ECA Academy
Your GMP/GDP Information Source

Lab Data Integrity

Meeting FDA & EU Concerns

All participants get a free copy of the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities“ Guidance

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, Germany

Part 1: Establishing the Controls for Ensuring Laboratory Data Integrity

19 - 20 March 2018,
Copenhagen, Denmark

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

20 - 21 March 2018,
Copenhagen, Denmark

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 Data Integrity Manager“.
Please find details at www.gmp-certification.eu

Lab Data Integrity (Part 1 & Part 2)

19-21 March 2018, Copenhagen, Denmark

Objectives

These two 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 mainly 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. In preparation for the final sessions there will be workshops dealing with specific data integrity topics. At the end, attendees will read the laboratory audit report, determine if there are any findings and classify them. Then feedback selected audit findings to the quality control manager and head of quality assurance.

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 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, 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 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 both issued draft data integrity guidance documents in August 2016. ECA published a first draft of the Data Governance and Data Integrity guidance in October 2016 and the GAMP Forum published the Guide on Records and Data Integrity in April 2017.

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

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

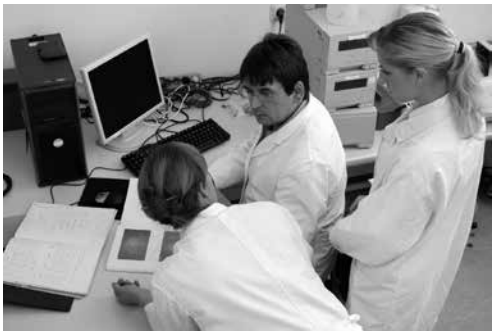
Reviewing Data
- Role of the second person review
- Determination that the reportable result is correctly calculated
- Identification and correction of errors for paper and electronic systems
- Do you have complete data?

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

WORKSHOP IV:
Facilitated Discussion
Paper, Hybrid and Electronic Reporting Processes
- Discussion of the strengths and weaknesses of reporting processes

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

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.
- Discussion and feedback session with the teaching team

WORKSHOP III:
Spreadsheet 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

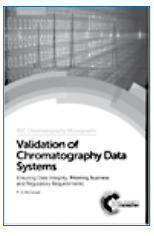
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Bob has been a consultant for over 30 years. He has been involved with the validation of computerised systems for over 25 years and is the author of the second edition of a book on the validation 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

District Government of Upper Franconia, Germany

Franz Schönfeld is a pharmacist by profession. After his graduation he worked at a hospital in Nuremberg and at a retailer in Bayreuth. In 2003 he joined the local GMP inspectorate in Ansbach before he was relocated to Munich and later to Bayreuth. He is head of the national expert group for APIs and excipients.

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.

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

In the evening 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.

Analytical Quality Control Working Group
IT Compliance Group

Guidance Document: Data Governance and Data Integrity for GMP Regulated Facilities
Every participant of this Course will receive the Guidance Document (71 pages) covering the following topics:

- Objectives and Scope of this Guidance
- Background
- Regulatory References, Guidance and Requirements
- Data Integrity Governance
- Policies, Procedures & Processes
- Establishing Criteria for Data Integrity and Security of Records based on ALCOA+ Principles
- Auditing for Data Integrity and Security of Records
- Illustrative Appendices
- References / Technical Glossary

GMP Data Governance – Principles for Data Integrity and Assurance
On 22-23 March 2018, i.e. on Thursday to Friday of the same week, ECA offers another GMP Education Course in Copenhagen about GMP Data Governance – Principles for Data Integrity and Assurance

This course will cover the following topics:

- Definitions of Data Governance
- Regulations and Regulatory Guidance for Data Handling - Expectations of an EU GMP Inspector
- Case Study: Corporate Data Integrity Policy
- Data Governance Roles and Responsibilities
- Case Study: Corporate Culture and Organisation for Data Governance and Data Integrity
- Data Owners versus Data Stewards
- Changing the Culture of an Organisation
- Data Integrity Training
- Data Integrity Audits of Processes and Systems
- Investigating Data Integrity Violations
- Auditing a System and Identifying Data Integrity Problems

The courses **Lab Data Integrity - Meeting FDA & EU Concerns** (19-21 March 2018) will be an ideal precursor to the Education Course **GMP Data Governance–Principles for Data Integrity and Assurance** (22-23 March 2018).
Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses or all three courses will receive a 350 € discount (not valid for EU GMP Inspectorates).

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Lab Data Integrity (Part 1 AND Part 2)**, 19-21 March 2018, Copenhagen, Denmark
☐ **Lab Data Integrity (Part 1 only)**, 19-20 March 2018, Copenhagen, Denmark
☐ **Lab Data Integrity (Part 2 only)**, 20-21 March 2018, Copenhagen, Denmark

I also register for
☐ **GMP Data Governance – Principles for Data Integrity and Assurance**, 22-23 March 2018, Copenhagen, Denmark

☐ 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)

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.

