



GMP Webinar

Annex 1 - Application of Disinfectants and their Validation

Date:

Thursday, 09 July 2020, 14.00 – 15.30 h CEST

Speaker:

Dr Thomas Meindl, consultant pharmaceutical microbiology,
Laboratory LS SE & Co. KG, Germany



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, which resulted 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 will inform you about the requirements for the use of disinfectants in pharmaceutical production, which are formulated in more detail in the new annex.

Starting from a qualified cleaning, a disinfection strategy must be developed and validated as part of the Contamination Control Strategy. The validation shows that the methods, processes and materials described lead to the desired result under the individual clean room conditions. An important prerequisite for this is up-to-date data on the respective house germ flora. The selection of disinfectants is based on the results of operational hygiene monitoring as well as on risk-based approaches, which can be used to plan the frequency of use and the selection of disinfectants.

- Inhouse Isolates as a basis for decision-making for a risk-based approach
- Suitable disinfectant validation
- Evaluation of disinfectant studies

Target Audience

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

- Aseptic Manufacturing, Quality Assurance, Quality Control, Auditing, Inspections
- who are involved in
- Contamination Control, Monitoring, Qualification and Validation, Self Inspection, Quality Affairs, Process Simulation/Media Fill

Speaker



Dr Thomas Meindl, Specialist consultant for pharmaceutical microbiology, Laboratory LS SE & Co. KG, Germany

Dr Thomas Meindl is a graduate biologist and has been working in various functions for more than 15 years at Labor LS SE & Co. KG, one of the largest contract laboratories for pharmaceutical microbiology in Europe. In his current position he advises clients from the pharmaceutical and medical device industry on the design of testing strategies, particularly in microbiological issues.

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 "Annex 1 - Application of Disinfectants and their Validation"

on Thursday, 09 July 2020, 14.00 – 15.30 h, Speaker: Dr Thomas Meindl

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
08 July 2020

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.