



# GMP Webinar

## **GMP Update 2017/2018**

Date:

Tuesday, 12 December 2017, 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-Webinar GMP Update 2017/2018

## 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, 17, 21)
- The FDA/ EU MRA (and the future of the Quality Metrics Initiative)
- The extended MRA with Japan
- News from Europe (e.g. update ATMP guidance)
- Update Elemental Impurities guidance
- New EU Clinical Trial Regulation and guidance
- 2018 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 GMP-Webinar: GMP Update 2017/2018 on Tuesday, 12 December 2017, 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](http://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**  
**11 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!)

## Do I need specific software?

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.

You will find the detailed system requirements here:

## 1. System requirements

| Windows           |         |           |   |   |     | Mac  |      |      |      | Linux                                     |
|-------------------|---------|-----------|---|---|-----|------|------|------|------|---|
|                   | Version | Vista     | 7 | 8 | 8,1 | 10,6 | 10,7 | 10,8 | 10,9 | Siehe <a href="#">Linux-Unterstützung</a> |
| Internet Explorer | 7       | Teilweise | — | — | —   | —    | —    | —    | —    | —   |
|                   | 8       | ✓         | ✓ | — | —   | —    | —    | —    | —    | —   |
|                   | 9       | —         | ✓ | — | —   | —    | —    | —    | —    | —   |
|                   | 10      | —         | ✓ | ✓ | ✓   | —    | —    | —    | —    | —   |
|                   | 11      | —         | ✓ | ✓ | ✓   | —    | —    | —    | —    | —   |
| Firefox           | Neueste | ✓         | ✓ | ✓ | ✓   | ✓    | ✓    | ✓    | ✓    | ✓   |
| Chrome*           | Neueste | ✓         | ✓ | ✓ | ✓   | ✓    | ✓    | ✓    | ✓    | —   |
| Safari            | 5       | —         | — | — | —   | ✓    | ✓    | ✓    | —    | —   |
|                   | 6       | —         | — | — | —   | —    | ✓    | ✓    | —    | —   |
|                   | 7       | —         | — | — | —   | —    | —    | —    | ✓    | —   |

Windows-Support:

- JavaScript and Cookies enabled
- ActiveX enabled und Blocking disabled for Microsoft Internet Explorer (recommended)
- Webex Plug-In for Firefox or Chrome activated
- Java 6.0 or later version

Mac-Support:

- JavaScript und Cookies enabled
- Plug-Ins in Safari enabled
- Java 6.0 or later version

With this [Test-Link](#) you can check if your system meets the requirements to participate in a WebEx Meeting and install the necessary plug in as well.

Please enter your name and email address for this test. If the installation is not possible due to technical restrictions please contact your IT department. WebEx is considered as standard webinar service today and preparations are easy to be made.

## 2. Participation in the webinar

You will receive an email with a link to register your data one day prior to the webinar. Please follow the instructions in this email. Registration of your data is **mandatory** for receiving your Log-In information which you will receive after successful registration.

Please log in about 15 minutes before the webinar starts in order to fix any occurring technical problems.

Please enter the webinar by entering **your correct name** and the **email noted at your registration**.

Registration with Cisco WebEx is not required. If any screen regarding this will occur please ignore this.

**Important:** Participation is only possible if the host already started the webinar. After this you will be able to enter the virtual conference room.

### 3. Audio and media files

Sound transmission will be provided via VoIP. There is no telephone line needed, only PC speakers or headset are required.

Please check the technical requirements for VoIP transmission with your IT department.

Please be advised that upon entering the webinar all participants will be muted. If questions occur during the webinar please ask them in writing via the Q&A tab.

### Can I forward questions to the speaker?

Yes, you can ask questions, but only in live webinars of course. During the webinar, you can submit your questions in writing. For this purpose, there is the button "Ask a question".

### What is the price for a Webinar?

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### How do I order a recorded Webinar?

To order a recorded webinar, simply choose the seminar you want from the recorded webinar list and send us the completed form. It is important that you also let us know when you plan on watching the recording. Along with your invoice you also get an access code for that day – this code is active for 24 hours only. Within this period you will be able to access and watch the recording any time.