

Venue

Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050

Fees (per delegate plus VAT)

Course 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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Course 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 and includes conference documentation, lunch on the second day and all refreshments. VAT is reclaimable.

If you book <u>both courses</u> simultaneously, the fee for <u>each course</u> reduces as follows:
ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645