



# GMP Webinar

## **Microbiological Testing of Primary Packaging**

Date:

Thursday, 7 June 2018, 14.00 – 15.30 h (CEST)

Speaker:

Dr Marcel Goverde, Deputy Chair of ECA's Pharmaceutical Microbiology Working Group

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

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## Background

Although microbiological testing of drug products and raw material such as excipient and drug substance are quite clear regulated, hardly any guidance for the testing of primary packaging is available. Therefore, it is up to the pharmaceutical company to develop a control strategy for microbiological testing of primary packaging as well as to establish suitable methods for testing. This can include to develop the necessary risk assessment and to define the specification for your company and their products..

## Educational Objectives

This webinar aims at giving you a comprehensive but still compact overview about the possibilities of microbiological specifications and testing of primary packaging.

It will cover:

- Regulatory Expectations
- Microbiological Specifications
- Testing Methods

## Target Audience

This webinar is made for all persons from

- Pharmaceutical Manufacturers
- Manufacturers of Packaging Material
- Contract Laboratories
- Authorities

which are involved in development and testing of packaging materials with a special focus on microbiological testing.

## Speaker



### Dr Marcel Goverde, MGP Consulting

Mr Goverde holds a PhD in Biology and runs since 2011 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

## 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 on the Internet 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,  
Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34  
[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de), [www.gmp-navigator.com](http://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](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 GMP Webinar: Microbiological Testing of Primary Packaging on Thursday, 7 June 2018, 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](http://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  
6 June 2018

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.