Lab Data Integrity

Meeting FDA & EU Concerns

Part 1: Establishing the Controls for Ensuring Laboratory Data Integrity, 24 - 25 February 2016, Prague, Czech Republic

Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls, 25 - 26 February 2016, Prague, Czech Republic

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Bob McDowall
R.D. McDowall Limited, UK

PROGRAMME:

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

ECA ACADEMY

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)

24 - 26 February 2016, Prague, Czech Republic

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.

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.
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. Several 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. Furthermore in August 2014, the FDA issued Level 2 guidance on their web site about the sharing of login credentials for computerized systems and the use of test injections for testing into compliance.

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. Similar to the FDA, European Inspectors have also undergone training in data integrity. The UK has also gone further by writing to the major suppliers of chromatography data system software requesting copies of the application and documentation to that the MHRA can understand how they operate and how falsification could occur.

As the regulators are tightening their inspection approaches it is important that managers, supervisors and users in regulated GMP laboratories understand the issues around data integrity. 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.

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
24-25 February 2016, Prague, Czech Republic

EU and FDA GMP Regulations Impacting Laboratory Data and Results
- EU GMP requirements
- MHRA Data Integrity Guidance
- 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
- Security issues

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

Recording of Data
- Paper-based systems
- Hybrid systems with paper printouts and electronic records
- Stand alone systems containing only electronic records
- Networked systems containing only electronic records

WORKSHOP II: Recording of Data
- Audit of an analytical record
- Scenarios covering paper based record, a hybrid system and an electronic system

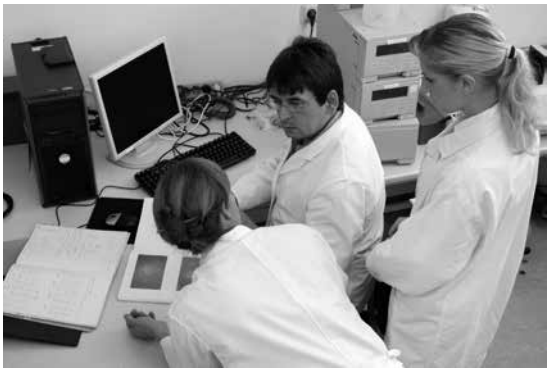
Transforming Data
- Converting laboratory data to information
- Identifying and handling errors on paper as well as electronic systems
- Calculations performed manually and by computer programs
- Issues with truncation and rounding of numbers
- Integrity and security issues of the records generated during transformation

WORKSHOP III: Data Transformation
- Using Excel correctly
- Data from printout transcription, rounding, truncation

Collation and Reporting Results
- Calculating the reportable value and comparison with the specification
- Paper processes versus electronic processes
- Linkage with out of specification investigations (OOS)

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
25-26 February 2016, Prague, Czech Republic

Introduction to Course 2 & Key Learning Points from Course 1
- Data integrity concerns of regulators:
- FDA warning letter and EU non-compliance concerns about data integrity
- FDA Compliance Program Guide 7346.832 for PAI
- MHRA requirement for self inspections to focus on data integrity
- Role of management in ensuring data integrity
- Key learning points from Course 1

WORKSHOP I: Risk Assessment and Prioritisation
- Working in groups, attendees will be given an inventory of computerised systems from spreadsheets to electronic systems in order to rank them in terms of potential data integrity risk and to prioritise them for audit.

WORKSHOP II:
FDA Key Laboratory Data Integrity Concerns

- Using some real FDA warning letters the teams will cross check that the output of Workshop I is congruent with the FDA concerns around laboratory
- Attendee validation of an updated data integrity audit list

WORKSHOP III:
Auditing Spreadsheets and Hybrid Systems

- Attendees will be provided with scenarios for auditing a spreadsheet and a standalone hybrid laboratory system to identify any data integrity issues
- Feedback and discussion with the teaching team

WORKSHOP IV:
Auditing Electronic Systems and Electronic Signatures

- Attendees will be provided with scenarios for an electronic system and also a signing sequence of electronic signatures to identify data integrity issues
- Feedback and discussion with the teaching team

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

- Each teams 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 VI:
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, UK

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

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 a book on the validation of chromatography data systems. 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.

Social Event

On 24 February, 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.

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

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Lab Data Integrity (Part 1 AND Part 2)**, 24 - 26 February 2016, Prague, Czech Republic
☐ **Lab Data Integrity (Part 1 only)**, 24 - 25 February 2016, Prague, Czech Republic
☐ **Lab Data Integrity (Part 2 only)**, 25 - 26 February 2016, Prague, Czech Republic

☐ 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)

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.

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.

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

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

D-69007 Heidelberg
GERMANY

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

Wednesday, 24 February 2016,
09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 25 February 2016, 08.30 h - 12.30 h

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

Thursday, 25 February 2016, 13.30 h - 18.00 h
(Registration and coffee 13.00 h - 13.30 h)
Friday, 26 February 2016, 08.30 h – 16.00 h

Venue

InterContinental Prague
Parizska 30
110 00 Prague 1, Czech Republic
Phone +420 296 631 111
Fax +420 296 631 123

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