Speakers

Bob McDowall
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GMP Inspector

GMP Certification Programme
Certified Data Integrity Manager

Data Integrity

Requirements for a GMP-compliant Data Life Cycle

With an optional full-day pre-course session **Audit Trail Review**

Live Online Training on 19 November and
20-22 November 2024

Save up to € 590,- by booking both courses!

Highlights

- Understand the Regulatory Requirements for an Audit Trail (review)
- Identifying GMP Relevant Data
- Review of Audit Trail Entries
- Technical Controls to Aid Second Person Review of Audit Trails
- FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'
- WHO, MHRA and GAMP Data Integrity Guidances - Key Points
- Data Integrity – EU Requirements
- Principles of Data Integrity
- Data Governance
- Role of Management in Data Integrity
- IT Support for Data Integrity
- Implementing Data Integrity Training
- Data Integrity and Cloud Computing
- Supplier Chain Data Integrity
- European Inspector's Point of View
- Data Integrity Questions as Part of an Inspection

Attendees will get a free electronic copy of ECA "GMP Data Governance and Data Integrity Guide" - Version 3

Objectives

- You will learn the current regulatory requirements and regulatory expectations for an audit trail (review)
- All GMP-relevant data (changes and deletions) should be audit trailed – you will learn how to identify GMP-relevant data
- Event and audit logs: you will understand the differences between and what the regulators expect
- How should an audit trail review be performed? You will get familiar with the content and the frequency of an audit trail review

Background

Audit Trail Reviews are required by international regulations like US 21 CFR Part 11 and EU GMP Guide Annex 11. Clause 9 requests:

"Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed."

Regulators focus on the (creation), modification and deletion of (GMP-relevant) data while many IT systems are not able to generate audit trails at all or they are not able to generate audit trails for GMP-relevant data.

Therefore, this course is designed to support you to identify GMP-relevant data and how to perform and document an Audit Trail review as part of a second person review.

Target Audience for both Live Online Training Courses

This Live Online Training is designed for managers and staff from health care industries as well for auditors who are responsible for the organisation and execution of audit trail (reviews) in their companies.

Programme

Why Is An Audit Trail and 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?

Audit Trail vs. System Log

- Audit trail content
- Log files
- What and when should I review?
- Meaningful audit trails for a meaningful review

Case Study / Faciliated Discussion: 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?

What are GMP-relevant Data?

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

Case Study / Faciliated Discussion: 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. Examples from production, laboratory and QA examples of GMP relevant data will be provided.

Review of Audit Trail Entries

- Guidance for frequent is "frequent review" of audit trails
- Process versus system: avoiding missing data integrity issues when only focussing on a per system review
- What are we looking for in an audit review?
- Suspected data integrity violation - What do we need to do?

Case Study / Faciliated Discussion: 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.

Technical Controls to Aid Second Person Review of Audit Trails

- 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?

Objectives

- Understand the current FDA and EU GMP regulations and guidance impacting data integrity from paper records to hybrid and electronic systems.
- Understand the FDA requirements for data integrity, MHRA Data Integrity guidance July 2016 and WHO guidance from September 2015.
- Learn what is required for a data governance system from senior management through to staff in laboratories, manufacturing and quality assurance.
- Understand the data life cycle and how it is linked with the business process and where problems can occur for both paper records, hybrid systems and electronic systems.

Background

Data Integrity is a global problem and currently a major concern with FDA and European Regulatory Agencies. Multiple FDA warning letters and EU GMP non-compliance reports have highlighted major data integrity failures and falsification in companies globally. The regulatory concern has been responded by the FDA issuing Compliance Program Guide that covers Pre-Approval Inspections. This document became effective in May 2012. 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 issued a new version of a Guidance for Industry on Data Integrity in March 2018. This document outlines a data integrity governance system and principles for defining quality and data integrity into processes and systems. The WHO guidance is complimentary to the MHRA guidance in that it provides guidance for data governance and also expectations for records in both paper and electronic form.

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 and begin programs to ensure that their processes and systems ensure data integrity.

Programme

Why is Data Integrity Important? – Setting the Scene

- Summary of falsification observed by FDA and EU inspectors 2005 – to date
- FDAISA act 2012 and October 2014 Guidance for Industry and the impact on inspections
- Inspection of computerised systems is changing: from paper to on-line
- MHRA expectation for data governance; data integrity guidance documents 2016
- FDA Level 2 guidance on data integrity: 2010 and 2014 postings
- Impact of WHO guidance for data integrity

Principles of Data Integrity

- The ALCOA+ criteria for data integrity
- Data life cycle in the process workflow – managing controls
- Paper versus hybrid versus electronic systems
- Validation of computerised systems for data integrity controls
- Scope: production information versus laboratory data: why are laboratory data higher risk?

