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GMP Webinar
Medical Devices and Combination Products: Update on Post-Market Surveillance

An introduction to the new ISO TR 20416

Date:
Wednesday 2 September 2020, 14.00 - 15.30 h CEST

Speaker:
Torsten Kneuss, Bayer, Germany

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

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Background
The monitoring of how a medical device, respectively, a combination product performs on the market, is a vital component of the lifecycle. A Post-Market Surveillance system implemented helps not only to comply with specific regulations but also supports to improve the quality of the products. It helps to get an understanding of the product, about the safety and performance of the product, and helps to avoid critical issues by early identification of problems. Also, Post-Market Surveillance helps to have an eye on the market and how it further develops related to changes that might impact the use of the product.

This Webinar provides an introduction to Post-Market Surveillance and to the technical report ISO TR 20416, which provides additional background information, especially for medical device manufacturers.

Educational Objectives
Participants get an understanding of:
- the purpose and process of Post-Market Surveillance
- for which product types this process needs to be applied
- which elements the Post-Market Surveillance consists of
- how the ISO TR 20416 helps to implement a Post-Market Surveillance process in compliance with the (EU) MDR 2017/745

Target Group
All people involved in Post-Market Surveillance for Medical Devices and Combination Products, e.g., staff in Quality Assurance, Vigilance, Supplier Management, as well as people engaged in Audits and Inspections.

Speaker

Torsten Kneuss, Bayer AG, Berlin, Germany
Torsten Kneuss studied Business Administration and Engineering. Since 1999 he has been working with pharmaceutical packaging materials, medical devices and combination products, including several years within the field of quality control, development, operations, and pharmacovigilance. Since November 2017 he is, as a Quality Manager Combination Products, responsible for devices and combination products within Bayer AG.

Fees (plus VAT)
Single participation: € 199,- for ECA Members
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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
"Medical Devices and Combination Products: Update on Post-Market Surveillance"
on Wednesday, 2 September 2020, 14.00 - 15.30 h CEST
Speaker: Torsten Kneuss
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 1 September 2020

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