ECA Academy
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GMP Webinar/Panel Discussion
rFC – Bacterial Endotoxin Testing using Recombinant Assays

Date:
Wednesday, 08 July 2020, 14.00 – 16.00 CEST

Speaker/Panel Members:

Dr Ingo Spreitzer, Section 1/3 Microbiological Safety, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines
Dr Johannes Reich, Endotoxin & Pyrogen Test Service, Microcoat Biotechnologie GmbH
Dr Sven Deutschmann, Chair ECA Pharmaceutical Microbiology Working Group, Adventitious Agents Testing & Alternative Microbiological Methods, Roche Diagnostics GmbH
Thierry Bonnevay, Global Microbiology Analytical Expert, Sanofi Pasteur
Jay Bolden, Senior Biologist at Eli Lilly and Company

Email your questions in advance to the panel at
microbiology@gmp-compliance.org

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

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Background

In November of 2019 the European Pharmacopoeia (Ph. Eur.) Commission adopted a new General Chapter 2.6.32 entitled: "Test for bacterial endotoxins using recombinant factor C (2.6.32)". The new Chapter will be published in the coming weeks in Ph. Eur. Supplement 10.3 and available on the EDQM website. The chapter will be effective as of January 1, 2021.
Guidelines for using the test for bacterial endotoxins state in the that the test methods given in monographs and general chapters have been validated in accordance with accepted scientific practice and current recommendations on analytical validation. In consequence, the methods described in general chapters do not have to be re-validated per se, other than in consideration of their use for a specific substance or product in a specific analytical environment."
Thus allowing the recombinant Factor C test to be used as an alternative to the Limulus amoebocyte lysate assay (LAL assay).

Educational Objectives

The following points will be presented in 5 short contributions and subsequently discussed in an open panel discussion with the possibility to submit questions:

- Comparison of LAL and rFC test methods
- Benefits of recombinant test methods
- Regulatory Status (US and Europe) of recombinant Factor C Test
- Experiences in pharmaceutical quality control using rFC test
- Different approaches - experiences of a contract laboratory

Target Audience

This Webinar is of interest to professionals from pharmaceutical and biopharmaceutical manufacturers, authorities and suppliers with responsibilities in
- Quality Assurance and Quality Control
- Inspection and Auditing
or who are involved in Endotoxin or Pyrogen testing.

Pre-Submission of Questions

The participants in this online panel discussion have the opportunity to send questions in advance and during the event, which will be included in the panel discussion. If more questions are submitted than can be discussed in the time frame, the Scientific Board or the discussion leader will select the questions.
You can submit questions to the panel at microbiology@gmp-compliance.org up to the day before the event. Questions can be also entered directly during the event.

Fees (plus VAT)

Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership.
You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

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.

Group Participation (fee per person):

3-10 Persons EUR 211,65
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

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.

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.

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

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Do you have any questions?
For questions regarding content please contact:
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For questions regarding organisational aspects please contact:
Ms Marion Grimm, Phone +49(0)6221 / 84 44 18
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Registration for the GMP Webinar "rFC – Bacterial Endotoxin Testing using Recombinant Assays" on Wednesday, 08 July 2020, 14.00 – 16.00 CEST
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 07 July 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

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Phone | Fax

E-Mail (mandatory for your registration)