



With inside information of a former FDA Investigator and Compliance Officer

# GMP meets Development

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

27 – 28 September 2012, Berlin, Germany

## SPEAKERS:

**Helen M Brannan**

*Vastern Consultants, U.K.*

**Wolfgang Schmitt**

*Concept Heidelberg, Germany*

**Jef van Schuerbeek**

*Consulting bvba, Belgium*

**Mark Tucker, Ph.D**

*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

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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

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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 Audience

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This course has been designed for R&D personnel involved in Pharmaceutical Development, IMP Manufacturing, Quality Control and Regulatory Affairs.

## Moderator

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Wolfgang Schmitt, *Concept Heidelberg*

## Programme

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### 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

### Important Documents in Pharmaceutical Development

- Early documentation
- CTD
- PSF: style and content

### 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

### 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

### 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

## Interactive Sessions:

### 1. How to handle Changes in IMP Development and Manufacturing

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

### 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 (CEPIC, 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



## Social Event

On 27 September, 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.

## 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.

### **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.

### **Mark Tucker, Ph.D.**, *former FDA Investigator and Compliance Officer*

Mark Tucker was a Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he had 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. Currently he is running his own consultancy business.

### **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:  
**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



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

### GMP meets Development

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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
  - 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:

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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).

#### Date

Thursday, 27 September 2012, 9.30 - 18.00 h  
(Registration and coffee 9.00 - 9.30 h)  
Friday, 28 September 2012, 8.30 - 15.00 h

#### Venue

RAMADA Hotel Berlin-Alexanderplatz  
Karl-Liebknecht-Straße 32  
10178 Berlin, Germany  
Phone +49 (0)30-3010 411 0  
Fax +49 (0)30-3010 411 550

#### Fees

ECA Members € 1,490.- per delegate + VAT  
APIC Members € 1,590.- 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 "ECA7338" to receive the specially negotiated rate (single room € 129,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 30 August 2012. 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:

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+49-62 21 / 84 44 39, or per e-mail at  
w.schmitt@concept-heidelberg.de.

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

Ms Nicole Bach (Organisation Manager)  
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