ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Heinrich Prinz
PDM Consulting, Germany

Dr Gabriele Schönberger
formerly Boehringer Ingelheim, Germany

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

NEWS

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GMP for Beginners

Understanding the importance of GMP

Live Online Training
14-15 October 2025

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

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 2017/1572
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

- 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

- 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, 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

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

Q&A Session 3

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

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

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Reservation Form (Please complete in full)

GMP for Beginners – Live Online Training
14-15 October 2025

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
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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 https://www.gmp-compliance.org/privacy-policy). 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, 14 October 2025, 09.00 h – 17.30 h CEST
Wednesday, 15 October 2025, 09.00 h – 17.00 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax - or search and register directly at www.gmp-compliance.org under the number 21729.

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.

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

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