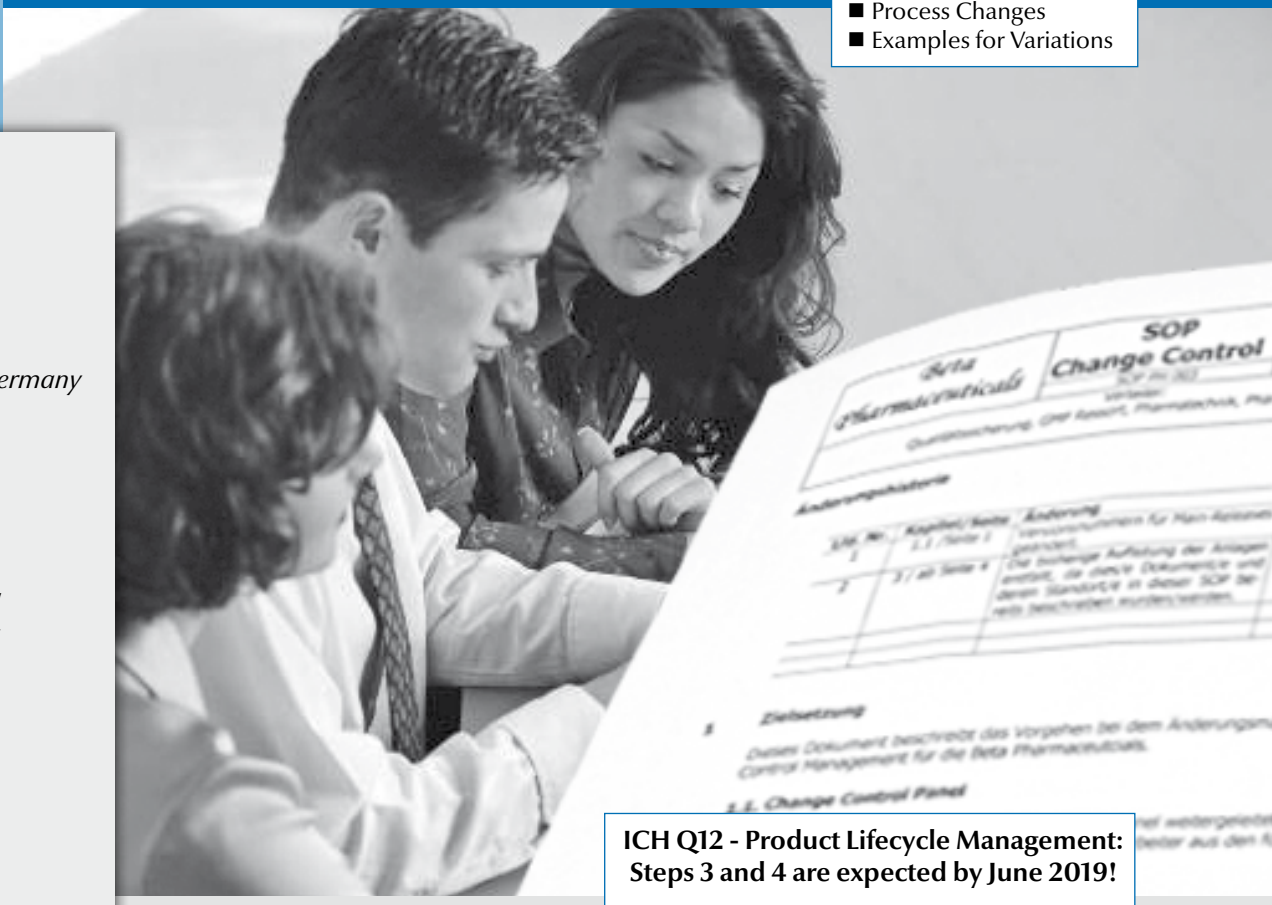
20 YEARS ECA Academy
Your GMP/GDP Information Source

Change Control
New Aspects and Best Practices

Including
- Technical Changes
- Process Changes
- Examples for Variations



ICH Q12 - Product Lifecycle Management: Steps 3 and 4 are expected by June 2019!

SPEAKERS:

Dr Rainer Gnibl
GMP Inspectorate, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Aidan Madden
FivePharma, Ireland

Dr Martin Melzer
Chemgineering, Germany

8-9 October 2019, Heidelberg, 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

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

Change Control – New Aspects and Best Practices

8-9 October 2019, Heidelberg, Germany

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 - Inspectors Expectations for GMP Compliance

- Essentials for SOP on Change Control
- Internal & external Changes
- PQS Interfaces
- EU requirements
- Change in Quality-Culture?

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)

Change Control Management; General Points to Consider: How to manage it, who's involved and when does it apply

- Identification and classification of changes
- Risk and impact analysis of changes
- Change control as management tool
- Management of changes with suppliers and contractors

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

Change Control in the context of Product Lifecycle Management

- Product Development Strategies and Change Control
- Post Approval Change Management/ Comparability Protocols
- ICH Q 12 Product Lifecycle Management

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

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.

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: http://www.tls-heidelberg.de

Lufthansa Bus: http://www.transcontinental-group.com/en/frankfurt-airport-shuttles

PMJ: http://www.pmj-fahrservice.de

Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. http://www.bahn.de

Speakers

Dr Rainer Gnibl

GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for theDistrict Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

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.

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.

Dr Martin Melzer

Chemgineering Business Design GmbH, Germany

Dr Martin Melzer is Senior Consultant GMP Compliance. Before that he was GMP Inspector in a German Field Inspectorate in Hannover. During that time he was representing the German inspectorates in EMA and PIC/S Working Groups for the preparation of the new GDP Guidelines. He was heading the GDP Expert Group of the German GMP inspectors from 2008 up to 2011. Before that he was working at Solvay Pharmaceuticals GmbH and a company of the Diapharm 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
8-9 October 2019, Heidelberg, Germany

☐ 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
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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 %.

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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.

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

Tuesday, 8 October 2019, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 9 October 2019, 8.30 – 15.30 h

Venue

Hotel Chester Heidelberg
SRH Hotel Handels- und Betriebs GmbH
Bonhoefferstraße 10
69123 Heidelberg, Germany
Phone +49 (0)6221 9983 - 700
Email info@chester-heidelberg.de

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 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.

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For questions regarding reservation, hotel, organisation etc. please contact:
Ms Sonja Geppert (Organisation Manager) at +49-62 21/84 44 16, or per e-mail at geppert@concept-heidelberg.de.