ECA
European Compliance Academy

First experiences with the new Variations Regulation and supporting Guidelines

Handling Changes and Variations

15 – 16 March 2012, Vienna, Austria

SPEAKERS:

DR PETER BACHMANN
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DR WILHELM SCHLUMBOHM
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HIGHLIGHTS:

- The new European Variations Procedure
- The CMDh Best Practice Guides and Explanatory Notes
- Documenting Variations
- Grouping Variations
- National, European and Global Changes
- Changes in packaging material
- Changes in ASMFs and CEPs
- Variations and Lifecycle Management

This conference is recognised for the ECA GMP Certification Programme „Certified Regulatory Affairs Manager". Please find details at www.gmp-certification.eu

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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 procedures
- How to handle changes in packaging material
- How to manage changes in ASMFs and CEPs

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

- Grouping of variations
- Classification of variations

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 the evening of the first conference day 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.

Programme

The new European Variations Procedure – an Overview

- Introduction and legal background
- General provisions of the Commission Regulation (EC) No 1234/2008
- Supporting Guidelines
- Classification of variations
- Procedural handling of variations
- Grouping and worksharing of Variations
- Coordination group and arbitration
- Conclusion and 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 worksharing and recommendations on unforeseen variations
- The explanatory notes on how to complete the Variation Application Form

How to document a Variations Procedure

- Documentation requirements for different types of variations
- Timelines
- Why a Change Control System?
- Major parts of a Change Control SOP
- Efficient company internal communication
- Hints and tips for lowering the workload

Workshops

I. Exercises for grouping of variations
II. Exercises for classification of variations

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

How to manage changes in a multi customer situation using ASMFs or CEPs

Handling National, European and Global Changes

- Changes in national applications
- Variations Project Management
- Starting and processing the notification procedure within Europe
- Changes and variations in the US
- Handling global changes and variations
- Impact of Q8, Q9, Q10 and PAT

How to handle Changes in Manufacturing Processes

- Background
- How to implement Changes
- Changes in the Manufacture of APIs
  - Example: Minor change in the API synthesis
  - Example: Site change
- Changes in the Manufacture of Drug Products
  - Example: Minor process change
- Practical Example: Manufacturing Sites outside the EEA
  - Proof of GMP compliance of the new site
  - QP declarations

Programme (cont.)

How to handle Packaging Changes

- Background
  - Packaging information in Module 3
- How to deal with these Changes
- Key questions
- Practical Examples
  - Change in supplier
  - Change in the foil composition
  - Change of packaging for 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.

MARIEKE VAN DALEN, *MSD, The Netherlands*
Marieke van Dalen studied chemical technology. She joined MSD (then still known under the name of Diosynth) in 1986 as group leader for the documentation and registration group. Today Marieke is the senior scientific project leader within the Regulatory group dedicated to API's. Marieke is an active member of APIC, participating in the variations task force and the Japan task force, and often representing APIC in Interested Parties meetings organized by EMA, EDQM etc.

CAROLINE DOODKORTE, *Janssen Biologics B.V., The Netherlands*
Caroline Doodkorte joined Janssen Biologics B.V, previously known as Centocor B.V, a division of Johnson & Johnson, in 1990 in In-Process Control,. 3 years later she moved to Quality Control and 9 years later to the Global CMC Regulatory Affairs department. She participated in various local and global project teams representing Global CMC Regulatory Affairs responsible for the co-ordination, preparation and filing of numerous CMC variations related to Drug Substance as well as Drug Product. She was a member of the EBE comparability subgroup that generated the EBE comparability concept paper.

DR JOSEF HOFER, *EXDRA GmbH, 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 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.

Special offer with Lufthansa - up to 20% discounted travel for all ECA Events Attendees

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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 € 200 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

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
Thursday, 15 March 2012, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 16 March 2012, 8.30 – 16.00 h

Venue
Renaissance Wien Hotel
Linke Wienzeile/Ullmannstraße 71
1150 Vienna, Austria
Phone +43 (0)1 89 102
Fax +43 (0)1 89 102 300

Conference fees
ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
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 "ECA7201" 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 25 January 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, GERMANY
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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.

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Reservation Form (Please complete in full)

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Please choose one workshop
☐ Exercises for grouping of variations
☐ Exercises for classification of variations

☐ Mr ☐ Ms

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.
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 HEIDELBERGwill 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)!

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