



With inside information of a former FDA Investigator and Compliance Officer

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

23 – 24 September 2010, Vienna, Austria

SPEAKERS:

Helen M Brannan

Vastern Consultants, U.K.

Dr Andreas König

form. Schering Plough

Wolfgang Schmitt

Concept Heidelberg, Germany

Jef van Schuerbeek

Consulting bvba, Belgium

Mark Tucker, Ph.D

*Genentech Inc., USA
former FDA Investigator and Compliance Officer*

Dr Hans-Peter Volkland

gmp-experts, Germany

PROGRAMME:

- Legal Requirements and Authority Inspections
 - EU and FDA – what is really required
 - GMP in API Development
 - PSF and CTD
 - Pre-approval Inspections
- GMP Issues and best Practices
 - Qualification and Validation
 - Analytical Development
 - IMP Manufacturing, Packaging and Supply
 - Outsourcing Activities
- Case Studies and practical Examples
 - Cleaning Validation
 - Deviations
 - Changes
 - Stability Studies
 - APIs

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Objectives

During this Course, specialists from the pharmaceutical industry and a former FDA Compliance Officer 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**? A lot of data gained in the development studies will later be documented in the CMC part of the submission and many development lots are produced on the same equipment where clinical trial batches are manufactured.

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 Group

This course has been designed for R&D personnel involved in pharmaceutical development, IMP manufacturing, quality control and regulatory affairs.

Moderator

Wolfgang Schmitt, *Concept Heidelberg*

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
- ICH Q8:
 - the intention,
 - what's it about
 - how it is changing Pharmaceutical Development

Mark Tucker, Ph.D.

Important Documents in Pharmaceutical Development

- Early documentation
- CTD
- PSF: style and content

Helen Brannan

Analytical Development

- From method development to method validation
- How to deal with genotoxic and other impurities
- Quality control and IMP release
- Analytical Qualification

Dr Andreas König

Packaging and Supply of Clinical Trial Materials

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

Jef Van Schuerbeek

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?

Dr Hans-Peter Volkland

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

Mark Tucker

Outsourcing in IMP-Manufacturing and Control

- Inhouse or Outsourcing?
- How to identify the ideal partner
- Risk-based qualification of suppliers and service providers
- Monitoring of the service quality

Helen Brannan

Interactive Sessions:

1. How to handle Changes in IMP Development and Manufacturing

- Change Management
- Changes in the process development
- IMPD-related changes

Dr Andreas König

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

Jef Van Schuerbeek

3. GMP in API Development

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

Dr Hans-Peter Volkland

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

Dr Hans-Peter Volkland

How to implement a Cleaning Validation in Pharmaceutical Development

Wolfgang Schmitt



Social Event

On 23 September, you are cordially invited to a social event in Vienna. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Helen M Brannan, *Vastern Consultants, U.K.*

Helen Brannan is an experienced Quality Assurance professional with over ten years experience in the biotech/ pharmaceutical industry, in both GMP and GCP regulated environments; with a strong background in R&D, Drug Development and Quality Control. She is a Qualified Person (QP) under the permanent provisions of EU Directive 2001/83/EC and established her own consultancy in 2008, providing a range of independent pharmaceutical quality assurance consultancy services primarily to companies engaged in product development and clinical trials.

Dr Andreas König, *Quality König, Germany*

Andreas König was Vice President Global Quality Operations Animal Health at Schering Plough. From 1997-2000 Dr Andreas König was head of QC and QA at the Friedberg site of Fresenius Kabi. In 2001 he moved to Intervet where he became Head of Quality Operations Pharma. In 2005 he was appointed Global Quality Director at Intervet and 2008 he became Vice President at Schering Plough. Since 2010 he is running his own consultancy business.

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 22 years in pharmaceutical R&D, among others at Lilly Clinical Operations in Belgium, before he became a freelance consultant.

Mark Tucker, Ph.D., *Genentech Inc., USA and former FDA Investigator and Compliance Officer*

Mark Tucker is Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he has the full strategic responsibility for GMP Compliance. Before joining Genentech in 2002, Mark was Director, Investigations Branch at U. S. Food and Drug Administration (FDA). He also served as an Investigator and Compliance Officer with the FDA, where he represented the FDA at meetings with firm management and industry groups outlining and defending FDA positions. He started his career as Assistant Professor at the University of Southern California and Adjunct Assistant Professor at the Research and Education Institute, Harbor/UCLA Medical Center.

Dr Hans-Peter Volkland, *gmp-experts, Germany*

Dr Hans-Peter Volkland has worked for several years in R&D and in various quality positions (QA, QC, Validation and Qualification). In 2001 he joined PCS (Pharmaceutical Consultancy Services) as Senior Consultant and Senior Auditor. In 2006 he set up his own consultancy company, focusing on GMP consulting, auditing and training for the Pharma and API business.

Easy Registration



Reservation Form:
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Reservation Form:
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Please choose TWO sessions: How to handle Changes in IMP Development and Manufacturing
 Stability Studies throughout the Development of a new Product
 Mr Ms GMP in API Development

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

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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 %.

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).

Date

Thursday, 23 September 2010, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 24 September 2010, 8.30 – 15.00 h

Venue

Renaissance Wien Hotel
Linke Wienzeile/Ullmannstr. 71
1150 Vienna
Austria
Phone +43 1 89 102
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Fees

ECA Members: € 1,521.- per delegate + VAT
APIC Members: € 1,605.- per delegate + VAT (does not include ECA Membership)
Non-ECA Members: € 1,690.- per delegate + VAT
EU GMP Inspectorates: € 845.- per delegate + VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all 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 conference. Please use this form for your room reservation or be sure to mention "VA 6451 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 12 August 2010. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.

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For questions regarding content:

Wolfgang Schmitt (Operations Director) at +49-62 21 / 84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Jessica Stürmer (Organisation Manager) at +49-62 21 / 84 44 43, or per e-mail at stuermer@concept-heidelberg.de.