



# GMP Webinar *Recording*

## **GMP Update 2018/2019**

Date of the recording: 05 December 2018

Speaker: Dr Bernd Renger



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

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# GMP-Webinar GMP Update 2018/2019

## 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 (allegedly) 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-GMP Guide (e.g. Annexes 1, 2, 17, 21)
- Update FDA/ EU MRA
- The revised MRA with Switzerland
- Status EU Clinical Trial Regulation and guidance
- Brexit and its consequences for pharma
- 2019 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 Immediate Past Chair of the European QP Association. Prior to that he was VP Quality Control at Vetter Pharma-Fertigung GmbH. He began his career at Hoechst AG in 1977 and has held various management positions in the quality area at Mundipharma, Byk Gulden (today Takeda), and Baxter BioScience AG in Vienna.

## 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 [http://www.gmp-compliance.org/eca\\_about.html](http://www.gmp-compliance.org/eca_about.html).)

## 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. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, [schopka@concept-heidelberg.de](mailto:schopka@concept-heidelberg.de)** for details.

## Group Participation (fee per person):

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

## Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://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.

## Registration

By mail, fax, e-mail or online on the Internet at [www.gmp-compliance.com](http://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,  
email: [w.schmitt@concept-heidelberg.de](mailto:w.schmitt@concept-heidelberg.de).

For questions regarding technical aspects:  
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13  
email: [schopka@concept-heidelberg.de](mailto:schopka@concept-heidelberg.de)

**Registration for the Webinar *Recording: GMP Update 2018/2019* of 05 December 2018, Speaker: Dr Bernd Renger**  
**Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).**

**Date on which you want to watch the recording online** \_\_\_\_\_

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## 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

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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!)