ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers

Dr Joachim Ermer
Ermer Quality Consuting, Germany

Sigrid Guhr
AbbVie, Germany

Dr Ulrich Kissel
European QP Association, KisselPharmaConsulting, Germany

Katja Kotter
Vetter Pharma-Fertigung, Germany

Sue Mann
Sue Mann Consultancy, U.K.

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

Live Online Training from 6–8 November 2023

Highlights

- Legal Requirements and Authority Inspections
  - EU and FDA - what is really required
  - ICH Q8
  - Data Integrity
  - Pre-approval Inspections
  - GMP/GDP/GCP Interface
- GMP Issues and Best Practices
  - GMP from Phase 1 to Phase 3
  - Qualification and Validation
  - Analytical Development
  - IMP Manufacturing, Packaging and Supply
  - Change Control
  - The Role of the QP
- Case Studies and Practical Examples
  - PSF and CTD
  - Cleaning Validation
  - Deviations
  - Stability Studies
  - Data Integrity

With a View on the Detailed Commission guideline on GMP for IMPs!

Objectives

During this Live Online Training Course, specialists will share their **expert knowledge** about **all important GMP aspects** in Pharmaceutical Development and Investigational Medicinal Product (IMP) Manufacturing. You will be able to elaborate and discuss both **EU and FDA requirements.**

Background

Not only in the manufacturing of marketed products (c)GMP Compliance is mandatory. Also in the manufacturing of IMP supplies, compliance with the applicable GMP Guidelines is obligatory. But which GMP requirements are the applicable ones? And **do the requirements differ from clinical phase 1 to phase 3**? And what is the role of **ICH Q8, Q9, Q10 and Q12**?

With the third revision of ICH E6 (ICH E6(R3)), the GMP for IMP principles will be expanded to the following: Risk-based approaches should be considered when implementing proportionate measures to ensure GMP and the appropriate shipping and handling of the IMP.

Previously, the WHO already published two new draft documents relating to Development and GMP for IMPs: „Good Practices for Research and Development Facilities of Pharmaceutical Products" and „GMP for IMPs".

In addition, instead of the current EU GMP Annex 13 (Manufacture of IMPs), the Detailed Commission guidelines on GMP for IMPs for human use apply since 31 January 2022.

Complex challenges have to be faced and resolved to guarantee high quality products. The safety of the drug and hence also the patient should always be the main focus. Terminated studies or studies without reliable results will lead to extensive extra costs and delays in the whole development and approval process.

This Live Online Training has been designed by the ECA to broaden your knowledge and to consolidate the various GMP aspects which need to be considered in a successful development of a new pharmaceutical product.

Target Audience

This Live Online Training Course has been designed for R&D personnel involved in Pharmaceutical Development, IMP Manufacturing, Quality Control, Quality Assurance, and Regulatory Affairs.

Participants' comments

„Very good organization and moderation! Great speakers."
Dr Teodora Ivanova, B. Braun Melsungen AG, Germany

„Very competent and good speakers, good topics, very good presentation style."
Dr Sandra Bruder, Germany

„Great course, giving good overview and also special detailed information on GMP in Development, especially IMP´s – also for me as experienced QP in Pharmaceutical Development."
Dr Simone Wengner, Catalent Pharma Solution, Germany

„Subjects interesting, speakers speak in a comprehensible way also for not mother tongue, not too fast. Good support with slides. Very available to answer questions."
Dr Maria Giammaruco, Menarini Ricerche S.p.A., Italy

Programme 6 November 2023

Global GMP Requirements from Phase 1 to Scale-up and Transfer

- Global requirements: applicable law, directives, guides and guidelines: what is really required
- A comparison of FDA and European requirements and expectations

The GMP/GDP/GCP Interface

- Reconstitution
- Pre-requisites for randomisation and blinding
- Distribution
- Site-to-site transfers
- Shelf life extension
- The QP: Where does the responsibility end?

IMP Manufacturing: How much Qualification and Validation is needed?

