



GMP Webinar

Endotoxin Masking - Low Endotoxin Recovery Update

Date:

Thursday, 08 October 2015, 15.00 – 16.30 h (CET)

Speaker:

Johannes Reich, University Regensburg, Germany



GMP Webinar Endotoxin Masking - LER Update

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?

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

Educational Objectives

In this webinar you will get an insight into the current situation:

- 1) Background
- 2) Conflictive observations
- 3) Understanding conflictive results
- 4) Optimization of current detection methods
- 5) Regulatory review

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 testing
- QA staff who has to evaluate endotoxin results and deviations

Speaker



Johannes Reich, University Regensburg, Germany

Johannes Reich studied business administration and chemistry in Regensburg. Currently, he is working on his doctoral thesis 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 as product manager at Profos AG in Regensburg.

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.

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 www.gmp-compliance.org/eca_about.html.)

Group Participation (fee per person):

3-10 Persons € 169,15 11-20 Persons € 149,25 more than 20 Persons € 129,35

Technical Requirements

To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.

Your Internet browser must have following features to use the GMP Webinar system:

- 1. Adobe Flash-Player must be installed.
- 2. Javascript must be allowed.
- 3. Port 1935 must be released.

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.

Do you have any questions?

For questions regarding content: Mr Axel Schroeder, phone +49 62 21 - 84 44 10, E-Mail: schroeder@concept-heidelberg.de,

For questions regarding technical aspects: Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59, zimmermann@concept-heidelberg.de.

Registration for the GMP Webinar: Endotoxin Maski	ing
on Thursday, 8 October 2015, 15.00-16.30 h CET	_
Speaker: Johannes Reich, University Regensburg, G	ermany
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 8	84 44 34
or you register online at www.gmp-compliance.org	•
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Ple	ase tick:		
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	☐ 3-10 Persons		
	☐ 11-20 Persons		
	☐ more than 20 Persons		

Important: Deadline is 12 noon on 7 October

	□ more than 20 Persons		
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General Terms and Conditions

If you cannot attend the conference you have two options:

E-Mail (mandatory for your registration)

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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