



# GMP Webinar *Recording*

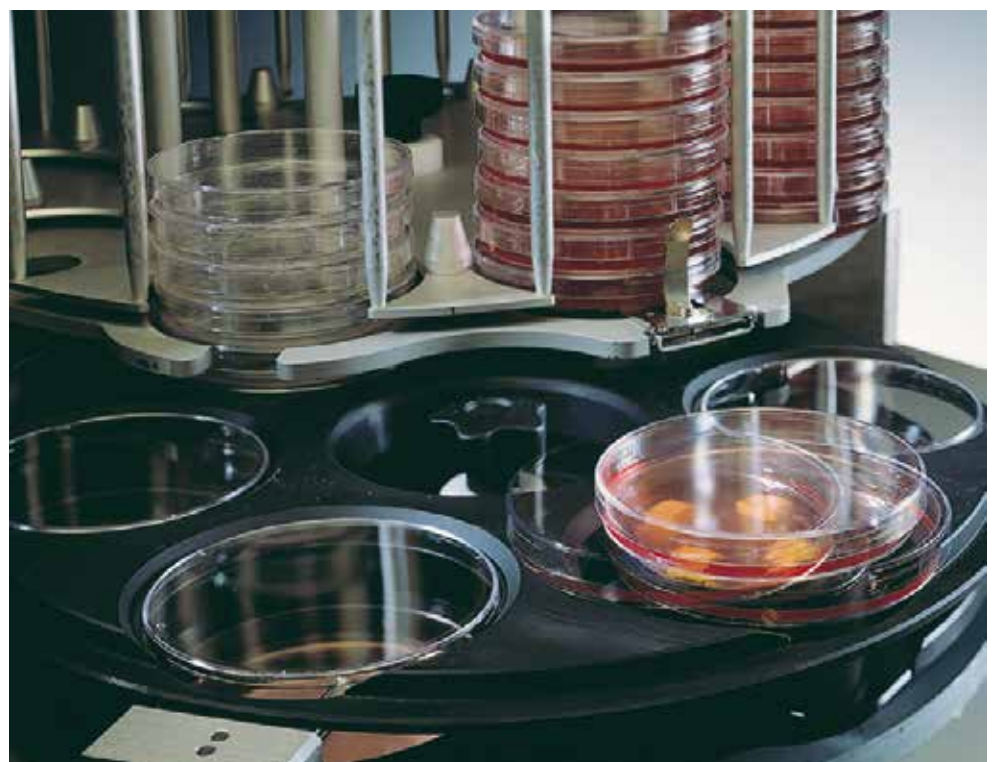
## **Microbiological Control of Non-Sterile Drug Products and Raw Materials**

Date of the recording: 23 May 2019

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 Pharmacopoeia 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 Pharmacopoeia.

## 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](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](mailto: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

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## Registration

By mail, fax, e-mail or online at [www.gmp-compliance.com](http://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,  
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## Do you have any questions?

### For questions regarding content:

Mr Axel H. Schroeder, Phone +49(0)6221 - 844410,  
email: [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de)

### For questions regarding technical aspects:

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

## Registration for the Webinar *Recording: Microbiological Control of Non-Sterile Drug Products and Raw Materials of 23 May 2019, Speaker: Dr Marcel Goverde*

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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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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you

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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

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