



GMP Webinar

GMP-compliant Operation of Pharmaceutical Water Systems

Date:

Wednesday, 17 June 2020, 14.00 – 15.30 h CEST

Speaker:

Fritz Röder, Merck Healthcare KGaA

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

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Background

Pharmaceutical Water is unique and comprises a lot of special circumstances that are not common in the GMP area. There is no test for identity, the process is running continuously and cannot be switched off – except for maintenance reasons. That is the reason why many questions arise day by day concerning operation & compliance. And this can become critical for the manufacture of medical products. Water in pharmaceutical quality is used in many processing steps and in almost every manufacturing process of pharmaceutical products. And here, no matter whether the water system is shut down for technical or compliance reasons: the pharmaceutical production is shut down also.

Educational Objectives

In the webinar, typical mistakes and problems from the daily business are explained, frequent questions from inspections are discussed and answered. Is your water system compliant? How long do you allow your water loop to stop until you have to start an investigation? And what is the minimum Reynolds number during normal operation? How often do you have to take samples after a microbiological OOS result?

- How to set up a suitable control strategy
- Problems and their remediation: root cause analysis in water systems
- Common compliance questions in practice
- Typical questions and possible answers in inspections

Target Audience

This webinar aims at persons responsible for the trouble-free technical and GMP-compliant operation of pharmaceutical water systems - especially from production, engineering and QA or Microbiology.

Speaker



Fritz Röder, Merck KGaA

Fritz Röder is Senior QA Manager Qualification/Validation & Engineering at Merck in Darmstadt. He is member of the EDQM water working group and the ISPE expert group "water". He has worked in different roles concerning procurement, operation and GMP approval of pharmaceutical equipment at companies like Bayer, Allergan & Merck.

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?

For questions regarding content:

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For questions regarding technical aspects:

Mr Ronny Strohwald, phone +49(0)6221 / 84 44 51

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Registration for the GMP Webinar "GMP-compliant Operation of Pharmaceutical Water Systems" on Wednesday, 17 June 2020, 14.00 – 15.30 h CEST

Speaker: Fritz Röder, Merck Healthcare KGaA

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
16 June 2020**

Title, First Name, Last Name

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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)

German law shall apply. Court of jurisdiction is Heidelberg.