



Speakers



Peter Bachmann
BfArM Germany



George Hartong van Lokven
Aspen Oss B.V., The Netherlands



Josef Hofer
exdra GmbH, Germany



Hiltrud Horn
Horn Pharmaceutical Consulting,
Germany



Wilhelm Schlumbohm
Berlin, Germany

Handling Changes and Variations

21/22 April 2020 | Heidelberg, Germany



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 of Variations
- Classification of Variations
- National, European and Global Changes
- Changes in packaging material
- Changes in ASMFs and CEPs
- ICH Q12: Variations and Lifecycle Management

**The final ICH Q12 Post-Approval Changes
Guideline - The latest updates!**

Objective

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
- What is, and what is not, an established condition (EC) according to ICH Q12?

Participants will have the opportunity to choose 1 out of 2 parallel workshops dealing with

- Grouping of variations
- Classification of variations (APIs)

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 final ICH Q12 Guideline for post-approval changes is expected to be published by the end of 2019. The guideline will introduce new concepts to facilitate the management of post-approval CMC changes in a more predictable and efficient manner. The new ICH Q12 concepts include, for example, "Established Conditions" (ECs) and "Post-Approval Change Management Protocols" (PACMPs) to extent regulatory flexibility.

Finally, a lot of regulatory work (e.g. variations) will have to be managed due to the Brexit.

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 conference will be of interest to personnel from Quality Units, Quality Control and Production of the pharmaceutical and the API industry.

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 & ICH Q12

- 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
- ICH Q12
 - What is, and what is not, an established condition subject to post-approval change reporting requirements?
 - Expected timelines for ICH Q12 implementation

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
- Post Approval Change Management Protocol (PACMP)

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



Workshops

1. Exercises for grouping of variations
2. Exercises for classification of variations - API related changes categorization differences worldwide

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

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

ICH Q12 - 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
- Established Conditions (ECs) and Post-Approval Change Management Protocols (PACMPs)

Speakers



Dr Peter Bachmann,
BfArM, Germany

Peter Bachmann has joined in 1999 the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of 'Drug Approval'. He was there as Head of the Subunit 'Variations' 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.



George Hartong van Lokven,
Aspen Oss B.V., The Netherlands

George was leading the Hematology and Clinical Chemistry department at a toxicological research (contract) laboratory in 's-Hertogenbosch prior to becoming active in quality- and project management at the same company. Since 2002 he is active in API registrations and currently he works as Regulatory Scientist CMC for Aspen Oss B.V.



Dr Josef Hofer,
exdra GmbH, Germany

Dr Josef Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs.). Working for and in 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.

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.



Date

Tuesday, 21 April 2020, 9.00 – 17.30 h

(Registration and coffee 8.30 – 9.00 h)

Wednesday, 22 April 2020, 8.30 – 16.00 h

Venue

Heidelberg Marriott Hotel

Vangerowstraße 16

69115 Heidelberg, Germany

Phone +49 (0)6221 – 908 0

Email Info.heidelberg@marriott.com

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.

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 course. Reservation should be made directly with the hotel.

Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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

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For questions regarding reservation, hotel,

organisation etc. please contact:

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thiel@concept-heidelberg.de

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.

TLS:

<https://www.tls-heidelberg.de/en/>

Lufthansa Airport Shuttle:

<https://frankfurt-airport-shuttles.palisis.com/?locale=en>

HLS:

<http://www.hls-online.com/PCS-Flughafentransfer.html>

Train:

You can also take a train to get from/to the airport, which takes less than one hour. <https://www.bahn.com/en/view/index.shtml>

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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 – otherwise the booking platform window will not open.

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

Reservation Form (Please complete in full)

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Please choose ONE workshop

- Exercises for grouping of variations
 Exercises for classification of variations

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

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 %
- Cancellation until 1 week prior to the conference 50 %
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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)! (As of January 2012). German law shall apply. Court of jurisdiction is Heidelberg.

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