



## Speakers



Dr Heinrich Prinz  
PDM Consulting



Dr Gabriele Schönberger  
formerly Boehringer Ingelheim



Dr Wolfgang Schumacher  
formerly F. Hoffmann-La Roche

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# GMP for Beginners

Understanding the importance of GMP



Live Online Training

13-14 March 2024

15-16 October 2024



## 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

## Objectives

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:



Commission 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.



To ensure a high quality transmission the presentations of this online training were recorded in advance.  
Two discussion panels: The online training includes live Q&A sessions with the speakers (each about ½ hour in the morning and at the end of the event days). This provides the opportunity to ask questions, which the speakers will then answer.

## Programme Day 1

### 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



### Q&A Session 1

### 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

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- 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

## Q&A Session 2

# Programme Day 2

## Risk Management

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- 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

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- Definitions: Qualification, calibration, maintenance
- Organizing qualification
- 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

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

## Q&A Session 3

## Audits and Self-Inspections

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- 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

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- 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

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

## Q&A Session 4

## 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, formerly Boehringer Ingelheim, Germany**  
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 of 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.



### Participants' comments:

*"Good example of practical cases, including pictures to support the sessions."*

*Sophie Anne Laroche, WHO World Health Organization, Switzerland*

*"Nicely paced and nothing missed."*

*Tim Bracegirdle, Valeos Pharma A/S, Denmark*

*"All trainers are very knowledgeable and experienced."*

*Kenny Chee, Esco Aster Pte Ltd., Singapore*

*"From now on I will always remember the difference between qualification and validation! :) Excellent examples and lots of useful hands-on information."*

*Anniina Pertovaara, Hankintatukku Oy, Finland*

*"To all presentations: Very good, clear, informative presentations, with the right amount of information and presented at the right place. Excellent presentations, with lots of information, transmitted in a clear way."*  
*Dr Fátima Sobral, Direção-Geral de Alimentação e Veterinária, Portugal*

*"Very informative."*

*Jennifer Martin, Cultivation Sector Consulting, USA*

Reservation Form (Please complete in full)



GMP for Beginners – Live Online Training

- 13-14 March 2024
- 15-16 October 2024

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cellation 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.

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Dates of the Live Online Training

March 2024

Wednesday, 13 March 2024, 09.00 h – 17.30 h CET  
 Thursday, 14 March 2024, 09.00 h – 17.00 h CET

October 2024

Tuesday, 15 October 2024, 09.00 h – 17.30 h CEST  
 Wednesday, 16 October 2024, 09.00 h – 17.00 h CEST

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 events 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 € 1,590  
 APIC Members € 1,690  
 Non-ECA Members € 1,790  
 EU GMP Inspectorates € 895  
 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](http://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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

Organisation and Contact

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

CONCEPT HEIDELBERG  
 P.O.Box 10 17 64  
 69007 Heidelberg, Germany  
 Phone +49(0)62 21/84 44-0  
 Fax +49(0)62 21/84 44 34  
[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Dr Andrea Kühn-Hebecker (Operations Director) at  
 +49(0)62 21/84 44 35, or at  
[kuehn@concept-heidelberg.de](mailto:kuehn@concept-heidelberg.de)

For questions regarding organisation please contact:

Mr Maximillian Bauer (Organisation Manager) at  
 +49(0)62 21/84 44 25, or at  
[bauer@concept-heidelberg.de](mailto:bauer@concept-heidelberg.de)