Participate in 4 Workshops!

Raw Data, Results and Reportable Values

A GMP-compliant Approach to QC Laboratory Data Management and Integrity

8 – 9 April 2014, Copenhagen, Denmark

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- Laboratory Data & Results
  - EU and US GMP Requirements
  - 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

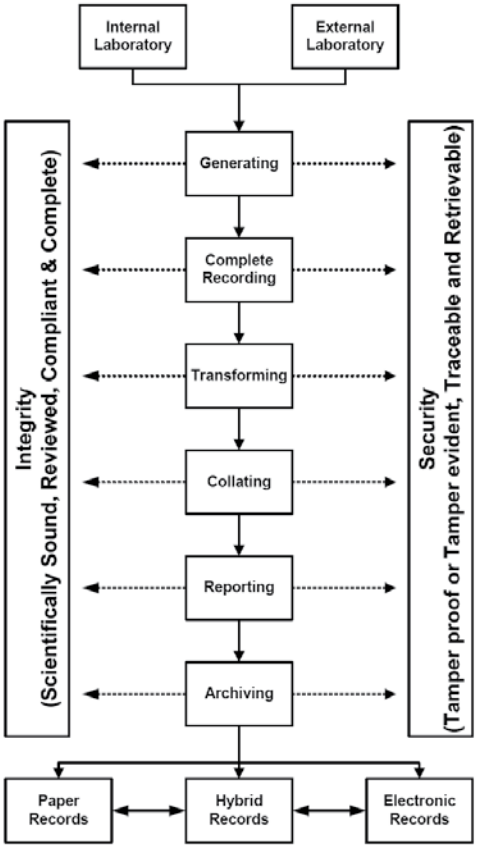
Raw Data, Results and Reportable Values

8 – 9 April 2014, Copenhagen, Denmark

Objectives

This course has the following objectives:

- To present the regulatory requirements and relevant critical regulatory observations concerning laboratory data integrity and security.
- To provide attendees with the tools and techniques to define "complete data" in the context of paper, hybrid and electronic records to ensure the integrity and security of laboratory records regardless of the mode of generation.
- To provide understanding of best practices in the life cycle of laboratory records shown in the diagram below:



Background

Demonstrating the integrity and security of laboratory data, records, results and information is paramount for a successful audit or inspection for any GMP regulated quality control laboratory.

US GMP regulations state that "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows: …..". In the FDA Guide to the Inspection of QC Laboratories is the statement "We expect raw data to be maintained in bound books or sheets for which there is accountability".

A number of high profile cases over the past few years have shown that data integrity is not maintained and can be fraudulent. The Able Laboratories fraud case in 2005 was one such instance where the data were fraudulently generated destroying any trust in the data integrity of laboratory data and the calculated results. However this is neither an isolated case, as shown by the 2012 Ranbaxy Consent Decree, nor the only area for concern as recent FDA warning letters indicated covering the integrity and security of laboratory data include the following citations throughout the whole pharmaceutical supply chain:

Lack of Electronic Data Integrity

Unacceptable practices in the management of electronic data were also noted. The management of electronic data permitted unauthorized changes, as digital computer folders and files could be easily altered or deleted. (FDA Warning Letter, July 2013).

Data Falsification (impacting the integrity of the whole laboratory)

Our review of the Chromatography Data System software found that your firm was testing samples unofficially, and not reporting all results obtained. Specifically, "test," "trial" and "demo" injections of intermediate and final API samples were performed, prior to performing the tests that would be reported as the final QC results.(FDA Warning Letter, July 2013).

Lack of Complete Data

Your laboratory control records do not include data derived from all of the tests necessary to establish compliance with standards. For example, the inspection found multiple raw data chromatograms in digital files labeled "test" and "demo," that were injected prior to the sample injections that were used to conclude that batches were in conformance with the specification. (FDA Warning Letter, July 2013).

Lack of Method Validation

Your firm has failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of test methods [21 C.F.R. § 211. 165(e)]. For example, your firm performed analytical method transfers for 236 protocols without determining whether those methods had been properly validated by your clients. (FDA Warning Letter, October 2010).

No or Inadequate Instrument Qualification

Several laboratory instruments used to analyze various drug components and drug products were either out of calibration, had not received proper maintenance according to your schedule, or a combination of both. (FDA Warning Letter, October 2010).

Inappropriate Use of Reference Standards

We observed 31 expired USP standards in a laboratory drawer next to a separate drawer containing unexpired standards. (FDA Warning Letter, October 2010).

Failure to Document Activities at the Time they are Performed

During this inspection, your QC Chemist admitted that, under the direction of a senior colleague, he had recorded false visual examination data in the logbooks for reserve samples. This QC Chemist was responsible for multiple entries in the API logbooks. (FDA Warning Letter, August 2013)

The course will be based on the life cycle of a laboratory record and look at the integrity and security of it throughout its life time. We will discuss paper records as well as hybrid systems and electronic records.

Assumptions
It is assumed that sample management is in place, analytical procedures are valid, instruments have been qualified and software has been validated. These topics will not be covered in detail during this education course.

Target Group

The education course is aimed at the following attendees
- Laboratory personnel working in GMP laboratories in the pharmaceutical industry, contract research organisations, contract manufacturing organisations and API manufacturers
- Qualified Persons
- Quality Assurance personnel
- Supply chain auditors
- Regulatory Affairs CMC submissions professionals

Programme

Introduction to the Course
- Course roadmap
- Topics to be covered

EU and FDA GMP Regulations Impacting Laboratory Data and Results
- EU GMP requirements
- FDA GMP requirements
- FDA Guidance documents OOS, Inspection of QC labs
- Inspection findings 483 and warning letters
- Defining "complete data"
- FDA Compliance Program Guide PAI (CPG 7346.832)

Fat Finger, Falsification or Fraud?
- Putting regulations and human nature into perspective
- To err is human – mistakes will be made but how to handle them?
- Dealing with mistakes before they become falsification or fraud
- Cultural and organisation issues with data integrity
- Criteria for laboratory data integrity

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 paper records, a hybrid system and an electronic system

Recording of Data
- Handling entries in laboratory notebooks and paper printouts from instruments
- Hybrid systems with paper printouts and electronic records
- Electronic systems just containing electronic records
- Use of electronic laboratory notebooks (ELN) to substitute paper records

WORKSHOP II: Recording of Data
- Audit of an analytical record
- Three scenarios covering paper records, a hybrid system and an electronic system

Transforming Data
- Converting laboratory data to information
- Identifying and handling transcription 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
- Excel
- 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)

WORKSHOP IV: Collation and Reporting Results
- Combining data
- Analytical procedure, SOP and worksheet of values

Archiving
- Security of paper and electronic records
- Backup of electronic records
- Retrieval of records

Speakers

Dr CHRISTOPHER BURGESS,
Burgess Analytical Consultancy Ltd., UK
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 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.

Dr BOB MCDOWALL,
McDowall Consulting, UK
Analytical chemist with over 35 years experience including 15 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems. Bob is also 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

At the end of the first course day 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.

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

Date

Tuesday, 8 April 2014, 09.00 - 18.15 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 9 April 2014, 08.30 - 16.30 h

Venue

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone: +45 33 96 50 00
Fax: +45 33 96 55 55

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT

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.

Accommodation

CONCEPT 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. 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

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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

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

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at +49-62 21 / 84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

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.

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 certification 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

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.

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

Raw Data, Results and Reportable Values
8 – 9 April 2014, Copenhagen, Denmark

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. 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)