



GMP Webinar

GMP Update 2015/2016

Date:

Tuesday, 08 December 2015, 15.00 – 16.30 h CET

Speaker:

Dr Bernd Renger



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

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GMP Update 2015/2016

Background

One might easily get the impression that the GMP world is continuously turning faster. Laws, regulations, and especially GMP or GDP requirements of the EU are constantly renewed, modernised and adapted against each other. To provide you with an overview is thus the goal of this webinar.

Educational Objectives

This webinar aims at giving you a comprehensive but still compact overview about the many innovations in the GMP area – those already realised and those planned:

- EU Directives
- EU-GMP Guide
 - Chapters 3, 5, 6 and 8
 - Annexes 1, 15, 16
- Guidelines on GDP for APIs
- Guidelines on risk assessment for excipients
- News from FDA
- MHRA's Data Integrity Guidance
- 2016 outlook

Target Audience

The webinar targets executives and staff in the pharmaceutical industry, who want to get a compact but yet comprehensive overview of all recent changes in the GMP requirements.

Speaker

**Dr Bernd Renger**

Dr Renger is a Qualified Person and runs his own consultancy. Prior to that he was VP Quality Control at Vetter Pharma-Fertigung GmbH. He began his career at Hoechst AG in 1977 and has since held various management positions in the quality area at Mundipharma, Byk Gulden (today Takeda), as well as at Baxter BioScience AG in Vienna. Dr Renger is a member of the Board of the ECA Foundation and Immediate Past Chair of the European QP Association.

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.

Fees (plus VAT)

Single participation: € 149.- for ECA Members
 Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

Group Participation (fee per person):

3-10 Persons € 169,15
 11-20 Persons € 149,25
 more than 20 Persons € 129,35

Technical Requirements

To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.

Your Internet browser must have following features to use the GMP Webinar system:

1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. 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.

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.

Do you have any questions?

For questions regarding content:

Mr Wolfgang Schmitt, phone +49 62 21 - 84 44 39,
 E-Mail: w.schmitt@concept-heidelberg.de,

For questions regarding technical aspects:

Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,
zimmermann@concept-heidelberg.de.

Registration for the GMP-Webinar: GMP Update 2015/2016 on Tuesday, 08 December 2015, 15.00 – 16.30 h CET

Speaker: Dr Bernd Renger

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

Please tick:

- Single Participation**
- Group Participation**
- 3-10 Persons
- 11-20 Persons
- more than 20 Persons

**Important:
 Deadline is 12 noon on
 7 December**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

Street

Postal Code/City

Phone

Fax

E-Mail (mandatory for your registration)

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 week 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.

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)!