GMP meets Development
GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

SPEAKERS:

Sigrid Guhr
AbbVie, Germany

Sue Mann
Sue Mann Consultancy, U.K.

Elfriede Maus
AbbVie, Germany

Dr Bettina Pahlen
Quality x Pharma Consulting, Germany

Jef van Schuerbeek
Consulting bvba, Belgium

7 – 9 May 2019, Heidelberg, Germany

PROGRAMME:

- Legal Requirements and Authority Inspections
  - EU and FDA - what is really required
  - ICH Q8
  - Data Integrity
  - Pre-approval Inspections
  - GMP/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

New in Annex 13 of the EU GMP Guide: Detailed Commission guidelines on GMP for IMPs!

This education course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager”. Please find details at www.gmp-certification.eu
Objectives

During this 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?

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 course 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 course has been designed for R&D personnel involved in Pharmaceutical Development, IMP Manufacturing, Quality Control, Quality Assurance, and Regulatory Affairs.

Programme

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

IMP in the Context of ICH Q8, Q9, Q10 and Q12
- How to integrate Quality by Design
- Risk Analysis in pharmaceutical development
- Life cycle concept

Important Documents in Pharmaceutical Development
- Early documentation
- CTD
- PSF: style and content
- Case studies

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

Packaging and Supply of Clinical Trial Materials
- GMP requirements
- Quality control of packaging and labelling
- Handling and sourcing of comparators
- Randomisation and blinding

Change Control in Pharmaceutical Development and IMP Manufacturing
- What is required
- What is important
- What are the benefits
- How to implement

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?

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

Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the most frequent air connections in Europe. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

TLS: http://www.tls-heidelberg.de
PMJ: http://www.pmj-fahrservice.de
Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. http://www.bahn.de
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

The GMP/GCP Interface

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

Interactive Sessions:

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

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

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?

You will be able to attend 2 of these parallel sessions. Please choose the ones you like to attend when you register for the course.

Case Studies:

- How to handle Deviations in an R&D Environment
- How to implement a Cleaning Validation in Pharmaceutical Development

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.

- 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.

- Elfriede Maus, AbbVie Deutschland GmbH, Germany (form. Abbott)
  Elfriede Maus leads Regulatory Compliance and Inspection Management at AbbVie Deutschland GmbH & Co.KG in Ludwigshafen. Working in Pharmaceutical Industry for more than 30 years she gained broad knowledge of regulations in various GxP areas. In different roles within QA for marketed products and R&D QA, she was/is responsible for managing regulatory inspections carried out by regulators from all over the world. She is a certified Auditor for Quality Management.

- Dr Bettina Pahlen, Quality x Pharma Consulting GmbH, Germany
  Bettina Pahlen, PhD, studied pharmacy at the University of Muenster, Germany, graduated in pharmaceutical chemistry and performed post-docs in USA and Germany. During the last 15 years she worked at university, authority and in different areas of the pharmaceutical industry (R&D, manufacturing, quality control, quality assurance). Since July 2007, she has been working as a consultant in the pharmaceutical industry focussing on GxP Quality Assurance aspects.

- 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.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.
**Reservation Form**

**CONCEPT HEIDELBERG**

P.O. Box 10 17 64

69007 Heidelberg

Germany

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**Fees (per delegate plus VAT)**

- **ECA Members**: €1,790
- **APIC Members**: €1,890
- **Non-ECA Members**: €1,990
- **EU GMP Inspectorates**: €995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days and refreshments. VAT is reclaimable.

**Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

**Conference language**

The official conference language will be English.

**Organisation and Contact**

The ECA Academy has entrusted CONCEPT HEIDELBERG with the organisation of this event.

**CONCEPT HEIDELBERG**

P.O. Box 10 17 64

D-69007 Heidelberg

GERMANY

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**For questions regarding content:**

Dr Andrea Kühn-Hebecker (Operations Director) at +49 (0)6221/84 44 35, or per e-mail at kuehn@concept-heidelberg.de

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**For questions regarding reservation, hotel, organisation etc.:**

Mr Rouwen Schopka (Organisation Manager) at +49 (0)6221/84 44 13, or per e-mail at schopka@concept-heidelberg.de

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**Important:** Please indicate your company's VAT ID Number

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**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 process fees: Cancellation

- **until 2 weeks prior to the conference**: 10 %,
- **until 1 week prior to the conference**: 50 %,
- **within 1 week prior to the conference**: 100 %.

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**Privacy Policy:**

Concept Heidelberg will only use your personal data as stated in the privacy policy at http://www.gmp-compliance.org/eca_privacy.html.

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**Reservation Form**

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Please choose TWO sessions:

- Transition of GMP Requirements from Phase 1 to Phase 3 and the Interface to Development Work
- Stability Studies throughout the Development of a new Product

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**Date**

- **Tuesday, 7 May 2019, 10.00 – 17.00 h**
  (Registration and coffee 9.30 – 10.00 h)
- **Wednesday, 8 May 2019, 9.00 – 18.00 h**
- **Thursday, 9 May 2019, 8.30 – 13.15 h**