ECA Academy
Your GMP/GDP Information Source

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

EU and FDA Perspective

SPEAKERS:

Natalie Kerns
Genentech/ Roche Group, USA

Dr Claudio Lorck
AbbVie, Germany

Sue Mann
Sue Mann Consultancy, U.K.

Jef van Schuerbeek
Consulting bvba, Belgium

10 – 12 May 2017, Prague, Czech Republic

PROGRAMME:

- Legal Requirements and Authority Inspections
  - EU and FDA - what is really required
  - ICH Q8
  - GMP in API Development
  - 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
  - APIs

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

GMP meets Development

10 – 12 May 2017, Prague, Czech Republic

Objectives

During this Course, specialists will share their **expert knowledge** about **all important GMP aspects** in Pharmaceutical Development and 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 and Q10?**

Complex challenges have to be faced to guarantee high quality products. The safety of the drug and hence the patient should be in the 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

IMPs in the Context of ICH Q8, Q9 und Q10

- 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

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. GMP in API Development

- ICH Q7, Chapter 19
- Useful other documents (CEFIC, APIC a.o.)
- Implementation of a QM System

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

Natalie Kerns
Genentech/ Roche Group, USA
Natalie Kerns is a Principle Technical Manager in IMP Quality Systems and Processes - Global Technical Development. Before that she held leading positions in Regulatory Affairs, Quality Assurance Change Control and Biochem Production Operations.

Dr Claudio Lorck, *Abbvie Deutschland GmbH, Germany (form. Abbott)*
Claudio Lorck is QP Lead for Clinical Product Supply EU. Before that he was Head of the Business Unit 'Clinical Trial Materials' and Qualified Person (QP) at Temmler. He started his career in Pharmaceutical Development, and became Quality Control Manager at Klinge Pharma. Later he was Quality Manager R&D and QP for IMPs at Fujisawa and Head of Clinical Trial Materials and QP at Astellas.

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.

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 frist course day, you are cordially invited to a social event in Berlin. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

GMP meets Development
10 – 12 May 2017, Prague, Czech Republic
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
- ☐ GMP in API Development

☐ 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)

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 %,
- until 1 weeks prior to the conference 50 %
- 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 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)

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

Wednesday, 10 May 2017, 10.00 – 17.00 h
(Registration and coffee 9.30 –10.00 h)
Thursday, 11 May 2017, 9.00 – 18.00 h
Friday, 12 May 2017, 8.30 – 13.15h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

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
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andrea Kühn-Hebecker (Operations Director) at +49-62 21/84 44 359, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at +49-62 21/84 44 22, or per e-mail at bach@concept-heidelberg

wa/vers1/21092016