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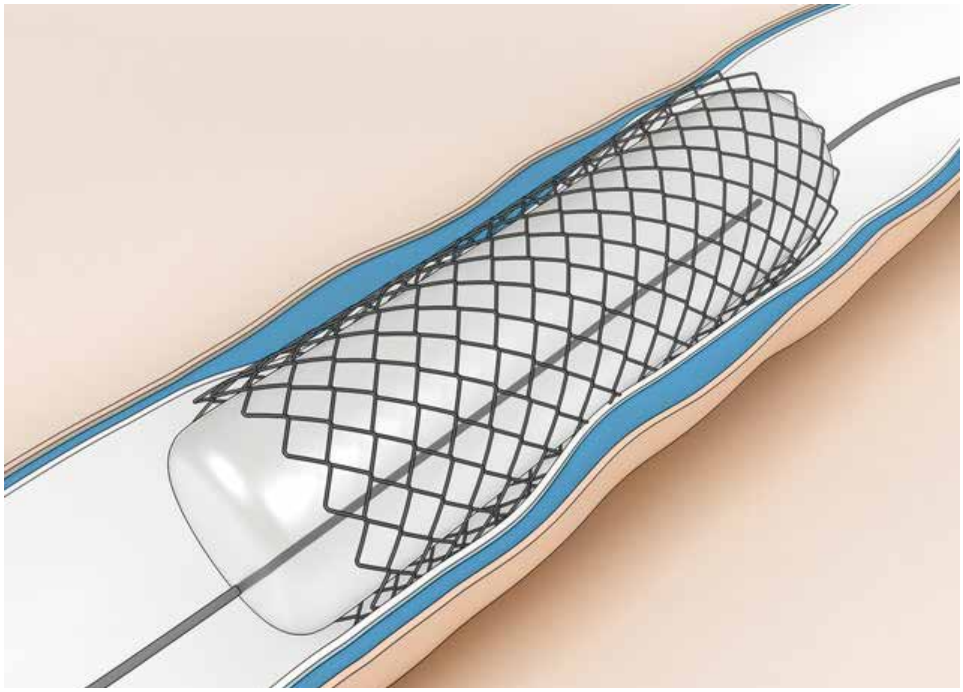
GMP Webinar
ISO 13485 Revision – What is new?

Date:
Monday, 06 June 2016, 14.00 – 15.15 h (CEST)

Speaker:
Ms Véronique Arnegger,
Chemgineering Business Design GmbH, Stuttgart, Germany



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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

GMP Webinar: ISO 13485 Revision – What is new?

Background
Medical devices are regulated by means of three EU-Directives (90/385/EWG, 93/42/EWG and 98/79/EG) as well as an additional directive in Europe. Harmonized standards are essential in the regulation of medical devices, as these standards represent the "state of the art" and therefore have a high relevance for medical device manufacturers (presumption of conformity).

One of the most important standards for medical device manufacturers is EN ISO 13485 "Medical Devices – Quality management systems – Requirements for regulatory purposes". This standard describes the requirements for a management system and covers the design and manufacturing process of medical devices. The distribution of medical devices in Europe is based on a CE Certification, mostly in combination with a notified body who are primarily in charge of the supervision of medical devices. They audit the QM System of medical device manufacturers, hence the implementation of ISO 13485.

ISO 13485 has been revised recently. After a transition period, ISO 13485-2016 will come into force. Unfortunately, there are differences between ISO 13485-2016 and ISO 9001-2015 which has also been revised recently. Especially the topic risk management has a higher relevance in ISO 13485-2016 than in the old, but still current version. For example, risk management should now also be implemented in the management review. Furthermore, new requirements, coming from FDA´s 21 CFR 820 (Quality System Regulations, QSR), are also implemented. Examples are the introduction of a medical device file and the new subchapters regarding design transfer, design history file etc. Additionally, statistical methods become more important in designing a product and software validation is addressed more explicitly.

Educational Objectives
The following topics will be discussed regarding the revision of ISO 13485 in the view of an industry representative

- History of ISO 13485
- What´s new in ISO 13485-2016?
- Possible implementation strategies regarding ISO 13485-2016
- ISO 9001-2015 and ISO 13485-2016
  - Similarities
  - Differences
  - How to close this gap?
- ISO 13485-2016 and GMP for Medical Devices (QSR, 21 CFR 820)
  - Similarities
  - Differences

Target Audience
The target audience are people who are interested in the changes carried out during the revision of ISO 13485, mainly medical devices manufacturers. Companies which bring combination products to the market and therefore have to apply ISO 13485 are also addressed.

Speaker

Ms Véronique Arnegger, Chemgineering Business Design GmbH, Stuttgart
Véronique Arnegger holds a diploma in business administration (Industry), International Regulatory Affairs Manager and Business Mediator. The last 15 years she worked within several leading positions within the medical device industry, especially within the quality management. In those functions, she was responsible for different Mock-, FDA and Notified Body Audits especially for the area of CAPA and CC. Since 2016 she is working with Chemgineering as Senior Consultant. In this function she is responsible for solving compliance problems and consulting medical device companies in preparation of FDA and Notified Body audits or technical documentation. She is also a lecturer.

Fees (plus VAT)
Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

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. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de for details.**

Group Participation (fee per person):
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

Technical Requirements
To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers. Your Internet browser must have following features to use the GMP Webinar system:
1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.
Please read the detailed technical requirements in this document: http://www.gmp-compliance.org/webinar/webinar_requirements.htm

Registration
By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. 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.

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.

Do you have any questions?
For questions regarding content:
Mr Sven Pommeranz,
phone +49-(0)6221-844447
E-Mail: pommeranz@concept-heidelberg.de
For questions regarding technical aspects:
Mr Matthias Zimmermann,
phone +49-(0)6221-844459
zimmermann@concept-heidelberg.de.

Registration for the GMP Webinar: ISO 13485 Revision – What is new?
on Monday, 6 June 2016, 14.00 – 15.15 h (CEST)
Speaker: Véronique Arnegger, Chemgineering Business Design
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34
or you register online at www.gmp-compliance.org.

Please tick:
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  ☐ 3-10 Persons
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Important: Deadline is 12 noon on 3 June 2016

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