

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 Petersen
Team Leader in Process and
Technical Support, 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
- 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
- Global GAP Analysis and Data Integrity Control Strategies
- Auditing a System and Identifying Data Integrity Problems



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 – EMA, WHO, 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

Margherita 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 Global GAP Analysis and Data Integrity Control Strategies

Philip Vaering, ALK, Denmark

- Identifying data integrity GAPs in a global organisation
- Ensuring focus on the most critical systems and issues (risk based approach)
- Driving global data integrity projects
- Data Integrity control strategies

Workshop 3: Auditing a System and Identifying Data Integrity Problems

- Laboratory
- Production
- Quality Assurance Systems

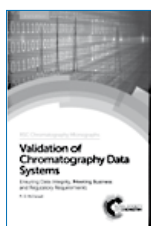
Moderator: Dr Christopher Burgess

Moderator

Dr Bob McDowall

R D McDowall Ltd., Bromley, Kent, UK

Literature



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.

Speakers



Dr Christopher Burgess, *Burgess Analytical Consultancy Ltd., UK, Chairman of the ECA Quality Control 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>.



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 Petersen

Team Leader in Process and Technical Support, 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 Team Leader at QA Hørsholm with solid experience in analytical technologies, production equipment and computerised systems employed at ALK. Has been driving global Data Integrity initiatives in ALK. Philip 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)

GMP Data Governance

22 – 23 March 2018, Copenhagen, Denmark

Mr. Ms.

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)

 + 49 6221 84 44 34



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.