



GMP Webinar

QP Flexibilities and Responsibilities during Covid-19 Outbreak

Date:

Tuesday, 28 April 2020, 15.00h – 16.30h CEST

Speaker:

Dr Ulrich Kissel

European QP Association

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

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Background

Due to the current Sars-CoV-2 outbreak, more and more people have started working from home; this includes Qualified Persons (QPs) but also auditors. But what do the regulators say when it comes to batch certification and remote audits?

The interpretation of the requirements by national inspectorates and their respective expectations are not harmonized across the European Union/EEA/UK. Some agencies like MHRA and HPRA are starting their own initiatives. The whole situation puts a lot of additional responsibility and pressure on the QPs. Transparency and information sharing is now very important.

Educational Objectives

This webinar will give you a comprehensive overview of the ongoing initiatives and discussions on possible QP flexibilities and responsibilities during the Sars-CoV-2 outbreak like:

- Remote certification (regulators' point of view)
- Remote certification (industry's point of view)
- Impacts in production or quality control
- Extended QP Discretion
- Use of remote audits

Target Audience

This Webinar has been designed for EU Qualified Persons (QP) but also QA personnel, upper management functions and other interested people who want to be informed about the current situation for QPs.

Speaker



Dr Ulrich Kissel

Dr Kissel is Chairman of the Board of Directors of the European QP Association (EQPA) and Director Regulatory Affairs on the Executive Board of the European Compliance Academy (ECA). He works as a consultant and external QP for the pharmaceutical industry. Prior to that he held management positions and worked as a QP at Roche.

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. 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?

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Registration for the GMP Webinar: "QP Flexibilities and Responsibilities during Covid-19 Outbreak" on Tuesday, 28 April 2020, 15.00h – 16.30h CEST
Speaker: Dr Ulrich Kissel

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
27 April 2020

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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

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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).

German law shall apply. Court of jurisdiction is Heidelberg.