



GMP Webinar

ICH Q10

The integration of pharmaceutical Quality Systems

Date:

Wednesday, 08 July 2020, 14.30 -16.00 h CEST

Speaker:

Christof Langer, OSConsulting



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background

Already in 2008, the International Council for Harmonisation (ICH) published the guideline ICH Q10 Pharmaceutical Quality Systems. This was adopted within the EU in Part 3 of the GMP Guidelines.

The document has created a regulatory basis for new, modern quality assurance systems (to be mentioned here are, among others, knowledge management, quality risk management, elements of continuous improvement, etc.) and emphasises the importance and management responsibility. The elements have been adopted in other chapters of the EU-GMP Guidelines and should be applied appropriately for each of the product lifecycle stages. Unfortunately, not all pharmaceutical companies have yet managed to integrate the systems effectively and successfully.

Educational Objectives

This webinar is designed to explain the regulatory requirements and their practical implementation in the pharmaceutical industry. This is conveyed through various examples.

Target Audience

This webinar is designed for those who deal with the topic of pharmaceutical quality systems and are looking for solutions and/or optimisation possibilities.

Speaker



Christof Langer
OSConsulting

Christof Langer is a biotechnologist and business economist, certified risk manager as well as Lean Six-Sigma Black Belt and a certified pharmaceutical auditor. Since 2009 he is an independent consultant and co-founder of biotechnology start-up companies in the field of allergy and oncology. Prior to that he was Managing Director at Baxter Bio-Science (now Shire) in Switzerland and the Czech Republic, responsible for operations.

Fees (plus VAT)

Single participation: € 199,- for ECA Members

Single participation: € 249,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at

<https://www.gmp-compliance.org/about-the-academy>).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons € 211,65

11-20 Persons € 186,75

more than 20 Persons € 161,85

Registration

By mail, fax, e-mail or online on the Internet at

<https://www.gmp-compliance.org/>. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

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Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Phone +49(0)6221 / 84 44-0, Telefax +49(0)6221 / 84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content please contact:

Wolfgang Schmitt, phone +49(0)62 21 - 84 44 39

E-mail: w.schmitt@concept-heidelberg.de

For questions regarding organisational aspects please contact:

Ms Isabell Neureuther, phone +49(0)62 21 - 84 44 49

E-mail: neureuther@concept-heidelberg.de

Registration for the GMP-Webinar: "ICH Q10"
on Wednesday, 08 July 2020, 14.30 - 16.00 h CEST

Speaker: Christof Langer

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important:
Deadline for registration is
12 noon on 07 July 2020

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