Case Study / Faciliated Discussion on Key Data Integrity Topics

- Recording results on paper
- Configuration of software applications
- Unique user identities for all users
- Unauthorised access
- Appropriate access privileges for each user role
- Is my chromatographic system ready? Role of "test" injections
- Audit trails – options for older systems
- Manual chromatographic integration
- Standalone versus network systems
- Protecting electronic records of standalone systems

Data Integrity – EU GMP Requirements

- EU GMP Chapter 4 – documentation
- EU GMP Annex 11 computerised systems
- Data integrity definitions
- Difference between paper and electronic systems

WHO, MHRA and GAMP Data Integrity Guidances - Key Points

- Data Governance System within the Pharmaceutical Quality System
- Data Life Cycle
- Spectrum of Systems: Paper to Electronic Systems with data integrity audit
- The GAMP Records and Data Integrity Guide

FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'

- Background
- Questions and Answers on Data Integrity

Case Study: Analysis of an FDA Warning Letter

- Trainers will analyse one of several FDA warning letters to identify key areas of regulatory concern

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Data Integrity Questions as Part of an Inspection / Data Integrity Observations

- Lab System
- QA System
- Manufacturing System

US 21 CFR 211 and EU GMP Chapter 4: Complete Data vs Raw Data vs Primary Record

- Why complete data and raw data are important for understanding data integrity
- EU GMP Chapter 4 requirements for raw data
- 21 CFR 211 requirements for laboratory records: complete data
- FDA Level 2 guidance: paper versus e-records
- Complete data / raw data / primary record example

Development and Scope of a Data Governance System

- Within a PQS, what is the scope of a data governance system?
- Who are involved?
- What are their roles?

Implementing Data Integrity Training

- Scope of data integrity training
- What cover in the training?
- Checking training effectiveness
- Integrating data integrity training with GMP training

Role of Management in Data Integrity

- Role of Senior, Production and Department Management in ensuring data integrity within an organisation and its suppliers
- Data governance within a Quality System
- Failures to address poor data integrity practices and no training

Case Study / Faciliated Discussion: Assessing a System for Data Integrity

- Using a checklist based on the data integrity criteria, trainers will assess a system for data integrity

Data Integrity in Paper Documentation

- GMP requirements for good documentation practice
- Application to paper documents
- Common problems from FDA 483 observations and warning letters and how to avoid them

Case study: Can Spreadsheets meet Data Integrity Requirements?

- Problems with spreadsheets
- Good Practice for using spreadsheets in a regulated environment
- Building data integrity features into a spreadsheet

User Account Management and Application Configuration

- Separation of roles and responsibilities between IT and the business
- Documentation of the configuration of an application e.g. audit trail, user types and access privileges
- User account management: the dos and don'ts
- User identities must be unique
- Regular review of each system users and privileges

Software Suppliers Responsibility for Data Integrity Compliance

- Regulatory requirements for software systems: procedural and technical
- Role of software suppliers
- Regulations push v market needs pull
- Implementing technical requirements for software: architecture, database and application
- Marketing literature versus marketing bullshit

IT Support for Data Integrity

- IT facilities, environmental controls and physical security
- Qualified IT infrastructure and validated IT systems
- Backup and recovery / Change control
- IT support including database administration
- Impact of IT infrastructure on data integrity

Supply Chain Data Integrity – Organisational Interfaces

- Approaches to ensuring data integrity of your suppliers
- Role of technical agreements and audits

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 parti-cipation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as record-ings. This means that you can watch the videos of the event „on de-mand" – whenever it suits you – on our web server. It is quite uncom-plicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compli-ance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Speakers

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

Analytical chemist with over 45 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. Bob is an ISO 17025 assessor and he has been involved with the validation of com-puterised systems for over 30 years and is the author of a book on the validation of chromatography data systems. He was also a contributor to the GAMP IT Infrastructure control & compli-ance and Lab System Validation 2nd edition Good Practice Guides. He is a core member of the GAMP Data Integrity SIG. He recently published his book on Data Integrity and Data Gov-ernance: Practical Implementation in Regulated Laboratories.

Yves Samson,
Kereon AG, Basel, Switzerland

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

Dr Franz Schönfeld,
District Government of Upper Franconia,
Germany

Dr Franz Schönfeld is a GMP and GDP inspector at thelocal inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

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 re-ceive 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 pro-grammes 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 pe-riod – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certifica-tion.org.

This could be of interest for you as well

Would you like to train a larger group of partici-pants in your company?

We offer practice-oriented GMP/GDP training courses on:
- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Reservation Form (Please complete in full)

Live Online Training

Audit Trail Review
☐ 19 November 2024

Data Integrity
☐ 20-22 November 2024

_____
Title, first name, surname

_____
Department   Company

_____
Important: Please indicate your company's VAT ID Number   Purchase Order Number, if applicable

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City   ZIP Code   Country

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Phone / Fax

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E-Mail (Please fill in)

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Dates of the Live Online Training Courses

Audit Trail Review
Tuesday, 19 November 2024: 09.00 h – 17.15 h CET

Data Integrity
Wednesday, 20 November 2024: 09.00 h – 17.00 h CET
Thursday, 21 November 2024: 09.00 h – 17.00 h CET
Friday, 22 November 2024: 09.00 – 13.30 h CET

Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

Audit Trail Review:
ECA Members € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice.

Data Integrity:
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
The conference fee is payable in advance after receipt of invoice.

Save money and book both courses:
ECA Members € 2,690
APIC Members € 2,790
Non-ECA Members € 2,890
EU GMP Inspectorates € 1,440

The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the numbers 21484 (Audit Trail Review), 21486 (Data Integrity) and 21485 (Audit Trail Review + Data Integrity).

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