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GMP Webinar
CAPA - Trending - Management Review for Medical Devices

Date:
Thursday, 02 July 2020, 14.00 – 15.30 CEST

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

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

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Background
For years, inadequate CAPA measures have been at the top of the FDA Warning Letter hit list for medical devices. This goes hand in hand with an equally often inadequate complaints management. CAPA deficiencies not only result in system deficiencies, but also in the frequent failure to recognise the recurrence of an error. Here, appropriate monitoring with a trend analysis fails. In particular, the Warning Letters repeatedly mention deficiencies in the documentation and verification of CAPA measures.

CAPA deficiencies are a mandatory part of the management review, so that senior management can react accordingly.

CAPA and Management Reviews have been requirements of the corresponding ISO standards (especially ISO 13485:2016) and 21 CFR 820 for years, MDR also requires both, but the requirements are very general. A guideline of the Global Harmonisation Task Force (GHTF) from 2010 also provides further assistance. However, how is CAPA management implemented in the medical device industry today so that all requirements of the regulations are met? How is a trend integrated into CAPA management and how are deficiencies correctly addressed in management reviews? These are questions that will be clarified in the webinar. Furthermore, exemplary CAPA deficiencies will be presented.

Educational Objectives
The following issues will be discussed:
- Oversight regulations: ISO 13485, GHTF Guideline CAPA, MDR, 21 CFR 820.100/198
- A more efficient CAPA System
  - Interface complaint management
  - Radicial Root Cause Analyse: e. g. „Five times why?"
  - Clear verification and validation of measures
- Monitoring and trending - a CAPA subsystem
- The managemen -review – CAPA´s final stage?
- Examples of FDA Warning Letter findings

Target Audience
Employees from companies, who are involved in CAPA Management, trending and management review (QM, manufacturing, quality control, etc.) are addressed. 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), Audits of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
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Presentation/Certificate
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Do you have any questions?
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Registration for the Webinar "CAPA - Trending - Management Review for Medical Devices" on Thursday, 02 July 2020, 14.00 – 15.30 (CEST)
Speaker: Dr Gerhard Bauer-Lewerenz
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 01 July 2020

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