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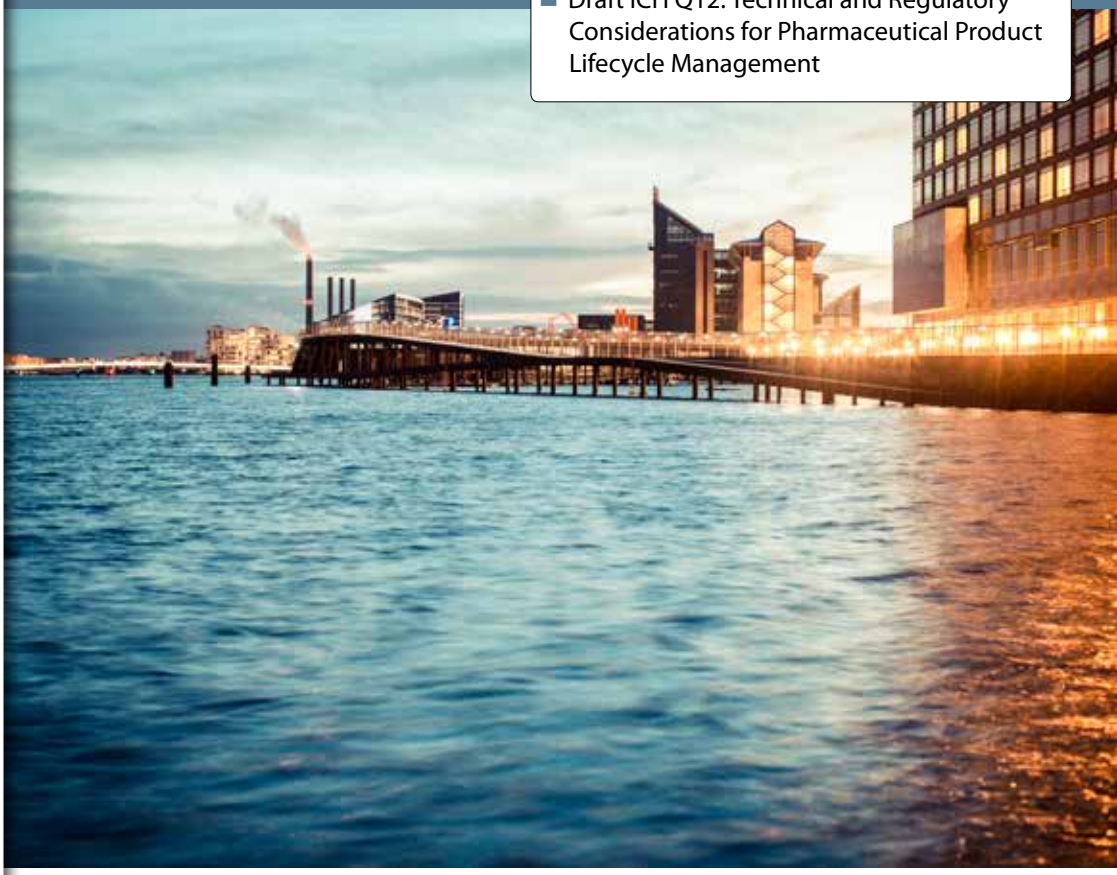
Handling Changes and Variations

- Brexit - and now? The latest updates!
- Draft ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management



Speakers:

Dr Peter Bachmann
BfArM, Germany

Mariska de Kleijn
Janssen Biologics B.V., The Netherlands

Dr Josef Hofer
exdra GmbH, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Wilhelm Schlumbohm
Berlin, Germany

Hilde Vanneste
Janssen Pharmaceutica NV, Belgium

26-27 March 2019, Copenhagen, Denmark

HIGHLIGHTS:

- The European Variations Procedure
- The supporting Guidelines on the categories of variations and the operation of the procedures
- 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 (Draft ICH Q12)

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

Handling Changes and Variations

26 – 27 March 2019, Copenhagen, Denmark

Objectives

This conference is intended to provide guidance on the provisions laid down in the EU variations regulation and the supporting guideline. You will get to know how the 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 2 parallel workshops dealing with

- Grouping of variations
- Classification of variations

Background

Since 1 January 2010 the Commission Regulation (EC) No. 1234/2008 is binding and directly applicable in all EU member states. It defines the 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. These Guidelines have been consolidated in one document and published as Chapter 5 of Eudralex Volume 2A (procedures for marketing authorization) in May 2013.

