

## Speakers



Sigrid Guhr  
AbbVie, Germany



Sue Mann  
Sue Mann Consultancy, U.K.



Elfriede Maus  
AbbVie, Germany



Dr Bettina Pahlen  
Quality x Pharma Consulting



Jef van Schuerbeek  
Consulting bvba, Belgium

# GMP meets Development

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

17 – 19 November 2020 | Heidelberg, Germany



## 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

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

## Objective

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.

## Social Event

At the end 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.

## Programme

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

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- 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

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

### Important Documents in Pharmaceutical Development

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

### Analytical Development (ICH Q14)

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- 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

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

### Change Control in Pharmaceutical Development and IMP Manufacturing

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

### IMP Manufacturing: how much Qualification and Validation is needed?

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- 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)

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- 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

*„Good interactive session and workshops.“*  
Kornelia Wiśniewska, ZF Polpharma S.A.

*„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

*„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

## 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/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?



### 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.

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Reservation Form (Please complete in full)

## GMP meets Development, 17 – 19 November 2020, Heidelberg, Germany

Please choose TWO workshop 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

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)

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

CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

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 can-

cellation 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](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, 17 November 2020, 10.00 – 17.00 h

(Registration and coffee 9.30 – 10.00 h)

Wednesday, 18 November 2020, 9.00 – 18.00 h

Thursday, 19 November 2020, 8.30 – 13.15 h

## Venue

Heidelberg Marriott Hotel

Vangerowstrasse 16

69115 Heidelberg, Germany

Phone +49 (0)6221 – 908 0

Info.heidelberg@marriott.com

## 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 first & second day, business lunch on 3rd day 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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Conference language

The official conference language will be English.

## Organisation and Contact

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

CONCEPT HEIDELBERG

P.O.Box 10 17 64

69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

info@concept-heidelberg.de

[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

### For questions regarding content please contact:

Dr Andrea Kühn-Hebecker (Operations Director) at +49(0)62 21/84 44 35, or at [kuehn@concept-heidelberg.de](mailto:kuehn@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc. please contact:

Ms Marion Grimm (Organisation Manager) at +49(0)62 21/84 44 18, or per e-mail at [grimm@concept-heidelberg.de](mailto:grimm@concept-heidelberg.de).