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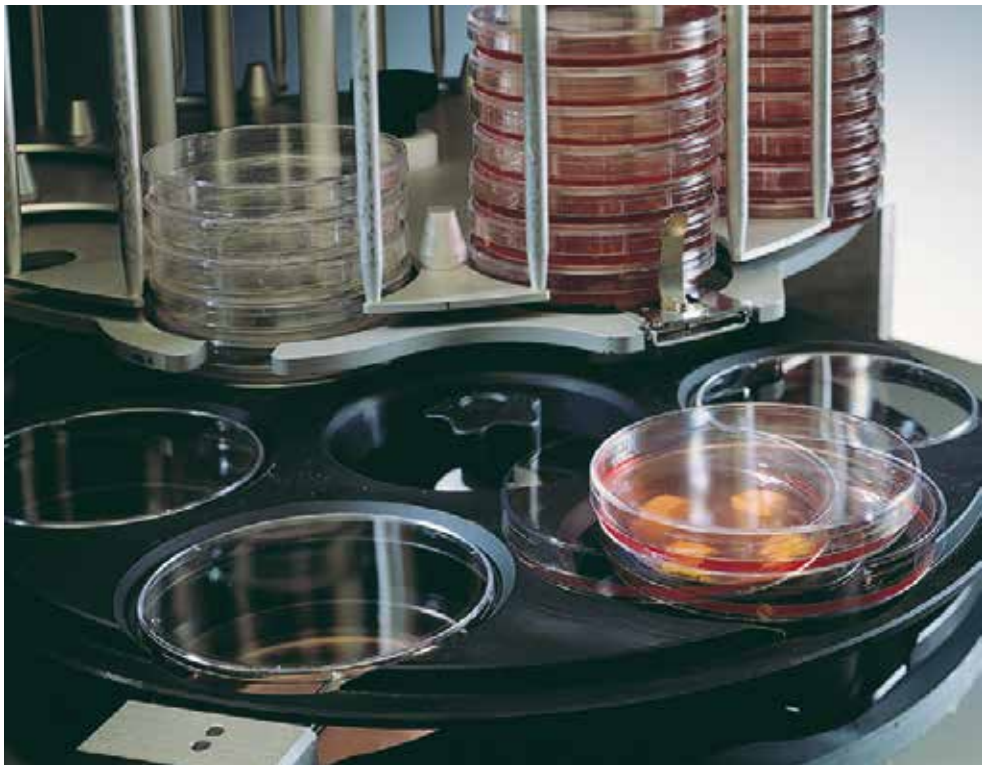
GMP Webinar
Microbiological Control of Non-Sterile Drug Products and Raw Materials

Date:
Thursday, 23 May 2019, 14.00 – 15.30 h CEST

Speaker:
Dr Marcel Goverde, MGP Consulting
Vice Chair ECA Pharmaceutical Microbiology Working Group



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

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Background

Although the microbiological testing of non-sterile drug products and raw materials are clearly defined by the Pharmacopeia there are still some challenges which can appear during development or routine testing. Therefore, it is up to the pharmaceutical company to have clear written procedure on the method itself as well as on the handling of special cases. The goal of this webinar is to give an overview of the methods described in Ph. Eur. chapter 2.6.12 and 2.6.13 or USP chapter <61> and <62>. Additionally, a short introduction to the new method for the testing of Burkholderia cepacia complex drafted in USP chapter <60> is given.

Educational Objectives

This webinar aims at giving you a comprehensive but still compact overview about the microbiological testing methods of non-sterile products according to the harmonized chapters of the Pharmacopeia.

Target Audience

The webinar targets to new staff who are in relation of pharmaceutical microbiology, but also to QA or QP who need to evaluate the data gathered by their microbiological lab or CMO as well as regulatory staff in charge of microbiological specifications.

Speaker

Dr Marcel Goverde, MGP Consulting

Mr Goverde holds a PhD in Biology and runs his own company for consulting, training and project management in GMP-relevant areas with focus on microbiology, hygiene and deviation management. He gathered 8 year of work experience in microbiological pharmaceutical industry at F. Hoffmann-La Roche Ltd and another year as QC expert for microbiology at Novartis Pharma. Since 2003 Mr Goverde acts as a Swiss delegate in the EDQM group for microbiological and statistical methods and since 2011 as board member and deputy chair of the ECA Pharmaceutical Microbiology Working Group. He is a regular speaker at different institutions.

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

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Do you have any questions?

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Registration for the GMP Webinar: Microbiological Control of Non-Sterile Drug Products and Raw Materials, 23 May 2019, 14.00- 15.30 h
Speaker: Dr Marcel Goverde
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 22 May 2019

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