



## Speakers



Dr Christopher Burgess  
Chairman of the ECA Analytical  
Quality Control Group



Dr Markus Dathe  
F. Hoffmann-La Roche AG,  
Switzerland



Dr Bob McDowall  
Member of the ECA IT Compliance  
Interest Group

# Data Integrity Quality Over- sight in the QC Laboratory

## Ensuring Data Integrity

Live Online Training on 13/14 April 2021



Post Live Online Training: Case Studies  
Audit Trail Review for CDS / Laboratory Systems on 15 April 2021

## Highlights

- Regulatory Guidance for Data Integrity Quality Oversight
- Knowing and Managing Data Integrity Risks
- Role of Quality Assurance in Control of Master Templates and Blank Forms
- Data Integrity Audits:
  - Priority and Frequency
  - Coverage
- Data Integrity Investigation:
  - Determining the Scope
  - Findings, Root Causes and CAPAs
- Data Process Mapping
- Raising Data Integrity Concerns
- 6 Case Studies

All participants get free access to the  
current version of the ECA  
„Data Governance and Data Integrity“  
Guidance

## Objective

The involvement of Quality Assurance in ensuring data integrity in GMP regulated laboratories is discussed in both the PIC/S and WHO guidance documents. However, turning guidance document recommendations into practice can be difficult, especially if members of QA are not familiar with the topics covered in these guides. This two-day, interactive workshop-based course is intended to fill this gap in the training spectrum. After an introduction covering the scope and regulatory requirements of quality oversight for GMP regulated laboratories there are presentations, Q&A sessions and case studies on the main topics of the course:

- Understanding process and record risk by using data process mapping
- Controlling master templates and blank forms
- Raising and handling data integrity concerns
- Data integrity audits
- Data integrity investigations

The case studies material is based on real world examples, so that the attendees can gain experience that they can take back to their own organisations.

## Background

Data integrity is a major topic in the pharmaceutical industry and organisations supporting it such as contract research and manufacturing organisations. The regulatory focus has been in Quality Control and Analytical Development laboratories working to GMP especially since 2012 with the updated FDA Compliance Programme Guide 7346.832 for Pre-Approval Inspections. This guide has as objective 3 the data integrity audit. Therefore, it is important that Quality Assurance be aware of the FDA approach as well as ensuring that laboratory activities are under control, compliant and ensure data integrity.

## Target Audience

- Managers and staff from Quality Control and Analytical Development Laboratories of pharmaceutical companies
- Contract Research Organisation and Contract Manufacturing Organisation laboratory personnel
- Quality Assurance staff involved in reviewing laboratory data or performing data integrity audits
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity

## Programme

### Introduction to the Course

---

- What will be covered in the course
- Introduction to the teaching team
- Roles of Quality Assurance and Quality Control defined and discussed

### Regulatory Guidance for Data Integrity Quality Oversight

---

- Review of data integrity guidances: PIC/S, WHO, EMA, MHRA, GAMP Guide for quality assurance role in data integrity and data governance
- Building a framework for quality oversight for Data Integrity (DI) in a GMP analytical laboratory within the QMS
- How culture can impact data integrity
- Identifying key QA roles in the Data Integrity programme

### Knowing and Managing Data Integrity Risk

---

- Data Process Mapping for Paper and Computerised Processes in the laboratory
- Identifying risk to records and mitigating them



### Case Study 1: Data Process Mapping

---

- Review of data process maps for paper and hybrid process
- Identification of record and data integrity risks
- Proposals for risk mitigation
- Course feedback and discussion

### Role of Quality Assurance in Control of Master Templates and Blank Forms

---

- Overview of regulatory guidance for blank forms – 1993 to date
- Process flows for master templates and blank form use
- Identifying the QA role in the process
- Look at alternative options from paper

### Raising Data Integrity Concerns

---

- Process for handling concerns outlined
- Confidentiality of the people and process
- How to handle whistle blowers

### Recap of Day 1 and Introduction to Day 2



## Case Study 2: Handling Data Integrity Concerns

- How should a concern be raised and to whom?
- How will the matter be kept confidential?
- Generating a high-level scope and action plan

## Overview of Data Integrity Audits and Investigations

- Regulatory guidance
- Approaches for DI audits – computer system inventories, paper processes and critical data identified
- Preventing overlap with computer system periodic reviews
- Dealing with data integrity violations: the DI investigation



## Case Study 3: Identifying Data Integrity Audit Priority and Frequency

- From a list of processes and systems attendees will identify the priority order of processes and systems to be audited
- From the priority, the audit schedule will be developed
- Frequency of DI audit of critical systems and paper processes



## Case Study 4: Developing the Data Integrity Audit Coverage

- Scope of the data integrity audit
- What will you audit?
- How will you audit a computerised system vs. a paper process?



## Case Study 5: Data Integrity Investigation – Determining the Scope

- A data integrity violation has been found during a data integrity audit and an investigation is to be launched
- In a facilitated discussion, the course will define the scope and boundaries of the investigation



## Case Study 6: Data Integrity Investigation – Findings, Root Cause and CAPAs

- A list of findings from the investigation will be given and attendees must determine if they are poor data management errors or falsification
- Identification of the root cause
- What are the CAPAs: immediate fixes and long-term remediation actions?



