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GMP Webinar

ECA Guide for the Evaluation and Investigation of Microbiological Deviations

Chapter 2:
Endotoxin Out of Specification (OOS) / Out of Trend (OOT) / Atypical Results

Date:
Tuesday, 21 July 2020, 14.00 – 15.30 h CEST

Speaker:
Jordi Iglesias, Technology and Market Development Manager
Microbial Solutions, Charles River

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

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Background
The handling of deviations, i.e. Out of Specification (OOS), Out of Limit (OOL), Out of Trend or typical test results is unfortunately insufficiently described from a regulatory point of view. The only existing guideline of the FDA unfortunately does not refer to microbiological issues.

For this reason, the Pharmaceutical Microbiology Working Group of the ECA decided two years ago to prepare a supporting document that provides guidance on how to deal with such microbiological deviations based on the experience of its members and regulatory expectations. After the first chapter "Guidance for deviation handling of microbiological environmental monitoring excursions in non-sterile pharmaceutical manufacturing", which has already been published, the second section, Endotoxin Testing Lab Investigations - OUT OF SPECIFICATION (OOS)/ OUT OF TREND (OOT)/ATYPICAL RESULTS INVESTIGATIONS is finalized now and will be published shortly.

Educational Objectives
During the webinar you will have the opportunity to learn about the content of the new guideline:
- Out of Specification (OOS)/Out of Trend (OOT)/Atypical Results Investigations
- Creating the Investigation Process Parameters
- OOS vs Invalid
- Performing the Laboratory Investigation
- How to use data generated by your company to proactively prevent OOS

Target Audience
This webinar is aimed at employees from the following areas
- Quality Assurance
- Quality Control
- Microbiology
- Contract Labs
- R&D
- Authorities

who are involved in the control of Endotoxins, administration of deviations/root cause analysis, batch release and audits and inspections.

Speaker

Jordi Iglesias, Technology and Market Development Manager, Charles River
Jordi studied Biology at the University of Barcelona. From 2004 to 2018 he worked as microbiological supervisor at Zoetis. In 2018 he joined Charles River Laboratories as Product Specialist. Today he is Technology and Market Development Manager.

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
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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?
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Registration for the GMP Webinar "ECA Guide for the Evaluation and Investigation of Microbiological Deviations" on Tuesday, 21 July 2020, 14.00 – 15.30 h CEST,
Speaker: Jordi Iglesias, Charles River
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**
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- ☐ 3-10 Persons
- ☐ 11-20 Persons
- ☐ more than 20 Persons

Important: Deadline is 12 noon on 20 July 2020

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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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