ECA Academy
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GMP Webinar
EMA´s Q & A regarding PDE

Date:
Thursday, 17 October 2019, 14.00 - 15.30 h (CEST)

Speaker:
Robert Schwarz, FH Campus, Vienna, Austria

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

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Background

Preventing cross contamination is an essential GMP-requirement and has already been mentioned in the EU GMP Guideline since its first publication in 1989. However, in the last years this requirement has become more and more relevant. There is a stronger focus on cross contamination since the EMA has published their „shared and dedicated facility guideline" regarding the use of multi-purpose equipment. In this guideline, health-based exposure limits (HBEL) and permitted daily exposure-values (PDE) are implemented as state of the art values. Consequently, the chapter 5 of the EU GMP Guideline and the Annex 15 have been revised in the same direction. A Question and Answers (Q&A) draft document and now the final version should interpret EMA´s „shared and dedicated facility guideline". De facto, these two Q&A´s have led to some confusion in the pharmaceutical industry.

Educational Objectives

- What is a Q&A document?
- The PDE concept – how was it developed?
- Why the use of HBEL/PDE values?
- How to get HBEL/PDE values?
- EMA´s Q &A document for the interpretation of EMA´s "Shared and Dedicated Facilities" guideline
- Comparison of the Q &A draft (2016) and the final version (2018) – What changes?
- Influence of the Q & A document on cleaning validation

Target Audience

We address staff from the pharmaceutical industry and API manufacturers who are interested in the topics cross contamination and cleaning validation, e.g. head of production, validation managers, QA-personnel etc.

Speaker

Robert Schwarz studied biotechnology and quality management. After working in a medicinal lab as medical/technical analyst Robert Schwarz joined Shire (formerly Baxter), Vienna in 2001. Until 2005 he was coordinator of environmental monitoring. From 2005 until 2018 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Since 2010, he additionally is university lecturer in the field of biotech (core topics validation/qualification, aseptic processing, cleanroom technologies and QC).

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 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 EUR 211,15
11-20 Persons EUR 186,75
ab 21 Persons EUR 161,85

Technical Requirements

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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 please contact
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For questions regarding technical aspects please contact
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13
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Registration for the GMP-Webinar: EMA´s Q & A regarding PDE
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Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
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☐ 3-10 Persons
☐ 11-20 Persons
☐ more than 20 Persons

Important: Deadline is 12 noon on 16 October 2019

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