ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Dr Markus Dathe
F. Hoffmann-La Roche, Switzerland

Dr Bob McDowall
Member of the ECA IT Compliance Interest Group

Dr Frank Sielaff
Regional Authority, Darmstadt, Germany

Audit Trail Review for Computerised Systems in Analytical Laboratories

Live Online Training on 22/23 September 2026

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

Critical review on the new Annex 11 proposal!

Objective

The objectives of this Live Online Training are:

- To provide an understanding of the regulatory requirements for Audit Trail Review of laboratory computerised systems
- To understand how to manage the review by exception
- To explain who should perform the Second Person Review
- To present and discuss 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 Live Online Training 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

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

Case Study 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

Case Study 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?

Case Study 3: Identifying GMP-relevant Data

Developing a matrix for risk-based Audit Trail Reviews. The participants 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?

Case Study 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?

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?

Case Study 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?

Key Learning Points and Q&A Session

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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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
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Reservation Form (Please complete in full)

Audit Trail Review for Computerised Systems in Analytical Laboratories, Live Online Training on 22/23 September 2026

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)

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If you cannot attend the conference you have two options:
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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 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.

Date of the Live Online Training

Tuesday, 22 September 2026, 09.00 – 16.45 h
Wednesday, 23 September 2026, 09.00 – 17.00 h
All times mentioned are CEST.

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 trainings 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)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

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.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22411.

Conference language

The official conference language will be English.

You cannot attend the Live Online Event?

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

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
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

For questions regarding organisation please contact:
Ms Sonja Nemec (Organisation Manager) at
+49(0)62 21/84 44 24, or per e-mail at
nemec@concept-heidelberg.de