Data Integrity
Requirements for a GMP-compliant Data Life Cycle

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

17 and 18 – 20 March 2020 | Prague, Czech Republic
25 and 26 – 28 August 2020 | Copenhagen, Denmark
08 and 09 – 11 December 2020 | Vienna, Austria

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- FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'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
- Case study: Data Integrity questions as part of an inspection

With 7 Workshops
Programme “Audit Trail Review”

Objective
- 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 courses
This course 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

Workshop 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?

Workshop 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. Examples from production, laboratory and QA examples of GMP relevant data will be provided.

Workshop 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.

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?

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 data integrity 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
### 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

### Workshop: Analysis of an FDA Warning Letter
- Working in teams, attendees will analyse one of several FDA warning letters to identify key areas of regulatory concern
- Group discussion of regulatory concerns identified

### 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

### Case study: Data Integrity questions as part of an inspection
- Lab System
- QA System
- Manufacturing System

### 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

### 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

### 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

### Workshop: Assessing a System for Data Integrity
- Using a checklist based on the data integrity criteria, attendees will assess a system for data integrity

### 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

### Supply Chain Data Integrity – Organisational Interfaces
- Approaches to ensuring data integrity of your suppliers
- Role of technical agreements and audits

### 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

### Key Learning Points and Final Discussion
- Summary of Data Integrity Requirements and Key Learning Points
- Final Discussions and close of the course
Speakers

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

Analytical chemist with over 40 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 computerised systems for over 25 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 & compliance and Lab System Validation 2nd edition Good Practice Guides. He is a core member of the GAMP Data Integrity SIG.

Dr Franz Schönfeld, District Government of Upper Franconia, Germany

Dr Franz Schönfeld is a GMP and GDP inspector at the local 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.

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”.

Social Event

On 18 March / 26 August / 9 December 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.
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%.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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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)!

German law shall apply. Court of jurisdiction is Heidelberg.

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