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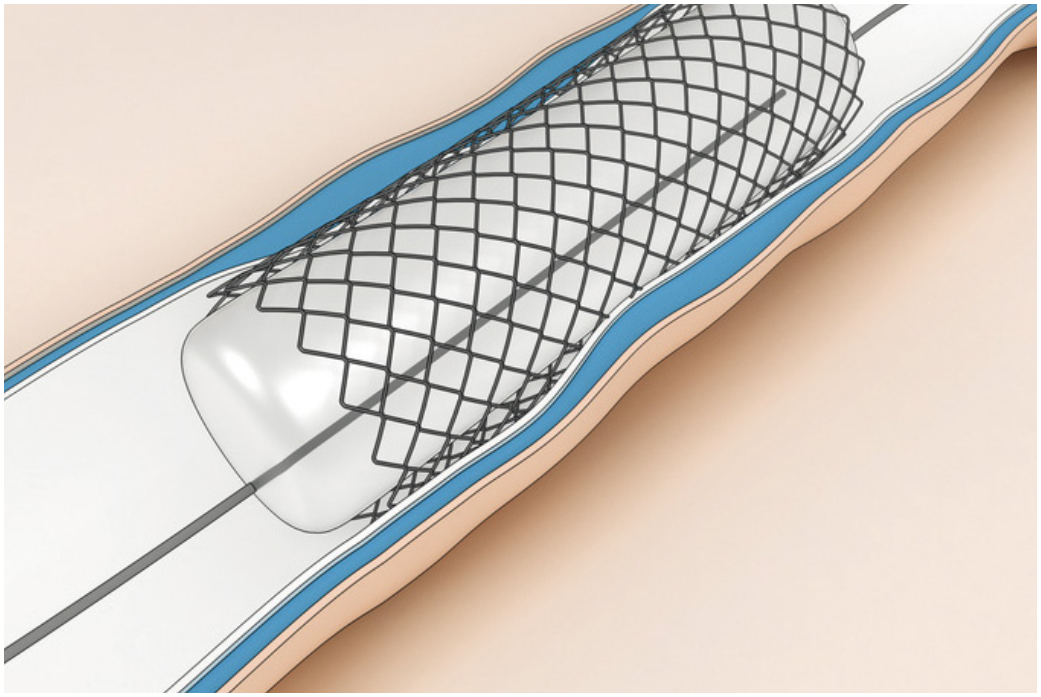
GMP Webinar

Data Integrity of Medical Devices

Development – Manufacturing – Controls: Requirements of ISO 13485

Date:
Wednesday, 20 January 2021, 14.00 – 16.00 h CET

Speaker:
Dr Holger Kost, Kettenbach GmbH & Co. KG, Eschenburg, Germany



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

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Background
The medical device industry is a strongly regulated business. Depending on the classification of the device, supervision from a Notified Body and partially from an authority is required. From the development of a medical device until the daily production and quality control, a lot of data come up, which can can be either generated manually or electronically. Besides, the data must be generated, handled and archived in such a way that the auditor/inspector has no objections to it. To assure this, the data management life cycle starts with the generation of data and ends with archiving or destructing. In the field of medical devices, only a few requirements from guidelines are available. There is an exception, though: the export of medical devices to the USA. In the USA, the compliance with 21 CFR 11 regarding the handling of electronic data is mandatory. Now, what can give some orientation for the EU market? What requirements are mentioned in ISO 13485? Could GMP rules for medicinal products/drugs also give hints for medical devices? All these questions and other items with focus on medical devices will be discussed during this webinar.

Educational Objectives
The following topics will be covered:
- Overview of Regulations: from ISO 13485 to 21 CFR 11
- What are Quality-Related Data?
  - Primary data, raw data, metadata, QC / QA data, Manufacturing data
  - Static and dynamic data,Classification of data
- Data integrity - Criteria and Principles
  - ALCOA and ALCOA+ criteria
  - Data Life Cycle Management, Data management and controls
  - Validation of computerised systems regarding data integrity
  - How to secure data integrity at and from a service provider
- GITP – Good IT Practice, what does this mean in terms of Data Integrity?
  - Paper vs. electronic data
  - User management – what is state of the art
  - Working with Excel sheets
  - Data protection and recovery, Disaster recovery
  - Audit Trail, Audit Trail Review
  - Change management
  - Cloud computing and data integrity – a real challenge

Target Audience
This webinar adresses employees who are responsible for data governance, e.g. (developers, QM, Regulatory Affairs, production, quality control etc.) in companies which develop, manufacture, and controls medical devices. Consultants for the Medical Device Industry are also addressed.

Speaker

Dr Holger Kost, Kettenbach GmbH & Co. KG, Germany
Dr Kost holds a PhD in biochemistry and analytical chemistry from the University Gießen. He worked for Novartis in different departments (development, manufacturing and QA) at different sites from 2001 – 2009. In his last function at Novartis, he was head of QC. He is a certified SixSigma+Lean Green Belt and GMP Auditor. From 2017 – 2019, he was site head QM at Abbott Diagnostics in Wiesbaden. Since April 2019, he heads the QM and Regulatory Affairs department at Kettenbach - a global medical device manufacturer.

Fees (plus VAT)
Single participation: € 249.- for ECA Members
Single participation: € 299,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

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.

Group Participation (fee per person):
3-10 Persons € 254,15
11-20 Persons € 224,25
more than 20 Persons € 194,35

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.

Technical Requirements
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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 Webinar "Data Integrity of Medical Devices " on Wednesday, 20 January 2021, 14.00 – 16.00 h CET
Speaker: Dr Holger Kost, Kettenbach GmbH & Co. KG
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 19 January 2021

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