ECA Academy
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GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Dr Peter Bachmann
BfArM, Germany

Marieke van Dalen
MARA Consultancy, The Netherlands

Dr Josef Hofer
exdra, Germany

Dr Wilhelm Schlumbohm
Berlin, Germany

NEWS

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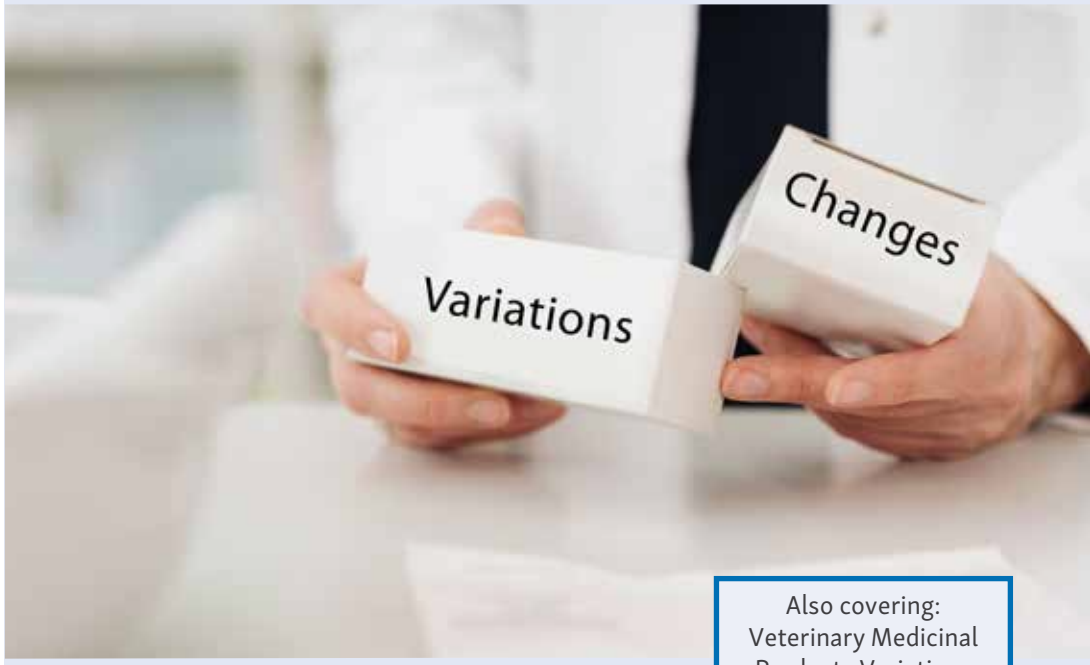
Handling Changes and Variations

05/06 November 2025 | Vienna, Austria



Also covering:
Veterinary Medicinal Products Variations

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
- Variations in Packaging
- Changes in ASMFs and CEPs
- ICH Q12: Variations and Lifecycle Management

Objective

This education course 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
- How to handle the complexity of the global supply chain
- How to handle changes in API manufacturing processes
- 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 was published in March 2020. The guideline introduces 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) needs to be managed due to the Brexit.

Target Audience

The education course 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 education course 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

Veterinary Medicinal Products Variations

- Regulatory basis for variations to veterinary medicinal products - what are the differences to the human provisions
- Two categories of variations:
  - Variations that do not require assessment (VNRA)
  - Variations that do require assessment (VRA)
- Veterinary variation guidance (Classification Guideline)

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

The Complexity of the Global Supply Chain

- The global API supply chain
- How to deal with different expectations
- International collaboration
- Differences between registered processes

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 world wide

How to manage API Changes in a Multi-Customer Situation using ASMFs or CEPs

- Why would you need to file a change
- Communication with the customers
- Differences between ASMFs and 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, Q12 and PAT

How to handle Changes in API Manufacturing Processes

- Examples of changes
- How to categorize a change
- What information to provide to whom

Variations in Packaging

- Container closure systems of medicinal products
- Packaging materials qualification & specification
- Variations in drug product manufacturing
- Regulatory documentation and strategy

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

In 1999, Peter Bachmann has joined 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.

Marieke van Dalen
MARA Consultancy, The Netherlands

Marieke van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. Marieke has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with helath Authorities all around the world.

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 Wilhelm Schlumbohm
Berlin, Germany

Dr Schlumbohm worked 30 years with German drug licensing authorities. He was an expert for the Certification Procedure of the European Pharmacopoeia and a member of the TAB for several years. He was also a member of the ASMF working group, and the CVMP co-opted member for quality. He is a pharmacist, holds a Ph D in biochemistry, and is further qualified as pharmacist for drug information and for public health.

Social Event

In the evening of the first course 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.

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GERMANY

Reservation Form (Please complete in full)

Handling Changes and Variations, 05/06 November 2025, Vienna, Austria

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 4 weeks prior to the conference 10 %,
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- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Wednesday, 05 November 2025, 9.00 – 17.30 h CET
(Registration and coffee 8.30 – 9.00 h) CET
Thursday, 06 November 2025, 8.30 – 14.00 h CET

Venue

Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Email info@doubletree-schonbrunn.at

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes 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.

Presentations / Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21921.

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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