ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Peter Bachmann
BfArM Germany

Marieke van Dalen
Aspen Oss B.V., The Netherlands

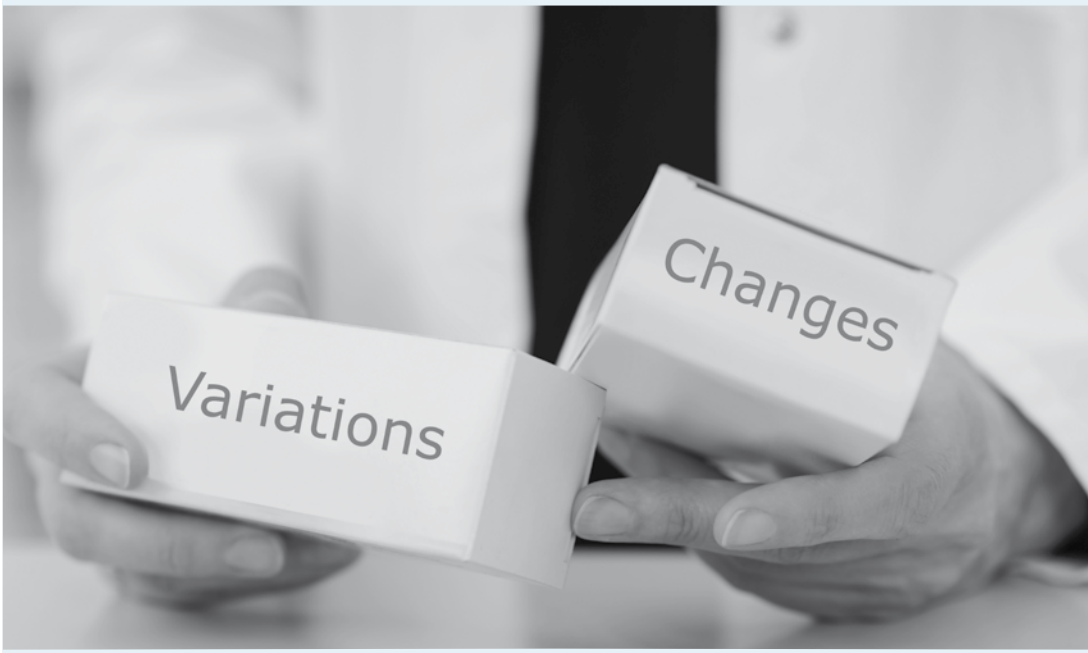
Josef Hofer
exdra GmbH, Germany

Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Wilhelm Schlumbohm
Berlin, Germany

Handling Changes and Variations

Live Online Training on 14/15 April 2021



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

ICH Q12 Post-Approval Changes Guideline - How to use the PACMP in Practice

Programme

Objective

This Live Online Training 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
- How to deal with PACMPs in practice?
- What is, and what is not, an established condition (EC) according to ICH Q12?

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 has been published and is now being implemented in the ICH regions. 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) will have to be managed due to the Brexit

Target Audience

The Live Online Training 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 Live Online Training will be of interest to personnel from Quality Units, Quality Control and Production of the pharmaceutical and the API industry.

Programme Day 1

Provisional timetable, the actual schedule may vary depending on the situation

09.00 - 09.15 h Welcome/Introduction

09.15 - 10.15 h 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

10.15 - 10.30 h Break

10.30 - 12.30 h (including 10 Minutes Break) 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

12.30 - 13.00 h Q&A Session 1

13.00 - 14.00 h Break

14.00 - 14.45 h Grouping of Variations – Case Studies / Examples

- 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

14.45 - 15.45 h 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

15.45 - 16.00 h Break

16.00 – 17.00 h Examples for classification of variations - API related changes categorization differences World Wide

17.00 - 17.30 h Q&A Session 2

Programme Day 2

09.00 - 10.00 h 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)

10.00 - 10.45 h 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

10.45 - 11.00 h Break

11.00 - 12.00 h 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

12.00 - 12.30 h Q&A Session 3

12.30 - 13.30 h Break

13.30 - 14.30 h 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

14.30 - 14.45 h Break

14.45 - 15.30 h 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
- ICH Q12: Established Conditions (ECs) and Post-Approval Change Management Protocols (PACMPs)

15.30 - 16.00 h Q&A Session 4

Speakers

Dr Peter Bachmann
BfArM, Germany

Peter Bachmann has joint 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.

Marieke van Dalen
Aspen Oss B.V., The Netherlands

Marieke van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with over 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in a number of task forces. Marieke frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI etc.

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 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 PhD in biochemistry, and is further qualified as pharmacist for drug information and for public health. Currently he works as external advisor to drug regulatory authorities.

Date of the Live Online Training

Wednesday, 14 April 2021, 9.00 – 17.30 h
Thursday, 15 April 2021, 9.00 – 16.00 h

All times mentioned are CEST.

Technical Requirements

For our Live Online Training Courses, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or per e-mail at
kuehn@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49 (0)62 21/84 44 43, or per e-mail at
thiel@concept-heidelberg.de

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:„… All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,…". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

Handling Changes and Variatons is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. The Live Online Training „Handling Changes and Variations" is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP: APIs (ICH Q7); Medicinal Products; Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Technical Operations
- Medical Devices
- Packaging

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Why not online? GMP/GDP seminars, webinars and eLearning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Handling Changes and Variations
Live Online Training on 14/15 April 2021

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 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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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