ECA Academy
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GMP Webinar

Annex 1 – Decontamination Systems for Production Equipment, Process Devices and Cleanrooms

Date:
Thursday, 25 June 2020, 14.00 – 15.30 h CEST

Speaker:
Robert Schwarz, Trainer & Lecturer, FH Campus Wien, Austria

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

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Background

Annex 1 "Manufacture of sterile medicinal products" of the EU GMP Guide is currently being revised. A first draft of the revised version was published in 2017 and released for public comment, resulting in thousands of comments. A revised version was published in February 2020 and is open for limited comment by selected stakeholders.

Educational Objectives

This webinar informs you about the current status of the revision with regard to the topic decontamination or decontamination systems. This topic is of increasing importance in the significantly expanded field of contamination control strategies (CCS), since fumigation and fogging play an important role in connection with room and transfer decontamination. The current draft emphasises that measures for CCS must in many cases be seen in the overall context. Cleaning and decontamination as well as disinfection and sterilisation are not interchangeable, but are supporting pillars of the management of a holistic concept of contamination prevention and control in the production of sterile drugs, active ingredients or packaging materials.

Accordingly, this webinar will cover the following topics:

- Decontamination and regulations
- Selecting the appropriate decontamination agent
- URS and Equipment purchase
- Process Development
- Validation topics

Target Audience

This Webinar is of interest to professionals from pharmaceutical and biopharmaceutical manufacturers, authorities and suppliers with responsibilities in

- Quality Assurance and Quality Control
- Engineering & Validation

or who are involved in

- Sterile-/Aseptic Manufacturing
- Contamination Control and Monitoring

Speaker

Robert Schwarz, Trainer & Lecturer, Austria

Robert Schwarz studied biotechnology and quality management. After working in a medicinal lab as medical/technical analyst he joined Shire (formerly Baxter), Vienna in 2001. Until 2005 he was coordinator of environmental monitoring. From 2005 until 2018 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Additionally since 2010 he is university lecturer in the field of biotech (core topics validation/qualification, aseptic processing, cleanroom technologies and QC).

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 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.

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 "Annex 1 – Decontamination Systems for Production Equipment, Process Devices and Cleanrooms"
on Thursday, 25 June 2020, 14.00 – 15.30 CEST, Speaker: Robert Schwarz**
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 2020

Title, First Name, Last Name

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E-Mail (mandatory for your registration)