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GMP Webinar
The new Annex 21

Date:
Tuesday, 21 April 2020, 14:30h – 16:00h CEST

Speaker:
Dr Ulrich Kissel
European QP Association

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background

In March, after some delays, the new Annex 21 to the EU GMP Guideline was published as a draft. The document is entitled "Importation of medicinal Products".

The Guidance is aimed at Manufacturing and Importation Authorisation holders (MIA holders) who import human or veterinary medicinal products from third countries and summarizes the GMP requirements applicable to a Manufacturing Import Authorisation (MIA) holder which imports medicinal products (human and veterinary) from outside the EU/EEA. The following points are discussed:

- Physical transfer from a third country to the EU/EEA
- Certification by a Qualified Person
- Requirements for facilities and equipment
- Documentation needed
- GMP requirements for manufacturers and exporters in the third country
- Qualification and audits under the responsibility of the importing company
- Import testing
- Contractual regulations

Educational Objectives

This webinar will give you an overview of the most important points of the new appendix:

- What is really new and not yet addressed in any other guidance
- Are there contradictions to other documents?
- What needs to be considered?
- What is important for QPs?

Target Audience

Manufacturing and Importation Authorisation holders (MIA holders) who import human or veterinary medicinal products from third countries.

Speaker

Dr Ulrich Kissel

Dr Kissel is Chairman of the Board of Directors of the European QP Association (EQPA) and Director Regulatory Affairs on the Executive Board of the European Compliance Academy (ECA). He works as a consultant and external QP for the pharmaceutical industry. Prior to that he held management positions and worked as a QP at Roche.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
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more than 20 Persons EUR 161,85

Registration
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Organisation/Contact
CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?
For questions regarding content:
Mr Wolfgang Schmitt (Director Operations)
Phone +49(0) 6221 - 84 44 39,
Email: w.schmitt@concept-heidelberg.de

For questions regarding technical aspects:
Mr Rouwen Schopka, Phone +49(0)6221 - 84 4413
Email: schopka@concept-heidelberg.de

Registration for the GMP Webinar: "The new Annex 21"
on Tuesday, 21 April 2020, 14.30h – 16.00h CEST
Speaker: Dr Ulrich Kissel
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important: Deadline is 12 noon on 20 April 2020

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