



GMP Webinar Endotoxin Update – the current hot Topics

Date: Thursday, 12 September 2019, 14.00 – 15.30 h CEST

Speaker: Dr Johannes Reich, Microcoat Biotechnologie GmbH



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

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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

- Overview of detection methods (RPT, MAT, LAL, rFC)
 - Challenges during bacterial endotoxin testing
 - Interpretation of test results
 - Endotoxin detection and Depyrogenation
 - Low Endotoxin Recovery
- Detection of Pyrogens beyond Endotoxin

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

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 plugin. 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: Endotoxin Update - the current hot Topics on Thursday, 12 September 2019, 14.00 - 15.30 h CEST 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.

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□ Single Participation

- **Group Participation**
- □ 3-10 Persons
- □ 11-20 Persons
 - □ more than 20 Persons

Important: Deadline is 12 noon on 11 September

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General Terms and Conditions

If you cannot attend the conference you have two options:

We are heapy to welcome a substitute collegue at any time.
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.