ECA Academy
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GMP Webinar
Medical Device Technical Documentation – changes caused by MDR

Date:
Tuesday, 9 March 2021, 14.00 – 15.30 h CET

Speaker:
Dr Gerhard Bauer-Lewerenz, Bauer-Lewerenz Consulting, Bad Homburg, Germany

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

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Background
Since the introduction of the medical device regulation in the 90ies, the Technical Documentation had a central role in medical device compliance. It is the basis for conformity assessment and therefore essential for the marketing of the product. The still effective Medical Device Directive specifies only a few concrete requirements regarding the content of the Technical Documentation. A Notified Body recommendation, which is more specific, dates back to 2000.

The Medical Device Regulation (MDR) now specifies the requirements for the Technical Documentation in much detail in Annex II. Annex III then addresses the Technical Documentation in the context of Post Market Surveillance (PMS). Due to postponement of the effectiveness of the MDR to 26 May 2021, there is now one more year to comply with these new requirements.

Educational Objectives
Due to the new Medical Device Regulation and its Annexes II and III, new requirements regarding the Technical Documentation(TD) of medical devices are also coming up. During the webinar, the TD will be addressed within in the context of the product life cycle - from development to post-market surveillance and market discontinuation. This comprises:

- Goals for the Technical Documentation
  - Special issue: Grouping of medical devices
- Content of the TD according to the Medical Device Directive
- Content of the TD according to the Medical Device Regulation
  - Changes / How to handle legacy products
- The SOP „Technical Documentation"
  - Content, creation, control, review
- Key components of risk management and risk analysis
- Documentation of design – product design and development process
- The TD in Post Market Surveillance
- Tasks of the responsible person regarding the TD
- The TD in audits

Target Group
This webinar is intended for employees from medical device/combination product companies, who are involved in the creation and/or maintenance of the Technical Documentation. Of course, consultants in this field, who want to get information from the view of the medical device industry, are also addressed.

Speaker

Dr Gerhard Bauer-Lewerenz, Bauer-Lewerenz Consulting, Bad Homburg, Germany
Dr Bauer has more than 25 years of professional experience in the Life Science Industry. He has experience as project manager, Head of Controlling, Head of Procurement, external and internal consulting (GMP Compliance), Auditing of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US.

Fees (plus VAT)
Single participation: € 249,- for ECA Members
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Registration
By mail, fax, e-mail or online on the Internet at https://www.gmp-compliance.org. 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.

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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
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Important: Deadline is 12 noon on 8 March 2021

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