Training in a GMP Environment

Compliant and effective development and management

5-6 November 2015, Barcelona, Spain

SPEAKERS:

Michael Hopper
GxPpro

Linda Reijinga
Ferring

Bernd Renger
Bernd Renger Consulting

Martin Wesch
Wesch & Buchenroth, Law Office

LEARNING OBJECTIVES:

- European Requirements
- Training needs Analysis
- Design & Delivery of Learning & Development Presentation
- Efficient Routine GMP Training Programs
- GMP Training vs Technical on the job Training
- Case study Training Management System
- Optimising Quality of Training
- Evaluating Training
- Presentation of Training Management Systems during Inspections

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

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Objectives

- You will understand the EU GMP requirements with regard to " Training programme should be available" and how to interpret them
- You will learn about the content of a training programme and who is responsible for what
- "The effectiveness of a training programme should be verified". What does this mean? You will get to go through a case study from a pharmaceutical company and you will understand the limitations from the legal point of view
- You will learn how to optimise the quality of training and how to present your training system during inspections
- You will learn how to write standards that can be used to determine competence of Trainees

Background

Requirements for training are laid down in the EU Directive 2003 / 94 – "The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified..." - and in the EU GMP guide in chapter 2 - "Personnel should be qualified and manufacturer should provide training for all personnel whose activities could affect the quality of the product. Training programmes should be available"

How can you implement these general 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 support you with information from practitioners as well as with information from the legal base. It will show you how to operate your training system in a GMP compliant and effective way and what is current best practice.

Target Audience

Managers and staff from pharmaceutical companies, Training Managers, Training specialists and suppliers who are responsible for developing, executing and evaluating training programmes.

Social Event

On 5 November 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.

Programme

European Regulations

- GMP-Requirements
- Data security laws
- Cooperation with Work Council
- Assessment of effectiveness

Training needs Analysis

- Sources of Information
- Processes for collecting data
- Structuring Training
- Role Profiles/Job Descriptions
- Competence
- Training vs Development & CPD
- Human Error
- The learner journey
- Business Objectives

Design & Delivery of Learning & Development Presentation

- Considering Learning Styles
- Blended learning
- Engaging the learners
- SOP Training & Human Error
- Methods of delivery
- Knowledge Management

Design & Delivery Workshop

How Training is designed can have a significant impact on the transfer of learning to the trainee and subsequently, the effectiveness of your workforce. During this workshop you will have the opportunity to consider how to Design training based on Training curriculum.

Efficient Routine GMP Training Programs

- Classroom Training versus e-learning or read and understand
- Training of SOPs – in full or partial?
- How many SOPs do we need to know?
- Refresher training – how often?
- Is there a need to align GMP training with business objectives?

GMP Training versus Technical on the job Training

- Can technical on the job training and GMP training be separated?
- Side by side learning of new technologies using mentor systems
- Training runs – how many times?
- Sharing experience – how to formally document correctly
- How to qualify mentors?

Practical example: TMS of Ferring GmbH

- Structure and organization of TMS
- Revision of process / organizational form / responsibility structure
- Revision of TMS software
- Implementation and adaption of defined Training system into the TMS system (including eSig of participants, trainers and system responsible)
- Paperless documentation
- Factors of success

Optimising Quality of Training

- Online Questionnaire
  - Initial training
  - Repetitive training
  - Reading training vs Face to Face
  - Frame conditions
  - Future ideas
  - Trainer function
- Development of training catalogue
  - Objective: gain general knowledge
  - Topic based catalogue
  - Cross departmental required and optional trainings
  - Organization of booking in courses (automated)
- Implementation of internal trainer pool
  - Voluntary / feel qualified
  - Availability
  - Structure of training material

Evaluating Training Presentations

- Kirkpatrick Model
- Assessing Competence
- Vocational Qualification
- Apprenticeships
- Methods of assessment
- KPIs

Evaluating Training Workshop

Standards provide an excellent method of evaluating learners competence. Competence is a defined as a combination of skills and knowledge required to perform defined tasks, so measures the transfer of learning into the workplace. Standards also ensure that the evaluation is objective as all trainees need to demonstrate that they can work to the same standard. During this workshop, you will have the opportunity to develop standards as a tool for evaluating Training.

Presentation of Training Management System during Inspections

- Preparation for inspection
  - Preliminary measures
  - Training for organization and behaviour during inspection
- Presentation of Training system / requested documents
  - Structure and organization of Training system
  - Questions and focus
  - Requested documents

Speakers

Michael Hopper

GxPpro, U.K.

Michael (Mick) Hopper set-up GxPpro after leaving Pfizer. Mick has over 30 years experience of working in the pharmaceutical Industry, where he held several Technical, Management and QA roles. He also gained a green belt accreditation and led the implementation of several improvement initiatives including Human Error management, Quality Risk Management and yellow belt development. Mick has significant experience in working with UK Science based qualifications for laboratory technicians and process Operators

Linda Reijinga

Ferring GmbH, Germany

As QA-Manager, Linda Reijinga is responsible for GMP-Training, Project Management and the reporting of Quality KPIs . She has leaded the project of the Ferring EU hub release processes optimisation.

Dr Bernd Renger

Bernd Renger Consulting, Germany

Dr Bernd Renger is a member of the ECA Advisory Board and was Chairman of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Altana Pharma and Baxter BioScience.

Dr Martin Wesch

Wesch & Buchenroth, Law Office, Germany

Dr Martin Wesch is a lawyer specialised in medical and industrial law and working for the Stuttgart-based firm of lawyers Wesch & Buchenroth, which he founded in 2001. Since April 2002, he has been teaching industrial law at the University of Stuttgart. He is author of several publications, both in journals and books, to legal demands on quality assurance in manufacturing pharmaceuticals. In 2007 he received the Wallhäusser Prize for publications in that field from Concept Heidelberg.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

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:
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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
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- 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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Date

Thursday, 5 November 2015, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Friday, 6 November 2015, 08.30 h – 15.30 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.
VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

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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