



# GMP Webinar

## Remote Audits and Inspections

Date:

Thursday, 25 June 2020, 14.30 – 16.00 h CEST

Speaker:

Bernd Bödecker

Ex EU-GMP Inspector

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

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## Background

One important part of a supplier qualification process is the performance of an on-site audit. Currently, because of the Corona crises, the fact that an auditor has to visit a site presents a potential risk to all persons involved or might simply not be possible because of travel bans.

If an on-site audit is not possible, a risk-based supplier qualification process can be supported by a remote or virtual audit. Such an audit may be conducted through various communication channels such as video calls or other appropriate tools available. Many inspectorates, including FDA, MHRA and from EU have started to utilise remote paper based inspection approaches. But it needs to be well-prepared from both, the auditor and the auditee.

## Educational Objectives

Get a detailed overview of the possibilities and limits of a remote or virtual audit. Both perspectives will be considered, that of the auditee and that of the auditor:

- Legal background
- Methods & tools for distant assessment of suppliers and service providers
- Pros & cons of remote audits
- Reliance of QPs on results of remote supplier audits for batch certification
- Integration of remote auditing into the customer's QA system
- Risk-based selection of suppliers for remote audits
- Risk-based design of remote audits
- Auditor and auditee preparing for a scheduled remote audit
- Conducting the audit & follow-up

## Target Audience

GMP Auditors from Pharmaceutical and API Industry and those who are involved in preparing, managing and escorting audits and inspections.

## Speaker



### Bernd Bödecker

Recently retired EU-GMP Inspector (Trade & Industry Inspection Agency Hannover) with 35 years experience (>20y pharmaceutical industry +14y inspectorate). Now freelance GMP Consultant, also giving assistance to public and non-governmental health organizations dealing with GMP topics.

## 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 EUR 211,15

11-20 Persons EUR 186,75

more than 20 Persons EUR 161,85

## 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.

## 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 plugin. 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.

## 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

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## Do you have any questions?

### For questions regarding content:

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## Registration for the GMP Webinar "Remote Audits and Inspections" on Thursday, 25 June 2020, 14.30 – 16.00 h CEST

Speaker: Bernd Bödecker

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Please tick:

- Single Participation
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  - more than 20 Persons

**Important:**  
Deadline is 12 noon on  
24 June 2020

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## E-Mail (mandatory for your registration)

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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

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