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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)

Recorded Online Training: GMP for Beginners – Understanding the Importance of GMP

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 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.

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

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Why not online? GMP/GDP Training Courses/Conferences, Webinars and E-Learning
Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/on-demand-online-training/ recorded-online-training-webinars

Recording from 30 June / 1 July 2020

The total length of this recording is 11 h 20 min.

With your registration confirmation for this recorded version you will receive a link and the login. This login will be open for two days, in which you are free to watch the recorded version. Together with the link and login you will also receive the PDFs of all presentations. Please note that you will not need to install any additional software – the recording can be watched on any browser.

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.

Registration

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

Certificate

Each participant will receive a certificate of participationat the end of the access period.

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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ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Heinrich Prinz
PDM Consulting

Dr Gabriele Schönberger
ZS.CTIS Consulting

Dr Wolfgang Schumacher
formerly F. Hoffmann-
La Roche

GMP for Beginners

Understanding the importance of GMP

Recorded Online Training

Highlights

- GMP History & Trends
- Basic Principles of GMP
  - Personnel
  - Hygiene
  - Premises / Production
  - Documentation
  - Risk management
  - Qualification / Validation
  - Communication with clients/authorities
- Elements of a QA System
  - Change Control
  - Deviations
  - CAPA (Corrective Actions – Preventive Actions)
  - Failure Investigations
  - OOS (Out of Specification)
  - Audits – Inspections
  - Falsified Products

Programme

Objective

The Online Training is designed for people who have no or little knowledge of GMP.

- You get to know the most important pharmaceutical regulations and their importance,
- you get a basic overview of GMP requirements in pharmaceutical production, and
- you become familiar with technical terms from the field of GMP and their meaning

Background

In the manufacture and quality control of medicinal products, compliance with the GMP rules is the decisive aspect for manufacturing high-quality products. For this reason, every staff member in the pharmaceutical industry has to be familiar with the basic GMP requirements. The relevant European GMP regulations define the following prerequisites:

§ Commisson directive 2003/94/EC
The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the ***concept of quality assurance and good manufacturing practice ....***

§ EudraLex Vol. 4 Good manufacturing practice (GMP) guidelines
2.9 Besides the basic training on the ***theory and practice of Good Manufacturing Practice****, newly recruited personnel should receive training appropriate to the duties assigned to them.....*

In practice, many members of staff are often unaware of the contents and meaning of the different GMP requirements from Europe and US and their consequences for product quality. During this Online Training, speakers with long-standing experience in the training of employees introduce and explain the most important elements of a pharmaceutical GMP system in an easy-to-understand way.

Target Audience

The Online Training is directed to staff from the pharmaceutical industry having no or little experience with the current GMP requirements. This includes both employees who, after their vocational training, enter the pharmaceutical industry and experienced colleagues who work for the first time in a GMP-regulated environment. Participation is also recommended for personnel from suppliers who have to understand the quality requirements of their customers.

Participants' comments of June 2020 course:
„Very informative." Jennifer Martin, Cultivation Sector Consulting, USA

Welcome & Introduction

GMP History & Trends

- Development of GMPs
- GMP: Goal and general ideas
- Types of regulatory documents and their meaning
- The Dossier
- GMP for APIs, medicinal products and excipients - a comparison
- Authorities and industry groups: ICH, PIC/S, EMA, FDA, WHO, APIC, ISPE, IPEC
- Ph. Eur. & USP
- GMP in the US: Comparison of US and EU regulations
- Differences between European and FDA view on GMP / GMP vs cGMP
- Typical expectations of FDA and European inspectors

Hygiene / Personnel Hygiene

- General aspects and rules
- Hygiene program
- Personnel flow
- Medical examination
- Contamination
- Monitoring

Personnel and Training

- General aspects
- Qualification
- Key personnel
- Job descriptions
- Training (purpose, goals, contents, target groups)
- Planning and documentation of training

Documentation

- Structure of documentation
- Responsibilities for the documentation
- SOP
- Documentation in the manufacturing process
- Documentation in the quality control
- Batch record review
- Annual report / Product quality report
- Specifications

Premises / Production

- Requirements for room and equipment
- Classification of rooms
- Sterile production/isolator
- Maintenance of hygiene
- How to behave during production

General & Specific Aspects of a QA System

- Quality Management System (QMS) cited in the regulations
- General aspects of Quality Assurance
- How to implement and structure a system
- Responsibilities
- Deviations
- CAPA
- Change Control
- OOS
- Failure Investigations
- Self-inspections

Risk Management

- Main topics of ICH Q 9 / Part 3 EU GMP Guideline
- Risk management tools
- Use of risk analysis during qualification
- How to handle FMEA?

Qualification/Calibration/Maintenance

- Definitions: Qualification, validation, calibration, maintenance, risk analysis
- Organizing qualification and validation: the validation master plan (VMP)
- Steps in Qualification studies: DQ, IQ, OQ, PQ
- Qualification parameters of typical types of equipment: Clean rooms, water systems, production equipment, analytical equipment
- Performing risk analysis: tools and practical tips
- Calibration: critical types of equipment
- How to build up a calibration system
- Maintenance: Requirements and system
- Validation of computerised systems

Validation

- Definitions
- Process Validation
- PAT
- Validation Master Plan
- Cleaning Validation
- Computer Validation
- Validation of Analytical Methods

Audits and Self-Inspections

- Types of audits
- Requirements
- Dos and don'ts for the auditee - How to survive audits?
- Performing audits and self-inspections
- Good audit practices

Packaging/Storage/Transportation

- Packaging/Storage/Transportation in the regulations
- Managing of packaging process
- What is necessary to regulate in a pharmaceutical company
- WHO good storage practice – elements and requirements
- Transportation as part of storage
- How to maintain the quality during transportation

Falsified Products

- Regulatory requirements
- Responsibilities of QP and the pharmaceutical industry
- What measures can be taken
- Strategies against falsified products

Speakers

Dr Heinrich Prinz
PDM Consulting, Germany

Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant.

Dr Gabriele Schönberger, ZS.CTIS Consulting, Bingen, ehemals Boehringer Ingelheim

Dr. Schönberger is a pharmacist. From 1989 to June 2001 she was employed at Asta Medica AG, among other things as plant manager for parenteralia, head of validation within pharmaceutical production, IPC, regulatory affairs and packaging development. From July 2001 until end 2018 she was in the QA department of Boehringer Ingelheim GmbH. Currently she works as a consultant.

Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche Ltd., Switzerland

Dr Schumacher 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 a member of the ECA Advisory Board.

Your Benefits

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 Online Training is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropiate supplement to acquire this qualification. This Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org