ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Rainer Gnibl
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Change Control

New Aspects and Best Practices

6/7 October 2020 | Vienna, Austria

Highlights

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

The final ICH Q12 Post-Approval Changes Guideline - The latest updates!

Objective

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.

Particularly noteworthy is the adoption of the new ICH Q12 Guideline "Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management", which was finalised in Singapore by the ICH Q12 Working Group in November 2019. This guideline aims to promote innovation and continual improvement, and strengthen quality assurance and reliable supply of product, including proactive planning of global supply chain adjustments.

Target Audience

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 - 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 / Established Conditions (ECs)
- 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.

Speakers

Dr Rainer Gnibl
GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District 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 (Fachapotheker für Pharmazeutische Analytik, Fachapotheker für Arzneimittelinformation).

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.

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GERMANY

Reservation Form (Please complete in full)

Change Control, 6/7 October 2020, Vienna, Austria

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)

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 6 October 2020, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 7 October 2020, 8.30 – 15.30 h

Venue
Radisson Blu
Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
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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 course. 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.

Certificate of Participation
Shortly after the event, you will receive your certificate of participation by email.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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