



GMP Webinar Endotoxin Masking -Low Endotoxin Recovery

Date: Thursday, 25 September 2014, 14.00 – 15.30 h CEST

Speaker: Johannes Reich, University Regensburg, Germany



GMP Webinar Endotoxin Masking

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) Introduction

- a. Functionality of the LAL Test
- b. Test Control "PPC"
- c. Monitoring "Low Endotoxin Recovery"

2) Masking

- a. Definition
- b. Driving Forces (examples)
- c. Mechanisms

3) Solution approaches and perspectives

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 rela-

tionship 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.

Fees

€ 149.- plus VAT for ECA / EQPA members € 199.- plus VAT for non-ECA Members

Participation of a Group

The registration fee only authorises an individual to take part in the Webinar. Therefore, we do not issue more than one certificate per registration. With the registration fee being paid only once, it would infringe the copyright of CONCEPT HEIDELBERG as well as that of the speaker if the transmission was followed by several persons.

If you wish to register a group, please send an e-mail to info@concept-heidelberg.de or contact us by phone (+49 (0)62 21 / 84 44 51 Mr Strohwald). Prior to the Webinar date, we will help you to establish and test the Internet access.

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 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.

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- 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

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