## Post Live Online Training: Case Studies Audit Trail Review for CDS/Laboratory Systems on 15 April 2021

### Programme

#### What Is An Audit Trail and Why is Its Review Important?

- Part 11 and Annex 11 / Chapter 4 requirements for audit trail
- Regulatory requirements for audit trail review
- Guidance documents for audit trail review
- Do I really need an audit trail?
- Static data and dynamic data impacts on audit trail functionality

#### When is an Audit Trail not an Audit Trail?

- What do we look for in an application for auditing?
- Pros and cons for event logs and audit logs?
- Audit trail(s)?
- Part 11 compliant system – does this help data integrity?

#### Case Study 1: Which Audit Trail to review?

Attendees will be presented with an overview of the audit trails within an application and the content of each one. Which audit trails should be reviewed and when in the context of the work performed by the laboratory data system?

#### What are GMP-Relevant Data?

- Annex 11 requires that audit trails monitor GMP-relevant data – what are GMP relevant data?
- What are critical data?

#### Case Study 2: Identifying GMP-Relevant Data

Attendees will be presented with a list of records to identify if they are GMP records and how critical they are to help focus the second person review of audit trail data.

#### Review of Audit Trail Entries

- What are we looking for in an audit trail review?
- Process versus system: avoiding missing data integrity issues
- Regulatory requirement is “frequent review” of audit trails
- What do we need to validate and what to check?
- Suspected data integrity violation - What do we need to do?

#### Case Study 3: Reviewing Audit Trail Entries

Attendees will be provided with the output of an audit trail to review and see if any potential issues are identified for further investigation.

#### Controls to aid Second Person Review of Audit Trails

- Procedural controls for data review
- Technical considerations for audit trail review e.g. identifying data that has been changed or modified – how the system can help documenting the audit trail review has occurred
- Review by exception – how technical controls can help
- Have you specified and validated these functions?

## 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 Markus Dathe**  
F. Hoffmann-La Roche AG, Basel,  
Switzerland

Analytical and Process Chemist with more than 20 years of practical experience in laboratory, quality and informatics functions. Markus held several positions in life sciences and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP Coordinator in the Small Molecules Technical Development of Roche since 2011. He had been successfully leading global projects in the area of CDS, LIMS and QMS.



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

Analytical chemist with over 40 years' experience including 15 years working in the pharmaceutical industry; Bob has been a consultant for over 25 years. He has been involved with the validation of computerised systems for over 30 years and has recently published the second edition of 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. He was a contributor to the GAMP Good Practice Guide for Validation of Laboratory Systems, second edition and is a core industry member of the GAMP Data Integrity SIG. He is an SME for input and review of the GAMP Guide on Records and Data Integrity. His latest book is Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories.

## Date of the Live Online Training Data Integrity Quality Oversight in the QC Laboratory

Tuesday, 13 April 2021, 09.00 – 16.45 h CEST

Wednesday, 14 April 2021, 09.00 h – 17.00 h CEST

## Date of the Post Live Online Training: Case Studies Audit Trail Review for CDS /Laboratory Systems

Thursday, 15 April 2021, 09.00 h – 17.00 h CEST

## Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

### Data Integrity Quality Oversight in the QC Laboratory

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The fee is payable in advance after receipt of invoice.

### Data Integrity Quality Oversight in the QC Laboratory + Post Live Online Training: Case Studies Audit Trail Review for CDS/Laboratory Systems

ECA Members € 2,190

APIC Members € 2,290

Non-ECA Members € 2,390

EU GMP Inspectorates € 1,340

The fee is payable in advance after receipt of invoice.

### Post Live Online Training: Case Studies Audit Trail Review for CDS/Laboratory Systems

ECA Members € 790

APIC Members € 840

Non-ECA Members € 890

EU GMP Inspectorates € 445

The fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## 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

69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)

[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Ms Anne Günster (Operations Director) at

+49(0)62 21/84 44 50, or per e-mail at

[guenster@concept-heidelberg.de](mailto:guenster@concept-heidelberg.de).

For questions regarding organisation please contact:

Mr Ronny Strohwalde (Organisation Manager) at

+49(0)62 21/84 44 51, or per e-mail at

[strohwalde@concept-heidelberg.de](mailto:strohwalde@concept-heidelberg.de).

## Your Benefits

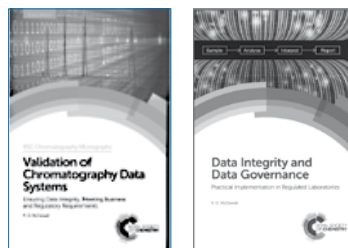
### Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

### This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

## 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) and his new book on Data Integrity and Data Governance: Practical Implementation in Regulated Laboratories, each with a discount of 20%!

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

---

---

---

---

---

**Reservation Form (Please complete in full)**

- Data Integrity Quality Oversight in the QC Laboratory, Live Online Training on 13/14 April 2021
- Post Live Online Training: Case Studies Audit Trail Review for CDS/Laboratory Systems on 15 April 2021

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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 %
    - Cancellation until 1 week prior to the conference 50 %
    - Cancellation 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 can-

cellation 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](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.