ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers

Sigrid Guhr
AbbVie, Germany

Katja Kotter
Vetter Pharma-Fertigung, Germany

Sue Mann
Sue Mann Consultancy, U.K.

Mag. Gabriela Schallmeiner
AQPA Deputy Chair,
Inspection Ready Consulting, Austria

Jef van Schuerbeek
Consulting bvba, Belgium

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

Live Online Training from 22–24 November 2022

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 (applies since 31 January 2022)!

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" 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

„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 22 November 2022

Welcome / Introduction

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

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

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?

Q&A Session 1

IMP Manufacturing: How much Qualification and Validation is needed?

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

Cleaning Validation / Verification in Pharmaceutical Development

Change Control for IMPs

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

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 2

Programme 23 November 2022

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

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

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

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 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

Q&A Session 4

Programme 24 November 2022

Important Documents in Pharmaceutical Development

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

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

Sigrid Guhr, AbbVie Deutschland GmbH, Germany (form. Abbott)

Sigrid Guhr is a mathematician and leads 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 present responsibilities include validation, qualification, and compilation of quality management systems for the software life cycle, vendor audits, risk analyses, and concepts for data integrity assurance.

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.

Mag. Gabriela Schallmeiner, AQPA Deputy Chair, Inspection Ready Consulting, Austria

Gebriela Schallmeiner is working for the pharmaceutical Industry as consultant and Qualified Person. She has many years of experience in leading quality and QC functions and as QP. She is deputy Chair and founding member of the Austrian Qualified Person Association (AQPA).

Jef van Schuerbeek Consulting bvba, Belgium

Jef van Schuerbeek spent more than 20 years in pharmaceutical R&D, among others at Lilly Clinical Operations in Belgium, before he became a freelance consultant.

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GERMANY

Reservation Form (Please complete in full)

GMP meets Development
Live Online Training from 22–24 November 2022

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 %
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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.

Date of the Live Online Training

Tuesday, 22 November 2022, 09.00 – 17.15 h
Wednesday, 23 November 2022, 09.00 – 17.00 h
Thursday, 24 November 2022, 09.00 – 13.00 h

All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095

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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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