ECA Academy
Your GMP/GDP Information Source

Speakers

Shorni Hardy
BioNTech US

Dr Sabine Hauck
dequra pharma consult hauck

Michael Hopper
GxPpro

Dr Katrin Prospero
Vetter Pharma-Fertigung

Linda Reijinga
Ferring

Dr Franz Schönfeld
GMP Inspector

Efficient GMP Training Systems

Requirements - Implementation - Compliance

Live Online Training on 19/20 November 2024

Highlights

- Design & Delivery of GMP Trainings
- Optimising Quality of Training with a Focus on Virtual Reality Training
- Presentation of Training Management Systems during Inspections
- Views and Expectations of an Inspector
- Evaluating Training
- Practical Examples
  - Ferring
  - Vetter Pharma-Fertigung
  - BioNTech US

Objectives

- You will understand the EU GMP requirements with regard to "Training programmes should be available" and how to interpret them
- You will learn about the creation and content of a training programme and how training systems are designed and implemented in different pharmaceutical companies
- You will learn about new training systems e.g. virtual reality
- You will learn how to optimise the quality of training and how to present your training system during inspections
- You will learn about the views and expectations of inspectors

Background

The training requirements for employees in the GMP-regulated environment are increasing. Pharmaceutical companies are required to plan and conduct training courses and to evaluate the success of the training.

Requirements for training are (among others) laid down in the Commission Directive (EU) 2017/1572 – *"The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified..."* and the EU GMP Guide Chapter 2.

How can you implement those regulatory requirements into you daily business? What is the meaning of *"effectiveness shall be verified"* and what are the consequences for your company?

This ECA course will show you how to operate your training system in a GMP-compliant and effective way from the point of view of inspectorates and pharmaceutical companies. What is currently best practice will be shown on the example of the training management system of different pharmaceutical companies.

Target Audience

This training is addressed to executives and employees from pharmaceutical companies and their suppliers who are

- Training managers/ training specialists
- Responsible for developing, executing and evaluating training programmes

Moderator

Sarah Schmidt, CONCEPT HEIDELBERG
(on behalf of ECA)

Programme

Design & Delivery of GMP Trainings

- Use of standards to design and evaluate learning
- Methods of delivery
- Blended learning
- Considering learning styles
- Engaging the learners
- Knowledge management

Optimising Quality of Training with a Focus on Virtual Reality Training

- Changed situation
- Employee survey
- Standardized training material
- Catalogue of topics / publication / booking of training
- Development of new training methods with a focus on VR
- Implementation and first experiences with virtual reality training

Presentation of Training Management System during Inspections

- Preparation for inspection
  - Training on basic behaviour during the inspection
- During the inspection
  - Presentation of the training system (frequently asked questions by inspectors)
  - Requested documents

Views and Expectations of an Inspector

- Regulatory requirements
- Responsibilities
- Types of training
- Assessment of training

Evaluating/Validating Training

- Kirkpatrick Model
- Design of assessment materials (based on standards)
- Methods of assessment & quality assurance
- Ensuring assessment decisions are objective
- KPIs

Practical Example: The Concept of the modular Training System at Vetter Pharma-Fertigung GmbH & Co. KG - Qualification from Day one

- Modular structure of the training system
- Training center: Place of learning
- The pharmaceutical trainer
- Time management and transfer of knowledge
- Success control versus control of effectiveness
- Escalation levels and their mechanisms in the event of repeated deviations

Experience from different Training Systems

- Development from different training styles
- Pros and cons of various approaches
- Suggestions for effective training

Practical example: Development of TMS at Ferring GmbH

- Design and structure of the training system
- Prerequisites / authority requirements
- Requirements for the software used
- Implementation of structure and mapping of the training system in a training documentation system (including eSig of training participants, trainers and system managers)
- Interfaces to relevant systems
- Paperless documentation.
- Reports (Controlling of training status / automation of processes)
- Switching to a new TMS

Practical Example: Training Management System Overview of BioNTech US

- To be announced

Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Speakers

Shorni Hardy
BioNTech US Inc., United States

Shorni Hardy is Global Process Owner for Training Management and Document Management at BioNTech US Inc. She has 18+ years of experience supporting Quality and Manufacturing processes in well-established and start-up global pharmaceutical companies.

Dr Sabine Hauck
dequra pharma consult hauck, Germany

Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance, regulatory affairs and corporate development. Her product experience spans from small molecules to cell therapies and includes a variety of dosage forms. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies in the field of pharmaceutical development, quality assurance, and regulatory affairs. Sabine is also active as the chair of the ECA ATMP interest group.

Michael Hopper
GxPpro Ltd., U.K.

Michael Hopper set-up GxPpro after leaving Pfizer. Michael has over 30 years experience and held several Technical, Management and QA roles.

Dr Katrin Prospero
Vetter Pharma-Fertigung GmbH & Co. KG, Germany

Since 2008 Katrin Prospero is responsible for the regulatory and GMP-relevant part of the training concept at Vetter, as well as the pharmaceutical training system.

Linda Reijinga
Ferring GmbH, Germany

Linda Reijinga is employed at Ferring since 1996. She has more than 20 years of experience in QA and is among other things responsible for the GMP Training System and the organisation of GMP Training of Ferring GmbH. Meanwhile, she is working in HR department and additionally responsible for GMP human resource development. In 2020 she implemented Virtual Reality Training Technology for Clean Room Training.

Dr Franz Schönfeld
District Government of Upper Franconia, Germany

Dr Franz Schönfeld is a GMP inspector at the centralised inspectorate for medicinal products of the 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.

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Reservation Form (Please complete in full)

Efficient GMP Training Systems
Live Online Training on 19/20 November 2024

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
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 http://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, 19 November 2024,
09.00 – 16.45 h CET
Wednesday, 20 November 2024,
09.00 – 16.00 h CET

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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

Organisation and Contact

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

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