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)

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.
German law shall apply. Court of jurisdiction is Heidelberg.

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 %.

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

Monday, 19 March 2018, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Tuesday, 20 March 2018, 08.30 h - 12.30 h

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

Tuesday, 20 March 2018, 13.30 h - 18.00 h
(Registration and coffee 13.00 h - 13.30 h)
Wednesday, 21 March 2018, 08.30 h – 16.00 h

Venue

Radisson Blu Royal Hotel
Hammerichsgade 1
1611 Copenhagen V, Denmark
Phone +45 (0)33 42 60 00
Fax +45 (0)33 42 61 00
royal.meetings.events@radissonblu.com

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

If you register for the ECA Education Course "**GMP Data Governance – Principles for Data Integrity and Assurance" on 22 to 23 March 2018** at the same time, you will receive a 350€ discount.
This is not valid for EU GMP Inspectorates.

ECA Academy
Your GMP/GDP Information Source

GMP Data Governance

Principles for Data Integrity Assurance

All participants get a free copy of the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities“ Guidance

SPEAKERS:

Dr Christopher Burgess
Chairman of the ECA Quality Control Group

Klaus Eichmüller
Wolnzach c/o Regional Council Darmstadt, GMP Inspectorate, Germany

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Roland Miksche
Vienna, Austria

Margarita Sabater
Member of the ECA Data Integrity Group

Philip Vaering
QA Chemist, ALK-Abelló A/S, Denmark

22 – 23 March 2018, Copenhagen, Denmark

PROGRAMME:

- Definitions of Data Governance
- Regulations and Regulatory Guidance for Data Handling - Expectations of an EU GMP Inspector
- Case Study: Corporate Data Integrity Policy
- Data Governance Roles and Responsibilities
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- Auditing a System and Identifying Data Integrity Problems

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

GMP Data Governance

22 – 23 March 2018, Copenhagen, Denmark

Objectives

The objectives of this ECA educational course are to provide:

- An understanding of the scope of data governance within a pharmaceutical quality system
- The roles and responsibilities of senior management for data governance
- Roles and responsibilities of data owners and data stewards in ensuring data integrity of specific systems and processes
- Ensuring the correct culture for data integrity

Background

Data integrity is the hottest regulatory topic today in GMP as a result of inspectors finding poor data management practices and data falsification. As a result, guidance documents have been issued by MHRA and WHO with other guidance due from EMA and PIC/S. In these documents, there is the phrase "Data Governance" used. The same definition of the term is used by MHRA and WHO:

The sum total of arrangements to ensure that data, irrespective of the format in which it is generated, is recorded, processed, retained and used to ensure a complete, consistent and accurate record throughout the data lifecycle.

As guidance, the "sum total of arrangements" is not very illuminating or informative. In fact, the definition of data governance from the draft WHO guidance starts with the phrase "Management leadership ..." which is much more informative and focussed.

This course is designed to help GMP organisations understand the term and implications of data governance. Data governance and data integrity is not just about correct numbers, it is much more than that and involves management leadership, influencing others, change of culture, effective training and personal honesty.

Target Audience

- Managers and staff from Manufacturing, QC/QA and Analytical Development Laboratories of pharmaceutical companies
- Contract Research Organisation and Contract Manufacturing Organisation manufacturing, laboratory and QA personnel
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity

Programme

Setting the Scene: Introduction to the Course and Scope of Data Governance

Dr Bob McDowall

- Data Integrity Model with focus on Data Governance
- Definitions of Data Governance
- Scope of Data Governance in ensuring Data Integrity: Who is involved?

Regulations and Regulatory Guidance for Data Handling - Expectations of an EU GMP Inspector

Klaus Eichmüller

- GMP Regulations – EU
- ICH Q10
- Data integrity guidance documents – WHO, MHRA and others

Case Study: Corporate Data Integrity Policy

Roland Miksche

- Scope and content
- Authorship and Approval

Data Governance Roles and Responsibilities

Dr Christopher Burgess

- Who is involved – in the whole organisation
- What do they have to do?