- Qualification vs. Validation
- What can be found in the regulations
- DQ/IQ/OQ of equipment
- How much process validation is needed?

Case Study / Interactive Session 1 Transition of GMP Requirements from Phase 1 to Phase 3 and the Interface to Development Work

- Challenges and Differences
- How to apply phase appropriate GMPs
- Managing a GMP Lifecycle

Q&A Session 1

Programme 7 November 2023

IMPs in the Context of ICH Q8-Q10, Q12 and Q14

- How to integrate Quality by Design
- Risk Analysis in pharmaceutical development
- Life cycle concept

Cleaning Validation / Verification in Pharmaceutical Development

- Cleaning validation vs. cleaning verification

Change Control for IMPs

- What is required
- What is important
- What are the benefits
- How to implement

Analytical Development (ICH Q14)

- From method development to method validation
- How to deal with genotoxic and other impurities
- Quality control and IMP release
- Analytical Qualification

Q&A Session 2

Case Study / Interactive Session 2
Stability Studies throughout the Development of a new Product

- Different types of products in CT studies (and support)
- APIs and various dosage forms
- Late stage stability strategies

The Role of the QP in Pharmaceutical Development and IMP Release

- Responsibilities
- Co-operation with Head of Production and Head of Quality Control
- Confirmation of Compliance, certification and batch release
- Comparators
- Complaints and recalls

Q&A Session 3

Programme 8 November 2023

How to handle Deviations in an R&D Environment

- Why we need a process for Deviations
- What we need to know
- How to do it

The FDA Pre-Approval Inspection (PAI)

- Involvement of the R&D Department
- What the FDA will look for
- What happens at FDA during and after the PAI
- Responding to FDA after the PAI

Important Documents in Pharmaceutical Development

- Early documentation
- CTD
- PSF: Style and content
- Case studies

Q&A Session 4

Case Study / Interactive Session 3
Data Integrity

- Manufacturer's understanding of data integrity, needs and benefit
- Regulatory expectations
- Hybrid systems (paper and electronic records) - how to ensure data integrity?

Packaging and Supply of Clinical Trial Materials

- GMP requirements
- Quality control of packaging and labelling
- Handling and sourcing of comparators
- Randomisation and blinding

Q&A Session 5

Speakers

Dr Joachim Ermer, Ermer Quality Consulting, Germany
Joachim has 30 years of experience in pharmaceutical analytics including global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management (Sanofi, Frankfurt). Since December 2020, he works as a consultant for topics of pharmaceutical analytics and Quality Control. He is member of the USP Expert Committee "Measurement and Data Quality", and of the Ph. Eur. Chromatographic Separation Techniques Working Party.

Sigrid Guhr, AbbVie Deutschland GmbH (form. Abbott), Germany
Sigrid Guhr is a mathematician and led GMP QA Qualification & Validation (EU) for equipment, facilities, utilities and computerized systems. She has more than 30 years of experience in the pharmaceutical industry, started as programmer, worked as a validation consultant, then as validation manager for computerized systems used by pharmacovigilance. Her recent responsibilities included validation, qualification, and compilation of quality management systems for the software life cycle, vendor audits, risk analyses, and concepts for data integrity assurance.

Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting, Germany
Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Katja Kotter, Vetter Pharma-Fertigung GmbH & Co. KG, Germany
Katja Kotter is Vice President Regulatory Affaires and Quality Compliance at Vetter. She has broad experience in managing authority inspections (including PAIs) and customer audits.

Sue Mann, Sue Mann Consultancy, U.K.
Sue Mann has more than 30 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support. In her last position, Sue was Vice President of International Quality Assurance at Shire Pharmaceuticals.

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GERMANY

Reservation Form (Please complete in full)

GMP meets Development
Live Online Training from 6–8 November 2023

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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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 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 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

Monday, 6 November 2023, 12.30 – 17.00 h
Tuesday, 7 November 2023, 9.00 – 17.00 h
Wednesday, 8 November 2023, 9.00 – 16.45 h

All times mentioned are 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 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 € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
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

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 Live Online Training.
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