



- Including
- Technical Changes
 - Process Changes
 - Variations

Change Control

New Aspects and best Practices

13-14 March 2012, Berlin, Germany

SPEAKERS:

- Richard M. Bonner**
*ECA Director Regulatory Affairs,
formerly with Eli Lilly*
- Dr Hiltrud Horn**
Horn Pharmaceutical Consulting
- Aidan Madden**
FivePharma
- Dr Cornelia Nopitsch-Mai**
Federal Ministry of Health (BMG), Germany
- Rico Schulze**
Local Authorities Dresden, Germany

HIGHLIGHTS:

- GMP and Regulatory Compliance
 - EU
 - FDA
 - European Variation Procedure
- The Change Control Process
 - Responsibilities
 - Change Control Request
 - Implementation of Changes
 - Technical changes
 - Risk Analysis
 - Classification of Changes
 - Documentation
- Workshop on Case Studies
- Interactive Session on the implementation and improvement of a Change Control System
- Examples for various Variations



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Objectives

During this course, you will **learn all relevant** aspects to implement and/ or improve your Change Control System fulfilling the regulatory GMP requirements. **You will get to know the whole process from initiation over implementation to regulatory submissions.** You will also have the possibility to work on practical examples.

Background

Change control systems should be an integral part of the quality management system of each company. Their task and aim is to ensure that all announced or requested changes are carefully checked and completely documented and authorised.

Before starting implementing the change, questions need to be answered like:

- How is the change classified?
- Is it a variation or a change?
- Who needs to be informed?
- What are the regulatory consequences?

A sound change control system is used to manage changes of all types. The Change Control process is necessary to prevent inappropriate changes from occurring. All GMP-relevant changes should only be made with a complete review and approval of the QA and any other department that might be impacted by the change.

Only if all functions involved in the process are working together and know what needs to be considered, the change control process will run smoothly and fast enough to benefit from the change.

It is of high importance to know all relevant aspects of the whole change control process and the consequences a change might have.

Target Group

This course is designed for all personnel involved in the Change Control process at their company and for decision makers who want to improve the existing systems. It is addressed to persons from Manufacturing, Quality Control and Quality Assurance but also from Regulatory Affairs.

Programme

Change Control: GMP Requirements

- European Requirements
- When to contact authorities
- Changes in personnel
- SMF changes
- Change Control in the light of inspections

How to handle changes in US

- 21 CFR 314.70
- Changes to an approved NDA and ANDA
- Examples (PAS, CBE, AR)
- Annual Report
- BACPAC – what now?

The Change Control Process through the product life cycle –how to manage it, who’s involved and when does it apply

- The importance of Change Control
- GMP-compliant Change Control
- Responsibilities
- General Requirements
- Implementation of Changes

Interactive Session:

How to implement a comprehensible Change Control Process in your company

- Change Control Handbook
- SOPs
- Forms

with practical advice how to implement and use them.

What’s a change and how to proceed

- Technical changes: Change Control or not
- How to deal with software updates
- Risk Analysis in Change Control
- Classification of Changes
- How to document changes

Workshop:

An interactive exercise to examine and evaluate some real examples of various changes.

The European Variation Procedure

- The new European Variations Regulation
- What needs to be submitted
- Grouping and Worksharing
- Line Extensions

Presentation and Discussion of examples for Variations:

- Type II Variation, Type IA or IB Notification.
- Variations in manufacturing process
- Variation analytical method
- Changes of composition and ingredients
- Changes of packaging material

Social Event

At the end of the first day of the course you are invited to take part in an evening programme. This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.



Speakers

Richard M. Bonner

ECA, formerly with Eli Lilly, U.K.

Dick Bonner is Regulatory Affairs Director at the ECA and also works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. Dick Bonner is a Qualified Person in Europe.

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 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.

Aidan Madden

FivePharma, Ireland

Aidan Madden is Managing Director and Senior Consultant with FivePharma. Before that he was Quality Manager at Wyeth, Senior Microbiologist at Baxter and QC Manager at Fort Dodge Laboratories. He was also working at Teagasc, a government research laboratory and at the National University of Ireland in Galway.

Dr Cornelia Nopitsch-Mai

Federal Ministry of Health (BMG), Germany

Dr Cornelia Nopitsch-Mai is scientist at the Federal Institute for Drugs and Medical Devices (BfArM) in the assessment of the quality part of the dossier. Currently she is located at the Federal Ministry of Health in Berlin. From 2000 to 2003 she was Assessor for the Certification Procedure (EDQM) in Strasbourg. Since 2003 she is member of the Technical Advisory Board (TAB) and she is the chairperson of the TAB since 2005.

Rico Schulze

Local Authorities Dresden, Germany

Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden. From 2008 to 2011 he was working at the Saxon State Ministry of Social Affairs. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group, and a member of the Expert Group on Medicinal Gases.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme "Certified Quality Assurance Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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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.

Easy Registration



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Date

Tuesday, 13 March 2012, 9.30 – 17.30 h
(Registration and coffee 9.00 - 9.30 h)
Wednesday, 14 March 2012, 8.30 – 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
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Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
(does not include ECA Membership)
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. Reservation should be made directly with the hotel not later than 12 February 2012. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "ECA 7135" to receive the specially negotiated rate (€ 125,- per night, incl. breakfast) for the duration of your stay. 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

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