EU and FDA Perspective

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

21 – 23 May 2014, Budapest, Hungary

SPEAKERS:

Dr Dietmar Gross
gmp experts, Germany

Joseph M. Jerkins
Genentech/ Roche Group, USA

Sue Mann
Sue Mann Consultancy, U.K.

Wolfgang Schmitt
Concept Heidelberg, Germany

Jef van Schuerbeek
Consulting bvba, Belgium

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

ECA ACADEMY

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

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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 usable 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 and Regulatory Affairs.

Social Event

On 21 May, you are cordially invited to a social event in Budapest. 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

- 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

Moderator

Wolfgang Schmitt, *Concept Heidelberg*

Speakers

Dr Dietmar Gross
gmp experts, Germany
Dr Dietmar Gross is Pharmacist and Senior Consultant. He gained industry experience at Holopack, a company offering parenteral process development, trial fillings and contract service manufacturing.

Joseph M. Jerkins
Genentech/ Roche Group, USA
Joseph Jerkins is Associate Director, IMP Quality Systems - Global Technical Development. Before that he held leading positions in IMP Quality Assurance, Biochem Operational Excellence and Cell Culture & Media Prep Production Operations.

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.

Wolfgang Schmitt
Concept Heidelberg, Germany
Before Wolfgang Schmitt started as Director Operations at Concept Heidelberg in 2006, he was Head of Quality Management at SOLIQS (Abbott's global Drug Delivery Business Unit) and later an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development QA, where he was responsible for GMP and GLP Compliance.

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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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21 – 23 May 2014, Budapest, Hungary
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)

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

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
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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 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 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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Date

Wednesday, 21 May 2014, 11.00 – 18.00 h
(Registration and coffee 10.30 – 11.00 h)
Thursday, 22 May 2014, 9.00 – 18.00 h
Friday, 23 May 2014, 8.30 – 14.30h

Venue of the Course

Hilton Budapest WestEnd
Váci út 1-3.
1062 Budapest
Hungary
Phone +36 1 288 5500
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Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
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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For questions regarding content:
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