



# GMP Webinar Endotoxin Highlights – the Essence of Experts' Thinking

Date: Wednesday, 17 January 2018, 14.00 – 15.30 h (CET)

Speaker: Dr Johannes Reich, Microcoat Biotechnologie GmbH



### Background

In the last years, the LAL test has become the preferred system to test for endotoxins - for the in process control as well as in the final inspection - and it is anchored in the pharmacopoeias.

However, in the recent past, the problem of low endotoxin recovery employs the pharmaceutical microbiology. Masking - or not? Evidence gaps? And how can I close them? And how to evaluate? But although the question about alternative methods like MAT or Recombinant Factors is frequently asked - what is the status of these methods in the Pharmacopoeias? What is the authorities thinking on their use.

These are the questions the pharmaceutical microbiologists as well as those responsible for the release have to deal with.

### **Educational Objectives**

- Background
- Conflictive observations
- Understanding conflictive results
- Optimization of current detection methods
- **Regulatory review**
- Development in Pharmacopoeias

### **Target Audience**

- Laboratory management and staff of pharmaceutical microbiology
- Microbiologists and laboratory assistants from contract laboratories
- Authority representatives involved in the topic
- Scientific staff from the area Pyrogen and/or Endotoxin testing
- QA staff who has to evaluate endotoxin data and handle deviations

#### Speaker

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## Dr Johannes Reich, Microcoat Biotechnologie GmbH, Germany

Johannes Reich studied business administration and chemistry in Regensburg. His doctoral thesis was on "function-structure relationship of Lipopolysaccharide

with recombinant factor C test systems" at the Institute for physical and theoretical chemistry. He deals with the problems of modern endotoxin detection methods and with the problem of low endotoxin recovery. In the meantime he worked for Profos. Currently he is Managing Director at Microcoat Biotechnologie GmbH with focus on the Endotoxin and Pyrogen testing.

# 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 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.

#### **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: Endotoxin Highlights – the Essence of Experts' Thinking on Wednesday, 17 January 2018, 14.00 – 15.30 h (CET) Speaker: Dr Johannes Reich, Microcoat Biotechnologie GmbH 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 16 January

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If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague 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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