Data Integrity Audits & Inspections

12/13 May 2020 | Prague, Czech Republic

Speakers

Danny De Scheemaeker
Janssen Pharmaceuticals

Dr Franz Schönfeld
GMP Inspector

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche

Francois Vandeweyer
formerly Janssen Pharmaceuticals

Highlights

- Data Integrity Inspections from the GMP Inspector’s point of view
- Critical Data – Which ones must be audited?
- Quality System / Data Governance Self-Inspection
- Workshop: Real life practical examples (non lab related)
- Laboratory Data Integrity Inspections
- Workshop: Laboratory Self-inspections
- Informatics (IT) Self-inspections
- Production Self-inspections
- Workshop: Participants develop an agenda for an audit of a SaaS service provider
- Risk-based Data Integrity assessments
- Data Integrity (Self) Assessments

Receive a Data Integrity Checklist as part of your conference documentation
Objectives

This education course will discuss the practical and proven techniques for conducting effective self-inspections/audits of various pharmaceutical operations, to identify the critical deficiencies associated with Data Integrity. A combination of presentations and case studies with participants’ collaboration will be offered to provide a maximum learning experience.

Participants will get to know all important elements of the Data Integrity inspection, the Data Integrity self-inspection and the customer Data Integrity audit processes. Furthermore, you will be informed about the importance of Data Integrity for the daily business in all areas of the company. Moreover, you will obtain a comprehensive overview of the regulatory requirements and recent audit and inspection trends.

As a production, QA or QC professional you will benefit by learning what the potential problem areas are – so you can take appropriate actions. You will become familiar with the audit tools that are available to you. And you will also have a chance to review and discuss current GMP compliance issues with the speakers.

Target Audience

This training course is designed for QA, QC and production professionals as well as GMP auditors who intend to specialize in Data Integrity auditing and who are facing FDA and EU inspections. It is further intended for professionals who are responsible for GMP Compliance and Auditing, at both the beginner and advanced levels. Regulatory professionals who are responsible for FDA inspections should also attend. All attendees will gain practical knowledge in establishing an effective Data Integrity compliance audit programme.

Programme

Data Integrity Inspections from the Inspector’s point of view

- Data Integrity Inspections as part of general GMP Inspections
- What the Inspectors looks at
- Typical Findings at Data Integrity Inspections
- Electronic Documentation and Paper Documentation

Critical Data – Which ones must be audited?

- Static vs. dynamic data
- Direct vs. indirect impact data
- GMP – GLP – GCP – GDP data
- Critical Service Provider Data

Quality System / Data Governance Self-Inspection

- The PQS
- Data Governance
- DI Risk assessments
- The Data Integrity Program

Workshop I

Real life practical examples (non lab related)
Attendees to build up a DI inspection strategy
- Introduction presentation
- Example 1: Production batch records
- Example 2: Calibration records
- Example 3: Rejected batches

Laboratory DI inspections

- Lab risk based approach
- LIMS challenges
- Supplier pre-set lab equipment
- Logbooks

Workshop II

Participants develop an agenda for an audit of a SaaS service provider
- Scope and audit team
- What to check?
- Critical areas / Security / Data Privacy
Informatics (IT) Self-inspections

- Key questions to be asked in IT Departments
- The role of IT in Data Integrity
- Key Data Integrity requirements for Software

Discussion, Q&A

Production Self-inspections

- ISA 95 Systems
- APIs/Dosage forms
- Chemical vs. Biotechnology
- CPP - Design Space Parameters

Workshop III

- Laboratory Self-inspections
  - How to develop a risk-based lab self inspection programme
  - Discuss two practical examples

Risk-based Data Integrity Assessments

How to identify gaps in your system
- Business process mapping
- Data and system categorisation, including system assessment
- Risk assessment and remediation
- Some examples

Data Integrity (Self) Assessments

How to identify and detect potential risks for Data Integrity failures:
- Area/ processes/system to cover
- Specific questions to consider

Moderator

Dr Wolfgang Schumacher

Speakers

Danny De Scheemaeker
Janssen Pharmaceuticals

Danny De Scheemaeker is Director External Quality small molecules at Janssen Pharmaceuticals (part of J&J). He is also Chair of the Data Integrity Task Force of APIC/CEFIC who developed the Practical risk-based guide for managing data integrity which has been published in 2019.

Dr Franz Schönfeld
GMP Inspector

Dr Franz Schönfeld is a GMP inspector at the centralised inspectorate for medicinal products of the government of Upper Bavaria in Germany. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the department of Quality Computer Systems. Since August 2016 he works as an independent Pharma consultant. He is a member of the ECA Advisory Board and chairman of the IT Compliance Group, an interest group of the ECA Foundation.

Francois Vandeweyer
formerly Janssen Pharmaceuticals

Francois (Swa) Vandeweyer joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. From 2009 – 2019 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019, he is a freelance consultant.

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.
General terms and conditions
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%.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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.

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 https://www.gmp-compliance.org/privacy-policy). 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
Tuesday, 12 May 2020, 09:00 – 17:00 h
(Registration and coffee 08:30 – 09:00 h)
Wednesday, 13 May 2020, 09:00 – 13.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 261 191 111
Email prague.corinthia.com

Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectors € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner and lunch on the first day and all refreshments. VAT is reclaimable.