ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Danny De Scheemaecker
Janssen Pharmaceuticals

Dr Franz Schönfeld
GMP Inspector

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche

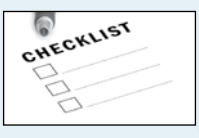
Francois Vandeweyer
formerly Janssen Pharmaceuticals

Data Integrity Audits & Inspections

Live Online Training on 12/13 October 2021

Highlights

- Data Integrity Inspections from the Inspector's Point of View
- Remote Data Integrity Audits
- Critical Data – Which Ones must be Audited?
- Quality System / Data Governance Self-Inspection
- Real Life Practical Examples (non Lab Related)
- Laboratory Data Integrity Inspections
- Informatics (IT) Self Inspections
- Production Self Inspections
- How to 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

Programme

Objectives

This online training 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 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.

Two Data Integrity Checklists!

All participants will receive two Data Integrity Checklists. One Checklist has been developed by APIC/CEFIC, the second Checklist has been developed by ECA´s Data Integrity IT Compliance Group. Both Checklists will be available in electronic format for daily use!

Id	Topic	Sub topic	Question	Category	Acceptance criteria	Does the system meet the criteria?	Description of gap	Comments
1	System life cycle management	Calibration/ Qualification/ Validation	Is the system calibrated/qualified/ validated in accordance with an approved life cycle management procedure? Comment: *Includes Paper based systems (procedures for paper batch records needs to be qualified completion of batchrecord, BMR, archive), ...)*	1 / 2 / 3 / 4 / 5 / 6	Documented objective evidence shall be present showing that the system performs as intended. A life cycle management process shall be followed to implement the system. Calibration/ qualification/ validation documentation for the system shall be maintained during the lifetime of the system and retained in accordance with the companies Retention Schedule.			
2	System life cycle management	Change control	Are changes to the system controlled according to the sites change management process?	1 / 2 / 3 / 4 / 5 / 6	All changes to the originated validated/ qualified state shall be captured in a Change Management process, including: - All system-, patch- and user roles changes; - All activities performed by Administrators; - Data changes outside the system (database, flat files).			
3	System life cycle management	Data migration	Is data verification executed as part of computer system validation activities when GxP data is migrated from a source system to another system?	5 / 6	Data migration from a source system to another system requires data verification as part of computer system validation activities. Data shall be verified for completeness and accuracy using a statistically relevant sample.			
4	System life cycle management	Transient Data Management	Are the requirements for temporary (interfacing) GxP data defined and documented? Examples:- *data translations, compression, scan-rates, ...*	3 / 4 / 5 / 6	Transient Data (interface) requirements shall be defined.			
5	System life cycle management	Transient Data Management	Is the interface validated for intended use? Definition of 'Interface': Data in this interfacing system is received from a sending system and forwarded to a receiving system without permanent storage of data in this interfacing system. These systems only transfer data. Note: Connections like RS-232 cords, Moxa-boxes,usb-cables, etc. shall not be treated as interfaces since they do not have user or security management and they do not temporarily store raw data before sending it to the receiving system. These connections shall be treated as being part of the sending system.	4	The interface shall be validated for intended use. During the set-up and validation, it should be guaranteed that: - the data residing at the receiving system is the exact representation of the data generated at the sending system. - no business users are able to manipulate this temporary data at the intermediate storage location.			

Programme

Data Integrity Inspections from the Inspector's Point of View

- Data Integrity Inspections as part of general GMP inspections
- What the Inspectors look 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

Real Life Practical Examples (non Lab related)

- Introduction presentation
- Example 1: Production batch records
- Example 2: Calibration records
- Example 3: Rejected batches

Laboratory Data Integrity Inspections

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

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

How to Develop an Agenda for an Audit of a SaaS Service Provider

- Scope and Audit Team
- What to Check?
- Critical Areas / Security / Data Privacy

How to Leverage the ISO 19011 Section for Remote Audits to the GMP Area

- Pros and Cons of remote audits
- Definition in the audit SOP and the annual audit Program
- Remote audit process

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

Speakers

Danny De Scheemaecker
Janssen Pharmaceuticals

Danny De Scheemaecker 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 to 2019 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019, he is a freelance consultant.

Your Benefit

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Data Integrity Audits & Inspections, Live Online Training on 12/13 October 2021

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:
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 weeks 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 HEIDELBERGwill 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 of the Live Online Training

Tuesday, 12 October 2021, 09:00 – 17:00 h CEST
Wednesday, 13 October 2021, 09:00 – 13.00 h CEST

Technical Requirements

For our Live Online Trainings and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

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.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon +49(0) 62 21/84 44-0
Telefax +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at
+49(0)62 21/84 44 65, or per e-mail at
becker@concept-heidelberg.de.

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