



# GMP Webinar Microbiological Testing – An Overview for QA, QPs and Newcomers

Date:

Tuesday, 18 June 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**

Microbiological testing is present in several stages during development and manufacturing of any drug product or raw material (excipient, drug substance, primary packaging). There is huge number of different microbiological tests. The goal of this webinar is to give an overview of the most important microbiological tests (such as sterility test, bioburden test, identification and evaluation of isolates, endotoxin testing, growth promotion test, preservation test, environmental monitoring or container closure integrity) and will give some ideas on alternative or rapid microbiological testing.

# **Educational Objectives**

This webinar aims at giving you a compact overview about the most important microbiological testing methods of sterile as well as non-sterile products according to the current regulations.

## **Target Audience**

The webinar targets to new staff who want to get an overview on microbiological quality control, 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

Dr Goverde holds a PhD in Biology and runs since 2011 his own company for consulting, training and project management in GMP-relevant areas with fo-

cus 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 <a href="http://www.webex.com/test-meeting.html">http://www.webex.com/test-meeting.html</a> 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

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg, Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34 info@concept-heidelberg.de, www.gmp-navigator.com

#### Do you have any questions? For questions regarding content:

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

### For questions regarding technical aspects:

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

Registration for the GMP Webinar: Microbiological Testing - An Overview for QA, QPs and Newcomers on Tuesday, 18 June, 14.00 - 15.30 h CEST Speaker: Dr Marcel Goverde

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Ple	ase	LICK:	
	Single Participation		
	Gr	oup Participation	
		3-10 Persons	
		11-20 Persons	
		more than 20 Persons	

Important: Deadline is 12 noon on 17 June 2019

Title, First Name, Last Name			_
Company	Department	VAT ID No. (mandatory)	_
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#### E-Mail (mandatory for your registration)

If you cannot attend the conference you have two options:

I. 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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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.