EU and FDA Perspective

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

20 – 22 May 2015, Berlin, Germany

SPEAKERS:

Joseph M. Jerkins  
Genentech/ Roche Group, USA

Dr Claudio Lorck  
AbbVie, Germany

Sue Mann  
Sue Mann Consultancy, U.K.

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Concept Heidelberg, Germany

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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
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 20 May, 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.

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

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

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.

Moderator

Wolfgang Schmitt, Concept Heidelberg
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GERMANY

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Reservation Form (Please complete in full)

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20 – 22 May 2015, Berlin, Germany

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

Title, first name, surname

Company

Department

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. If you cannot take part, you have to inform us in writing.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation fee = 10% of the fee paid.

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