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GMP Webinar *Recording*

Medical Devices and Combination Products: Update on Risk Management

An introduction to the new versions of ISO 14971 and ISO TR 24971

Speaker:
Torsten Kneuss, Bayer, Germany

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

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Background
The systematic analysis, controlling, and monitoring of risks for Medical Devices and Combination Products is required by several applicable regulations (e.g., the Medical Device Regulation or the 21 CFR Part 820). And it is essential to ensure that the product is and remains safe and effective. End of 2019, the third edition of ISO 14971 has been published, which is the standard for Risk Management of Medical Devices and is usually also applied to Combination Products. Even though the new edition is an evolution, not a revolution, it is recommended to recap the requirements and how they can be implemented in daily practice. Soon, the ISO 14971 will be accompanied by an update of the ISO TR 24971. This Technical Report provides additional guidance on how to implement a Risk Management according to ISO 14971.

This Webinar helps to get an understanding of ISO 14971 and the introduced changes, including the respective required actions, as applicable to manufacturers of medical devices and pharmaceutical companies dealing with single-integral products, respectively, with other types of combination products.

Educational Objectives
Participants get an understanding of:
- the Risk Management process according to ISO 14971
- for which product types this process needs to be applied
- which changes were introduced with the new version of the standard
- how the ISO TR 24971 helps to implement Risk Management in compliance with the (EU) MDR 2017/745
- particular issues and challenges with Risk Management for Combination Products

Target Group
All people involved in the Development and Life-Cycle Management of Medical Devices and Combination Products, which need to have a basic understanding of the Risk Management process, e.g., staff in Quality Assurance, Vigilance, Device/Combination Product Development, Supplier Management, 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.

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"Medical Devices and Combination Products: Update on Risk Management"
of Thursday, 13 August 2020
Speaker: Torsten Kneuss
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