

SPEAKERS:

DR PETER BACHMANN

BfArM, Germany

DR JOSEF HOFER

exdra GmbH, Germany

DR HILTRUD HORN

*Horn Pharmaceutical
Consulting, Germany*

DR GERD JILGE

*Gerd Jilge, Boehringer Ingel-
heim Pharma GmbH & Co. KG,
Germany*

**DR WILHELM
SCHLUMBOHM**

Berlin, Germany

HILDE VANNESTE

*Janssen Pharmaceutica,
Belgium*



The new EU Variations Regulation and supporting Guidelines

8 – 9 June 2010, Heidelberg, Germany

HIGHLIGHTS:

- The new European Variations Procedure
- The CMDh Best Practice Guides and Explanatory Notes
- Pharmacovigilance Changes
- The supporting Guidelines and their benefit for the API Industry
- Documenting Variations
- Grouping Variations
- National, European and Global Changes
- Changes in manufacturing and analytical test procedures
- Changes in packaging material
- Variations and Lifecycle Management

Objectives

This conference is intended to provide guidance on the provisions laid down in the new EU variations regulation and the supporting guidelines. You will get to know how the new regulation works and you will learn about

- How to efficiently submit and process variations
- Which benefits the supporting guidelines provide and how to use them
- What has to be considered during documentation of a variations procedure
- How to handle changes in manufacturing and analytical test procedures
- How to handle changes in packaging material
- Changes and variations in the pharmacovigilance system

Participants will have the opportunity to choose 1 out of 3 parallel workshops dealing with

- Grouping of variations
- Classification of variations
- Best practice communication during processing of a variation

Background

On 24 November 2008 the Commission Regulation (EC) No. 1234/2008 was published, which defines a new procedure for handling variations to the terms of marketing authorisations. Article 4 of this regulation calls for detailed guidelines explaining the different categories of variations types as well as procedural questions on the documents to be submitted in each case. The new regulation applies from 1 January 2010 and is binding and directly applicable in all EU member states.

The new regulation is intended to simplify the handling of the variations procedure and to provide more flexibility in the submission and processing of variations. However the new provisions are still of considerable complexity and it will take some time until API manufacturers and the pharmaceutical industry will have gained experiences with this new regulation.

Target Audience

The conference is designed for all persons involved in the compilation of pharmaceutical dossiers for marketing authorisations who want to become familiar with the new EU variations regulation, in particular for personnel from Regulatory Affairs. Furthermore, the course will be of interest to personnel from Quality Units, Quality Control and Production of the pharmaceutical and the API industry.

Social Event

On Tuesday, 8 June 2010, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the most frequent air connections in Europe. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

Lufthansa Shuttle Bus: Even if you do not fly, you can take this bus. It leaves Frankfurt Airport approximately once an hour. Contact: www.ics-logistik.de, phone +49 (0)621 - 651 620.

HLS Airport Shuttle Service Frankfurt: Germany's most experienced Airport Shuttle Service HLS brings you promptly and reliably from the airport to your hotel. Contact: www.hls-online.de, phone +49 (0)6221 - 3893999.

Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and usually takes less than an hour to get to Heidelberg.

The new European Variations Procedure – an Overview

- General provisions of the Commission Regulation (EC) No 1234/2008
- Classification of variations
- Supporting Guidelines
- Handling of variations
- Expectations

Submission and Processing of Variations – the CMDh Best Practice Guides and Explanatory Notes

- Best practice guides for the processing of different types of variations
- Best practice guides for the processing of grouped applications
- Best practice guides on work-sharing and recommendations on unforeseen variations
- The explanatory notes on how to complete the Variation Application Form

Safety, Efficacy and Pharmacovigilance Changes

- Changes in the SmPC, labeling or package leaflet
- Changes in the SmPC, labeling or package leaflet of a generic medicinal product
- Variations related to
 - The legal status of a medicinal product
 - Therapeutic indications
 - Significant modifications of the SmPC due to new quality, pre-clinical, clinical or pharmacovigilance data
- Simplifications for changes in the pharmacovigilance system

The supporting Guidelines of the new Variations Regulation – What's in it for the API Industry

- Changes in manufacturing process
- Update of a CEP
- Scale Changes
- Change in API manufacturer
- Changes in specifications and test procedures
- Additionally listed changes

How to document a Variations Procedure

- Documentation requirements for different types of variations
- Timelines
- Efficient communication
- Hints and tips for lowering the workload

Grouping of Variations – Case Studies

- Cases for grouping variations according to Article 7 in connection with Annex III of the Commission Regulation
- Possibilities to combine several changes into one single application
- Examples

Handling National, European and Global Changes

Workshops

- I. Exercises for grouping of variations
- II. Exercises for classification of variations
- III. Best practice communication

- Changes in national applications
- Starting and processing the notification procedure within Europe
- Changes and variations in the US
- Handling global changes and variations

How to handle Changes in Manufacturing Processes

- Background
- How to implement Changes
- Changes in the Manufacture of APIs
- Changes in the Manufacture of Drug Products
- Practical Example: Manufacturing Sites outside the EEA

How to handle Changes in Analytical Test Procedures

Programme (cont.)

