ECA Academy
Your GMP/GDP Information Source

Audit Trail Review for Computerised Systems in Analytical Laboratories

SPEAKERS:

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

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Dr Frank Sielaff
GMP Inspector, Regional Authority, Darmstadt, Germany

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

13/14 February 2019, Barcelona, Spain

LEARNING OBJECTIVES:

- Regulations and Guidance for Audit Trails and their Review
- Audit Trail Review as Part of a Data Integrity Strategy
- Validation of Audit Trail Functionality
- Audit Trail Review in Context of second Person Review
- Risk-based Approach to Audit Trail Review
- When is an Audit Trail not an Audit Trail?
- Where do Suppliers help us and where do they let us down?
- What are GMP-relevant Data?
- Review of Audit Trail Entries
- Controls to aid second Person Review of Audit Trails
- Key Learning Points
- OPEN DISCUSSION: Bring us your Audit Trail Problems

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

Audit Trail Review for Computerised Systems in Analytical Laboratories

13/14 February 2019, Barcelona, Spain

Objectives

The objectives of this ECA educational course are to provide:

- An understanding of the regulatory requirements for audit trail review of laboratory computerised systems
- Understand what is meant review by exception
- Who should perform the second person review?
- Discuss audit trail examples for attendees to identify potential data integrity issues
- Present examples of audit trail entries for attendees to identify potential data integrity issues

Background

EU GMP Annex 11 on computerised systems has required "regular review" of audit trail entries since its publication in 2011. In addition, the data integrity guidance documents issued by MHRA, WHO, FDA, EMA and PIC/S over the past few years reiterates the need for review of audit trail entries as part of a second person review of analytical data. However, like all regulations and guidances these documents emphasise the "what" that must be done but leave the "how" to each laboratory to interpret and then implement. For example:

- Do I need an audit trail function for all software?
- How regular is a regular review of audit trail entries?
- In some organisations, there is confusion about who should review audit trail entries - is this a laboratory or quality assurance role?
- What does a risk-based or review by exception of audit trail entries really mean and do all laboratory informatics applications offer this approach?

This is also compounded by the fact that most laboratory software applications were initially designed before data integrity issues took centre stage in the eyes of the regulators. How can GMP regulated organisations influence software suppliers?
This course is designed to help GMP organisations understand what is involved in a review of audit trail entries and how to conduct a risk-based review.

Target Group

- 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

Dr Bob McDowall

Regulations and Guidance for Audit Trails and their Review

- An overview of the regulatory framework: EU, FDA, MHRA, WHO and PIC/S regulations
- Data life cycle in Analytical Laboratories
- Audit Trails in GMP Inspections: What are the expectations of the inspector?

Dr Frank Sielaff

Audit Trail Review as Part of a Data Integrity Strategy

- Define ATR as element of the DI Strategy
- Risk-based Approach – how to apply
- Apply a systematic approach to define ATR
- Audit Trail Review concepts

Dr Markus Dathe

Validation of Audit Trail Functionality

- Specification of audit trail requirements in the URS: dos and don'ts
- Documentation of the application configuration for audit trail functionality
- Leveraging the supplier's development and testing into your validation effort
- User acceptance testing of audit trail functionality

Dr Bob McDowall

Workshop 1: Validation of Audit Trail Functionality

- The attendees will review user requirements for audit trail functions to highlight good and bad practices and from good requirements design tests to verify correct functionality
- Documenting the assumptions, exclusions and limitations of your chosen test approach

Dr Bob McDowall & Dr Markus Dathe

Audit Trail Review in Context of second Person Review

- Overview of the analytical process from sample to reportable result
- Highlight the use of computerised systems and audit trails
- Use technical controls to focus review effort
- Audit trail review issues for manually entered data into a laboratory system and electronic transfer between systems

Dr Bob McDowall

When is an Audit Trail not an Audit Trail?

- What do we look for in an application for auditing?
- Which audit trail(s) should I review?
- Event logs vs. audit logs

Dr Markus Dathe

Where do Suppliers help us and where do they let us down?

- What do we expect from the suppliers to support data and audit trail review?
- Identify and avoid typical pitfalls
- Data ownership
- Data packaging and storage – supplier vs. business

Dr Markus Dathe

Workshop 2: Which Audit Trail to Review?

Attendees will be presented with an overview of the audit trails within a chromatography data system and the content of each one.
Which audit trails should be reviewed and when?
Dr Bob McDowall & Dr Markus Dathe

What are GMP-relevant Data?

- Annex 11 requires that audit trails monitor GMP-relevant data – what are GMP-relevant data?
- What are critical data and how can they be determined?
- Direct/indirect, static/dynamic data
- Data, Audit Trail and criticality?

Dr Markus Dathe

Workshop 3: Identifying GMP-relevant Data

Using facilitated discussion, attendees will develop a matrix for risk based audit trail review. Then they will apply the principles to a list of laboratory records to identify if they are GMP records to help focus the second person review of audit trail data.
Dr Bob McDowall & Dr Markus Dathe

Review of Audit Trail Entries

- Guidance for "regular 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

Dr Bob McDowall

Workshop 4: Reviewing Audit Trail Entries Part 1

Attendees will be provided with a series of audit trail entries at the system level to review. Are there any potential data integrity issues to be followed-up?
Dr Bob McDowall & Dr Markus Dathe

Workshop 5: Reviewing Audit Trail Entries Part 2

Attendees will be provided with a series of audit trail entries at the data capture and interpretation level to review. Are there any potential data integrity issues to be followed-up?
Dr Bob McDowall & Dr Markus Dathe

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?

Dr Markus Dathe

Open Discussion: Bring us your Audit Trail Problems

Dr Bob McDowall & Dr Markus Dathe

Key Learning Points and Final Discussion

Dr Bob McDowall & Dr Markus Dathe

Moderator

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

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.

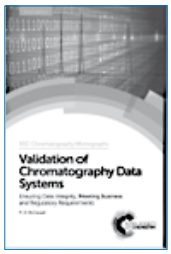
Speakers

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 20 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 new GAMP Guide on Records and data Integrity.

Dr Frank Sielaff
GMP Inspector, Regional Authority, Darmstadt, Germany
GMP Inspector at the Regierungspräsidium Darmstadt with the focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP inspectorate Frank was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

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.

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

Wednesday, 13 February 2019, 09.00 – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 14 February 2019, 08.30 h – 15.30 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
sants@barcelo.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.

Accommodation

Concept Heidelberg has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG with all further information 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
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For questions regarding content please contact:
Dr Günter Brendelberger (Operations Director) at +49-(0)62 21 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "Certified Data Integrity Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following 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
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity 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

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13/14 February 2019, Barcelona, Spain

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- until 1 weeks prior to the conference 50 %
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