The variations 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 provisions are of considerable complexity and it is important for API manufacturers and the pharmaceutical industry to be well informed about the latest status of the details of the provisions about handling changes and variations.

Additionally, the draft of the new ICH Q12 Guideline has been published for comment in December 2017. It introduces new concepts to facilitate the management of post-approval CMC changes in a more predictable and efficient manner. These new concepts include, for example, “Established Conditions” and “Post-Approval Change Management Protocols” to extent regulatory flexibility.

Finally, a lot of regulatory work (e.g. variations) will have to be managed due to the Brexit, which is expected to happen in March 2019.

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 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

In 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 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
- Impact of Brexit
- 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

- Specific issues for API manufacturers
- Need for changes
- How to inform your customers and get feed-back
- Differences between ASMF and CEP
- When can you implement the change
- Conclusions

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, Q12 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 (Draft ICH Q12)

- Reasons for variations
- Procedures and classifications
- Type II Variations: time scales
- Extension of an existing marketing authorisation
- Categorisation of new applications versus variation applications
- Draft Q12: Established Conditions (ECs) and Post-Approval Change Management Protocols (PACMPs)

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.

MARISKA DE KLEIJN, *Janssen Biologics B.V., The Netherlands*
Mariska de Kleijn joined the Global CMC Regulatory Affairs department of Janssen Biologics B.V, a division of Johnson & Johnson, in 2006 Prior to Janssen Biologics, she worked at the regulatory affairs department of several pharmaceutical companies (Asta Medica, Solvay Pharmaceuticals and Astellas Pharma Europe) for a total of 10 years. During her 20 years of international regulatory experience she participated in various local and global project teams responsible for the co-ordination, preparation and filing of numerous CMC and clinical variations related to drug substance and drug product for chemical as well as biological products.

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 with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll / now Abbott in Ludwigshafen with global responsibility within QC/QA /Regulatory Affairs/ Project Management/Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business more than 13 years ago. She is pharmacist with a Ph.D. and holds a Diploma in Pharmaceutical Medicine (Basel). Furthermore she is specialised pharmacist for pharmaceutical analytics and for drug information.

DR WILHELM SCHLUMBOHM, *Berlin, Germany*
Dr Schlumbohm worked more than 25 years with German drug licensing authorities in the field of assessment of the CMC parts of new drug applications. He is a member of the Working Group on Active Substance Master File procedures.

HILDE VANNESTE, *Janssen Pharmaceutica NV, CMC Regulatory Affairs*
Ms Vanneste started her professional career at Janssen Pharmaceutica, a division of Johnson & Johnson, in technology transfer of API synthesis. Then she moved to API production, and in 2004 she moved to the world wide CMC regulatory affairs and compliance department, initially for medicinal products and later on active pharmaceutical ingredients and currently biotech products, where she now assumed a leadership role.

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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:

ECA 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 Certified GMP Auditor
ECA Certified GDP Compliance Manager
ECA Certified Packaging Manager
ECA Certified Data Integrity Manager

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.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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, 26 March 2019, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 27 March 2019, 8.30 – 16.00 h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 (0)33 96 50 00
Scandinavia.meetings.events@radissonblu.com

Conference fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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.

Conference Language
The official conference language will be English.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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
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E-mail: info@concept-heidelberg.de
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For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Director Operations) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Marion Grimm (Organisation Manager) at +49 (06221/84 44 18, or per e-mail at grimm@concept-heidelberg.de

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Handling Changes and Variations

26-27 March 2019, Copenhagen, Denmark

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 %.

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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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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