Including
- Technical Changes
- Process Changes
- Examples for Variations

Change Control
New Aspects and best Practices

18-19 June 2015, Vienna, Austria

SPEAKERS:

Richard M. Bonner
ECA Chairman,
formerly with Eli Lilly, UK

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Aidan Madden
FivePharma, Ireland

Rico Schulze
GMP Inspectorate, Germany

HIGHLIGHTS:

- GMP and Regulatory Compliance
  - EU
  - FDA
  - European Variation Procedure
- The Change Control Process
  - SOPs needed
  - Responsibilities
  - Change Control Request
  - Implementation
  - Technical Changes
  - Risk Management
  - Classification of Changes
  - Documentation
  - Quality Metrics
- Workshops on Examples and Case Studies
- Examples for various Variations

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Change Control – News Aspects and Best Practices

18-19 June 2015, Vienna, Austria

Objectives

During this course, you will **learn all relevant** aspects to implement and/ or improve your Change Control System fulfilling regulatory and 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 (QMS) 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 a quality function 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 from Regulatory Affairs.

Programme

Change Control: GMP Requirements

- European Requirements
- When to contact authorities
- Changes in key 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
- Comparability Protocol (US) vs. Change Management Protocol (EU)

The Change Control Process through the Product Life Cycle (Part 1): 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 System in your Company

- EU Variation Procedure
- Change Control Handbook
- SOPs
- Change Control Protocol
- Forms

with practical advice how to implement and use them

List of examples:

As a delegate you will get a comprehensive list of examples for Variations.

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

The Change Control Process through the Product Life Cycle (Part 2):
Risk Management and Quality Metrics

- The final review and evaluation after implementation
- CC effectiveness check
- Applicable KPIs and Quality Metrics

Workshops:
Interactive exercises to examine and evaluate some real examples of various changes:

- Manufacturing process
- Cleaning process
- Analytical process
- Microbiological testing
- IMPD
- Manufacturer's Authorisation

Social Event

At the end of the first day of the course you are invited to take part in an evening program in the beautiful city of Vienna. 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 Chairman of the ECA and the European QP Association. He 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 Affaires 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 CEO of FivePharma, a Quality Services Company which he set founded in 2003. Prior to setting up FivePharma Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories. Aidan holds a BS Degree in Biochemistry and an MS Degree in Immunochemistry as well a Higher Diploma in Pharmaceutical Manufacturing Technology and a Professional Teaching Qualification.

Rico Schulze
GMP Inspectorate, 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 Affaires. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Change Control – New Aspects and Best Practices
18-19 June 2015, Vienna, Austria

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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

D-69007 Heidelberg
GERMANY

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. 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)

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

Thursday, 18 June 2015, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 19 June 2015, 8.30 – 15.30 h

Venue

Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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 when you have registered for the event. 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
P.O.Box 10 17 64
69007 Heidelberg, Germany,
Phone +49 (0)62 21/84 44-0
Fax +49 (0)62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Wolfgang Schmitt (Operations Director)
at +49 (0)62 21 / 84 44 39 or at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager)
at +49-62 21/84 44 51 , or per e-mail at
strohwald@concept-heidelberg.de.