ECA Academy
Your GMP/GDP Information Source

Speakers

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Computer Validation & Data Integrity GxP Basics

Live Online Training on 12 October 2023

What you need to know in GLP, GCP and GMP

Highlights

- What is GxP data?
- Examples of observations during inspections
- Review of data – Second person review
- Examples of data integrity risks in everyday life
- Basics of computer validation

All participants will receive the current version of the ECA Guide „Data Governance and Data Integrity"

Objectives

In this basic course, you will get an introduction and gain overview in the areas of computer validation (CSV) and data integrity (DI):

- What is computer validation?
- What is GxP data?
- Why is the topic of data integrity currently in the focus of the authorities?
- What are inspectors looking for?
- Why does the topic of "data" affect all sectors?

Through examples and Q&A sessions, you will be comprehensively familiarized with the topic of GxP data.

Background

The integrity of data is one of the basic principles of **GMP** and **GCP / GLP** etc. Therefore, it is often referred to as GxP data. In recent years, the issue of data integrity has increasingly become the focus of GxP inspections.

In clinical trials, for example, usually large amount of data is collected and this data is more and more electronically recorded and processed. The check of their data integrity is mandatory. In addition, sponsors contract out an increasing number of tasks in clinical trials to service providers. During inspections of commercial as well as academic trials, an increasing amount of deviations from GCP standards have been identified by the inspectors in view of sub-standard contractual arrangements and related procedures.

Amongst others, the expectation of the GxP inspectors is that companies have systems and procedures in place to ensure **data integrity** and risk-based **audit trail reviews**. Compliance with and adherence to these rules is therefore very important. To this end, employees must know and understand these rules.

In practice, the meaning and content of the various GxP requirements and their impact on product quality are often not or only partially aware. In addition, the relevant regulations and guidelines are subject to continuous changes and innovations. This event will therefore illustrate and expand on the practical implementation of these rules by means of examples and Q&A sessions.

Target Audience

Addressed are all employees of the pharmaceutical production and technology, IT, quality control and quality assurance, who work in the GxP environment. Both new and experienced employees, the course facilitates understanding of the GxP measures taken or to be taken and their implementation in the company.

Programme

Computer Validation (CSV) - Basics

- Structure and elements of CSV
- Guidelines - Annex 11 vs. GAMP 5
- Access concept - User administration
- Data backup
- IT Infrastructure
- Cloud Computing

Data Integrity in the GxP Environment

- ALCOA++ Principles
- Guidelines for data integrity
- Requirements for paper documentation
- Requirements for electronic systems
- Segregation of duties

What is GxP data?

- What is GxP data?
- Risk analysis of critical data
- Data vs. parameters - what is the difference?
- How long must data be retained?
- Requirements for the data archive

Q&A Session 1

DI Risks Based on Examples in Everyday Life

- Examples of risks in the daily handling of GxP data
- Situations from practice and possible solutions

Review of GxP data – Audit Trail Review

- Static and dynamic data
- What data is subject to review?
- ATR - Audit Trail Review

Review by A Second Person - Do we need it?

- Which documents need to be reviewed by the 2nd person?
- Control of blank forms (templates)

DI in GCP

- Data integrity in GCP:
  - Critical data
  - Verification
  - Risk-based Audit Trail Review

Examples of Observations during Inspections

- What do GxP inspectors look for?
- Preparation for an inspection - correct behavior
- Document unusable, entry forgotten - what to do?
- Examples

Q&A Session 2

Speaker

Wolfgang Schumacher
formerly F. Hoffmann-La Roche, Switzerland
Wolfgang studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. From 2001 to 2016 he was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche, Basle. He is currently chair of ECA´s DI&IT Compliance Group.

Lisbeth Bregnhøj
Medicines Inspector, Denmark
Lisbeth is a GCP inspector and leader of the development work on the new EMA guideline on computerized systems in clinical trials.

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CERTIFICATE

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 Live Online Training in detail and with which you document your training.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?
We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

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Reservation Form (Please complete in full)

Omputer Validation & Data Integrity GxP Basics
Live Online Training on 12 October 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training
Thursday, 12 October 2023, 9.00 h – 17.30 h

All times mentioned are CEST

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Fees (per delegate, plus VAT)
ECA Members € 1,090
APIC Members € 1,140
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The conference 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.

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Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.
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