



GMP Webinar

GMP-compliant Operation of HVAC Systems

Date:

Wednesday, 24 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

Not any pharmaceutical facility can be operated without an HVAC system, no clean room can be qualified without considering the HVAC system. And: HVAC systems operated in a wrong way can lead to cross-contamination in the worst case. But one is for sure: shut down of the HVAC systems leads also to shut down of the pharmaceutical production where a controlled environment is required - no matter whether the problems were caused by compliance or technical reasons. But experts in the HVAC field are often quite technically oriented, and "HVAC Compliance" is often neglected. How critical is pressure change in a room? And how much can you reduce the air change rate in non-production times in a cleanroom? How often do you have to repeat qualification measurements like air velocity or smoke studies?

Educational Objectives

In the webinar, typical technical and GMP issues of HVAC systems (sterile & non-sterile) and possible solutions are shown. In addition frequently asked questions in inspections are discussed:

- Good design can only be achieved in advance: what can be optimised later on?
- Repetition of qualification measurements: how and how often?
- Mistakes and their remediation: root cause analysis
- Compliance questions from oral solids, semi-solids and sterile manufacturing
- Typical questions from GMP inspections and possible answers

Target Audience

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

Speaker



Fritz Röder, Merck Healthcare 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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Registration for the GMP Webinar "GMP-compliant Operation of HVAC Systems" on Wednesday, 24 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:

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 - 3-10 Persons
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Important:
Deadline is 12 noon on
23 June 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

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