



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.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de



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 Chemgineering 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.

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

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 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
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content:

Dr Robert Eicher Phone +49(0)6221 - 844412,
email: eicher@concept-heidelberg.de

or questions regarding technical aspects:

Mr Rouwen Schopka, Phone +49(0)6221 - 84 4413
email: schopka@concept-heidelberg.de

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.

Please tick:

- Single Participation**
- Group Participation**
 - 3-10 Persons
 - 11-20 Persons
 - more than 20 Persons

Important:
Deadline is 12 noon on
24 June 2019

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). German law shall apply. Court of jurisdiction is Heidelberg.