- Changes in test procedures for active substances
- Changes in test procedures for starting materials, reagents and intermediates
- Changes in test procedures for the finished product

How to handle Packaging Changes

- Background
- How to deal with these Changes
- Practical Examples: Change of Packaging for
 - Tablets
 - Sterile products

Variations and Lifecycle Management

- Reasons for variations
- Procedures and classifications
- Type II Variations: time scales
- Extension of an existing marketing authorisation
- Categorisation of new applications versus variation applications

Speakers

DR PETER BACHMANN, *BfArM, Germany*

In 1999, Peter Bachmann has joined the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of 'Drug Approval'. There he was Head of the Subunit 'Variations' and responsible for the coordination and administration of variations to medicinal products. From September 2002 to July 2005 he was Head of the Unit 'Mutual Recognition Procedures' at the Department 'European Procedures'. At this time he was the German representative to the MRFG (Mutual Recognition Facilitation Group). Following the reorganisation of the BfArM in July 2005, Peter Bachmann was appointed as Senior Expert for 'European Drug Regulatory Affairs' at Department 'European and International Affairs' and is the German Member of the CMD(h). He is also the German Member of the NtA, a member of different other European and AdHoc Working Parties, a lecturer for 'Drug Regulatory Affairs' at the Universities of Bonn and Duisburg-Essen.

DR. JOSEF HOFER, *EXDRA GmbH, Grafting, Germany*

Dr Josef Hofer is Managing Director of EXDRA (Excellence in Drug Regulatory Affairs) GmbH working in and for the international pharmaceutical industry since 1980. Dr Hofer holds a lectureship at the University in Bonn for Drug Regulatory Affairs.

DR HILTRUD HORN, *Horn Pharmaceutical Consulting, Germany*

Dr Hiltrud Horn is managing director of Horn Pharmaceutical Consulting. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affairs and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

DR GERD JILGE, *Boehringer Ingelheim GmbH, Ingelheim, Germany*

In 1991 Dr. Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures for new drug products. In 2000 Dr. Jilge changed to Corporate Dept Drug Regulatory Affairs (Boehringer Ingelheim GmbH) with the focus on the preparation of the CMC documentation for the submission of new drug products. Since July 2007 he has been working in the Department Quality on the development of new analytical procedures for the testing of new drug substances.

DR WILHELM SCHLUMBOHM, *Berlin, Germany*

20 years with German drug licensing authorities, assessment of CMC parts of new drug applications, regulatory affairs. Rapporteur for the Certification Procedure of the Ph.Eur.

HILDE VANNESTE, *Janssen Pharmaceutica, Belgium*

Started professional career at Janssen Pharmaceutica, a division of Johnson & Johnson in 1996 in technology transfer of API synthesis, moved 6 years later to API production and 2 years later to world wide regulatory affairs and compliance, initially for medicinal products and later on for active pharmaceutical ingredients. She represents Janssen Pharmaceutica in APIC (Active Pharmaceutical Ingredients Committee), is member of the APIC executive committee and is the task force leader for the update of the variation regulations within APIC.

GMP Certification Programme

This conference is recognised within the GMP Certification Programme Module "Regulatory Affairs Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

Certified Validation Manager (ECA)
Certified QA Manager (ECA)
Certified API Production Manager (ECA)
Certified Quality Control Manager (ECA)
Certified Technical Operations Manager (ECA)
Certified Computer Validation Manager (ECA)
Certified Regulatory Affairs Manager (ECA)
Certified Microbiological Laboratory Manager (ECA)
Certified Sterile Production Manager (ECA)
Certified Biotech Manager (ECA)
Certified Pharmaceutical Development Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:

During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:

The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>



About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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

Date

Tuesday, 8 June 2010, 9.00 – 18.15 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 9 June 2010, 8.30 – 16.00 h

Venue

Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 - 917 0
Fax +49 (0)6221 - 21007



Conference fees

Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
APIC Members € 1,605.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 845.- 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 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 6476 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 10 May 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.

CONCEPT HEIDELBERG

P.O. Box 10 17 64
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 Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Marion Grimm (organisation manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

+49 6221 84 44 34

The new variations Regulation and supporting Guidelines

8 – 9 June 2010, Heidelberg, Germany

Please choose one workshop

- Exercises for grouping of variations
- Exercises for classification of variations
- Best practice communication

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

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)!