

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

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

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



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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.

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>

Lufthansa Bus: <http://www.transcontinental-group.com/en/frankfurt-airport-shuttles>

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>

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

IMPs 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

Participants' comments

"Presentations by Sue Mann were amazing: simple, complete, lively and powerful" AND "It is a great opportunity to discuss with other attendees and exchange on practices – learn from each other" - Isabelle Cochard, PhD, Sanquin Plasma Products, The Netherlands (June 2018)

"Good interactive session and workshops." - Kornelia Winiewska, ZF Polpharma S.A. (May 2017)



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.



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

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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
 Data Integrity

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
 P.O. Box 101764
 Fax +49 (0) 62 21/84 44 34
 D-69007 Heidelberg
 GERMANY

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:
 - until 2 weeks prior to the conference 10 %
 - until 1 week prior to the conference 50 %
 - within 1 week prior to the conference 100 %
 CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will 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 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

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 - 13.15h

Venue

Hotel Chester Heidelberg
 SRH Hotel Handels- und Betriebs GmbH
 Bonhoefferstraße 10
 69123 Heidelberg, Germany
 Phone +49 (0)6221 9983 700
 Email reservations@chester-heidelberg.de

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.

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