Workshop 1: Content of the Data Integrity Policy

Work on specific sections of the policy in groups

Moderator: Roland Miksche

Case Study: Corporate Culture and Organisation for Data Governance and Data Integrity

Margarita Sabater

- Role of Senior Management
- Interdependencies of function
- How to implement the change process

Data Owners and Data Stewards

Dr Bob McDowall

- What do they have to do?
- Roles and responsibilities
- Identifying and training the individuals

Workshop 2: Defining Roles and Responsibilities for Data Owners, Stewards, Staff & IT

- Laboratory
- Production
- Quality Assurance Systems

Moderator: Dr Bob McDowall

Changing the Culture of an Organisation
Margerita Sabater
- What is required?
- Behaviours: no blame culture & whistleblower line
- Defining expectations: expected and prohibited actions with consequences
- Delivering change

Data Integrity Training
Dr Bob McDowall
- Learning from outside the pharmaceutical industry
- Linking the data integrity policy and local procedures for processes and systems
- Assessing and measuring understanding

Data Integrity Audits of Processes and Systems
Dr Christopher Burgess
- Data Life cycle for manual and automated processes
- What data integrity controls are required throughout the life cycle?
- Security and confidentiality considerations

Investigating Data Integrity Violations
Philip Vaering
- Reporting the issue
- Sequestering the data and investigating the issue
- Resolving the problem

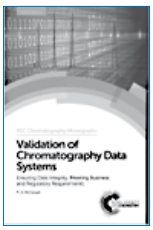
Workshop 3: Auditing a System and Identifying Data Integrity Problems
- Laboratory
- Production
- Quality Assurance Systems

Moderator: Dr Christopher Burgess

Moderator

Dr Bob McDowall
R D McDowall Ltd., Bromley, Kent, UK

Literature



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Speakers

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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>.

Klaus Eichmüller, *Wolnzach c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
After working in the pharmaceutical Industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer of medicinal products and importers. He was Deputy Head of the "Central Authority for Supervision of Medicinal Products in Bavaria" as long as it existed and is now Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hessen since March 2014.

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 30 years and is the author of a second edition of 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.

Roland Miksche, *Vienna, Austria*
After more than 15 years driving CSV, data integrity and all global IT-projects within the Quality Assurance Department of Shire, Roland implemented EBM, an electronic batch management system, at Shire and afterwards, as Senior Consultant of HGP Pharma Consulting at a customer in Germany. He made his final exam in biochemistry in Vienna, Austria, worked as analyst in accredited laboratories and as a sales and service expert for scientific equipment.

Margarita Sabater
Dako Denmark A/S, an Agilent Technologies Company, Member of the ECA DI Group
Margarita Sabater is currently compliance manager working in the improvement of Quality systems, a Validation specialist and educator at Agilent Technologies. Analytical chemist with over 20 years experience in the pharmaceutical industry. She has been involved with the qualification and validation of computerised analytical systems for over 10 years. Margarita has been working in the establishment of Data integrity policies, performing data flow analysis and risk assessments and educating in Data Integrity for the last 3 years.

Philip Vaering, *QA Chemist, ALK-Abelló A/S, Denmark*
He received his M.Pharm from the University of Copenhagen. He had a research employment at the Broad Institute of Harvard University & MIT, Boston, MA and also a research employment at the Technical University of Denmark. His current position is QA Chemist at QA Hørsholm with solid experience in analytical technologies employed at ALK. Currently project manager for Data Integrity initiatives in ALK. Philp was trained by data integrity expert John Avellanet, who trains FDA inspectors in data integrity.

Lab Data Integrity - Meeting FDA & EU Concerns

On 19 – 21 March 2018, i.e. on Monday to Wednesday of the same week, ECA offers another GMP Education Course in Copenhagen about Lab Data Integrity - Meeting FDA & EU Concerns.

This course will be divided in the following two parts:

Part I: Establishing the Controls for Ensuring Laboratory Data Integrity with the focus on paper / hybrid / e-records
and
Part II: Selfinspections and Audits to Confirm Effective Controls focussing on e-records

These courses will be an ideal precursor to the Education Course GMP Data Governance – Principles for Data Integrity Assurance (22.-23 March 2018). Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses or all three courses will receive a **350€ discount** (not valid for EU GMP Inspectorates).

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

Thursday, 22 March 2018, 09.00 h - 18.30 h
(Registration and coffee 08.30 h - 09.00 h)
Friday, 23 March 2018, 08.30 h - 16.00 h

Venue

Radisson Blu Royal Hotel
Hammerichsgade 1
1611 Copenhagen V, Denmark
Phone +45 (0)33 42 60 00
Fax +45 (0)33 42 61 00
royal.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

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

If you register for the ECA Education Course
Lab Data Integrity - Meeting FDA & EU Concerns - Part I AND Part II (19 - 21 March 2018)
OR **Part II only (20 to 21 March 2018)**
at the same time, you will receive a 350 € discount.
This is not valid for EU GMP Inspectorates.

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 Marion Weidemaier (Organisation Manager) at +49-62 21/84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

Social Event

In the evening 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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

GMP Data Governance
22 – 23 March 2018, Copenhagen, Denmark

I also register for (please tick)
☐ **Lab Data Integrity - Part I AND Part II** (19-21 March 2018)
☐ **Lab Data Integrity - Part II only** (20-21 March 2018)

☐ 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)

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)
German law shall apply. Court of jurisdiction is Heidelberg.

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.