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GMP Webinar
Risk Management regarding Combination Products

Date:
Tuesday, 21st January 2020, 14.00 – 15.30 h CET

Speaker:
Dr Peer Schmidt,
AbbVie Deutschland GmbH & Co. KG, Germany

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

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Background
With the application of the Medical Device Regulation (MDR) in May 2020 and the regulation about in-vitro diagnostics, the topic risk management will gain further importance for medical devices and IVDs. Risk management is the „backbone" during development, manufacturing and market surveillance of these products. Quality risk management is essential throughout the whole life cycle of a medical device. The risk management file is key for the description of product risks, their control, acceptance and monitoring. ISO 14971 represents the "state of the art" as an "implementation standard" but is being revised and currently available as a draft. ISO 13485:2016 also addresses the topic of risk management. In the pharmaceutical world, however, quality risk management follows ICH Q9. In the case of combination products, both perspectives must be observed and a risk management file must be kept for the medical devices element.

Educational Objectives
The topics addressed are:
- Regulations overview: ICH Q9, ISO 14971, ISO 24971, MDR - similarities & differences
  - Outlook: revision of ISO 14971
- US vs. EU requirements
- Focus on the patient
- Compliance or business reasons?
- Best Practice: Risk Management File, CQA and Risk tools: FMEA, Risk Matrix, hazard analysis, etc.
- Responsibilities regarding cross-contamination according to EU GMP chapters 3 & 5
- How do complaints, exceptions, planned changes etc., impact residual risk?

Target Audience
The webinar is intended for manufacturers who want to stay on top of the requirements for quality risk management for Medical Devices, especially developers, quality assurance, engineers and Regulatory Affairs. It also applies to drug manufacturers utilizing medical devices to administer their products (combination products). Finally, consultants in the Risk Management field are addressed.

Speaker

Dr Peer Schmidt,
AbbVie Deutschland GmbH & Co. KG, Germany
Peer Schmidt brings more than 15 years of experience in the development, manufacturing, registration and supervision of Medicinal Products, Medical Devices and Combination Products. As Senior Manager Global Quality Systems, he leads the AbbVie Center of Excellence for Quality Risk Management. He also acts as EU Authorized Representative and Management Representative for AbbVie´s Medical Devices. He holds a Ph.D. in Molecular Biology and was previously the Head of Quality Assurance at Abbott Biotechnology Germany.

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
more than 20 Persons EUR 161,85

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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.

Organisation/Contact
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Do you have any questions?
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Registration for the GMP Webinar "Risk Management regarding Combination Products"
on Tuesday, 21st January 2020, 14.00 – 15.30 h CET
Speaker: Dr Peer Schmidt
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
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Important: Deadline is 12 noon on 20 January 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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