ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

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

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

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GMP Inspector, Regional Authority, Darmstadt, Germany

Audit Trail Review for Computerised Systems in Analytical Laboratories

28/29 January 2020 | Barcelona, Spain

Highlights

- 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

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

Objective

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 how to manage the 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 a "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 reiterate the need for review of Audit Trail Entries as part of a Second Person Review of analytical data. However, like all regulations and guidance 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 computerised systems?
- What is meant by 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 included in a review of Audit Trail Entries and how to conduct a risk-based review.

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

Social Event

In the evening of the first 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.

Programme

Introduction to the Course

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?

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

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

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

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

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

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

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?

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?

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.

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 Trail Review?
- Suspected Data Integrity violation - What do we need to do?

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?

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?

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?

Open Discussion: Bring us your Audit Trail problems

Key Learning Points and Final Discussion

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.

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GERMANY

Reservation Form (Please complete in full)

Audit Trail Review for Computerised Systems in Analytical Laboratories, 28/29 January 2020, Barcelona, Spain

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)

General terms and conditions
If you cannot attend the conference you have two options:
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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.

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Date
Tuesday, 28 January 2020, 09.00 – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 29 January 2020, 08.30 h – 15.30 h

Venue
Barcelo Sants Hotel
Placa dels Paisos Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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 when you have registered for the conference. 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.
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grimm@concept-heidelberg.de.

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.

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