



GMP Webinar

WFI Production with Membrane Technology

How to
upgrade HPW
to WFI?

Date:
Tuesday, 25 June 2019, 14.00– 15.30 h CEST

Speakers:
Fritz Röder (Merck KGaA)
Jochen Schmidt-Nawrot (CRB Group GmbH)

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

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Background

In Europe it has become possible to produce water for injection (WFI) using non-distillation methods since March 2017. The change in the European Pharmacopoeia allows WFI production by means of suitable methods such as reverse osmosis. However, the EU Commission has also pointed out that in order to ensure the quality of a "cold-produced" WFI, other measures have to be taken than those required previously for the mandatory distillation. The robustness of this new process has to be demonstrated. The Q&A document prepared for this purpose by the EMA provides further assistance in some areas, but also leaves many questions unanswered. In addition, the monograph on Highly Purified Water (HPW) will be suppressed as of April 2019. Now, the most obvious question is: how will HPW - after its suppression from the European Pharmacopoeia - become *Water for Injection (WFI)*?

Educational Objectives

The Webinar on 25 June will address and answer the following questions:

- What is the current regulatory status? What do Pharmaceutical Associations say?
- Which technologies are appropriate for the cold production of WFI?
- Where do the new risks lie?
- What are the measures to counter those risks?
- What does happen to existing HPW systems?
- How to set up a suitable control strategy?
- What is the feedback from pharmaceutical "cold WFI" projects?

Target Audience

The target group of this Webinar are specialists from pharmaceutical companies (production, qualification, quality assurance) as well as from planning and plant engineering who are entrusted with the construction, operation or maintenance of WFI producing equipment.

Speaker



Fritz Röder (Merck KGaA) is Senior QA Manager Qualification, Validation & Engineering at Merck in Darmstadt. He is a member of the expert group "Water" of the EDQM and the working group "Pharma Water" of the ISPE DACH. He has many years of experience in water treatment through his activities in plant engineering and pharmaceutical companies, including Bayer, Allergan and Merck.



Jochen Schmidt-Nawrot (CRB Group GmbH) has been working in the field of pharmaceutical water for more than 20 years, among others at BWT (Christ), Hager + Elsässer and Chemgiengineering and is an expert for membrane processes. He is currently Lead Engineer Process Utilities for Pharma and Biotech at the pharmaceutical engineering service provider CRB in Basel. Through numerous publications on WFI without distillation, he has supported the approval of membrane technologies for the production of WFI in Europe.

Registration for the GMP Webinar: WFI Production with Membrane Technology on Tuesday, 25 June 2019, 14.00– 15.30 h CEST

Speakers: Fritz Röder (Merck KGaA), Jochen Schmidt-Nawrot (CRB Group GmbH)

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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.

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 for details.

Group Participation (fee per person):

3-10 Persons € 169,15

11-20 Persons € 149,25

more than 20 Persons € 129,35

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Registration

By mail, fax, e-mail or online 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.

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

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg, Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34
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Do you have any questions?

For questions regarding content:

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or questions regarding technical aspects:

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email: schopka@concept-heidelberg.de

Please tick:

Single Participation
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 3-10 Persons
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Important:
Deadline is 12 noon on
24 June 2019

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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 %.

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