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GMP Certification Programme
Certified Quality Assurance Manager

Speakers



Dr Rainer Gnibl
GMP Inspectorate, Germany



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Germany



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Dr Martin Melzer
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Change Control

New Aspects and Best Practices



Live Online Training on 6/7 October 2020



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
- Examples and Case Studies
- Examples for Various Variations

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

Objective

During this Live Online Training, 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 discuss practical examples during several Q&A sessions.

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 Live Online Training 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 Day 1

09.00- 09.15 h Welcome/Introduction

09.15 - 10.15 h

Change Control - Inspectors Expectations for GMP Compliance

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

10.15 - 12.00 h (includes Coffee Break from 10.45 - 11.00 h)
Change Control Management; General Points to Consider: How to manage it, who's involved and when does it apply

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

12.00 - 12.30 h

Q&A Session 1

12.30 - 13.30 h Lunch Break

13.30 - 15.30 h

How to implement a comprehensible Change Control System in your Company

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- 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.

15.30 - 15.45 h Coffee Break

15.45 - 16.45 h

Change Control in the context of Product Lifecycle Management:

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- Product Development Strategies and Change Control
 - Post Approval Change Management/ Comparability Protocols / Established Conditions (ECs)
 - ICH Q 12 Product Lifecycle Management

16.45 - 17.15 h

Q&A Session 2

Programme Day 2

08.30 - 09.15 h Case Studies/Examples

09.15 - 10.15 h

How to handle Changes in the 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)

10.15 - 10.30 h Coffee Break

10.30 - 11.30 h

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

11.30 - 12.15 h



Case Studies/Examples
of various changes:

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

12.15 - 13.00 h

Q&A Session 3

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.

Speakers



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

Dr Rainer Gnihl 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 Gnihl 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.



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
gempex GmbH, Germany

Dr. Martin Melzer is Principal Consultant at gempex GmbH, Germany. Before that he was consultant for GMP/ GDP aspects, GMP -Inspector in a German Field Inspectorate in Germany, QA/ QC manager at a production site for API and finished products, and head of laboratory for plant medicinal products.

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Reservation Form (Please complete in full)



Change Control
Live Online Training on 6/7 October 2020

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Date of the Live Online Training

Tuesday, 6 October 2020, 9.00 – 17.15 h CEST

Wednesday, 7 October 2020, 8.30 – 13.00 h CEST

Technical Requirements

For our webinars, 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.

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