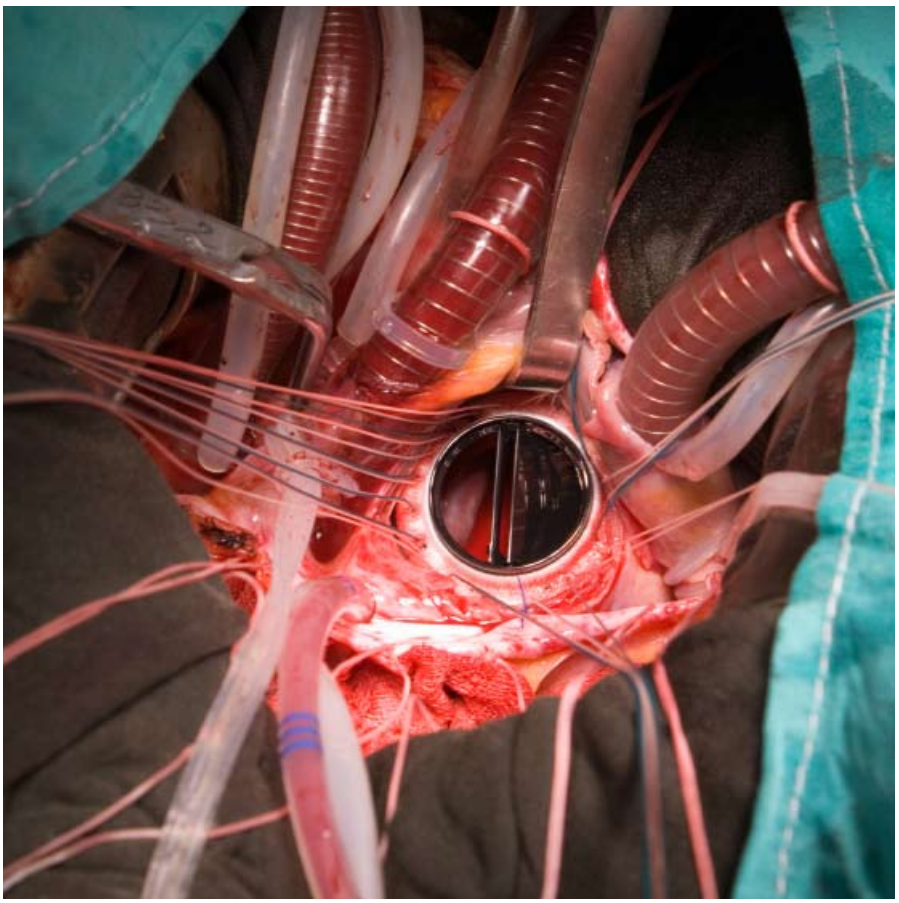
GMP-Webinar

The new EU Requirements for the Regulation of Medical Devices – what may come?

Date:
20 February 2013, 14.00 – 16.00 h

Speaker:
Dr Andrea Weiland-Waibel, Explicat Pharma GmbH, Hohenbrunn



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Background

With the implementation of the EU directives 90/385/EEC and 93/42/EC regarding active implantable medical devices and (non-active) medical devices the idea of „new approach" was implemented in Europe. The objective was: „Less state control with the same amount of security". The EU has thought about a revision of the regulations dating from the nineties already for some time now. The PIP scandal in France has further spurred these considerations. What reasons has the EU for a revision?

- There have been many technological and scientific innovations in the area of medical devices in the past 20 years.
- EU Member States interpret the current rules in different ways.
- It is not always possible to trace medical devices back to their supplier.
- A greater transparency as concerns safety and effectiveness of medical products is desirable.

In order to further address these points the EU has published two proposals for regulations at the end of September 2012 which will become directly applicable EU law when finalised.

Educational Objectives

Although the new proposals will only be finalised in 2014 they nevertheless show the actual way of thinking of the EU. Insofar it is important for manufacturers of medical devices to catch up on the current way of thinking of the EU in order not to lag behind and to eventually be able to take countermeasures with the help of special interest groups. The webinar's objective is to give a compact overview of the proposal for a new regulation on medical devices and to venture a look into the future.

- What is to be understood by the planned increased competencies of the notified bodies, also with regard to unannounced audits and stronger supervision?
- Which qualifications and functions could a qualified person have in the future?
- Which functions could the Medical Device Coordination Group have?
- Which measures are planned for a better traceability?
- What could stricter requirements for clinical evidence look like?
- What could be meant with introduction of classification rules?

The core elements of the proposals are presented in the Webinar and possible effects are discussed. We do not address the issue of IVDs.

Target Audience

This Webinar addresses manufacturers of medical devices and combination products who want to be up-to-date on the new EU proposals on medical devices and on the possible consequences.

Fee

€ 149.- plus VAT for ECA members
€ 199.- plus VAT 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.

Speaker

Dr Andrea Weiland-Waibel, Explicat Pharma GmbH, Hohenbrunn

The pharmacist Dr. Weiland-Waibel has held different managerial positions in the area development in the companies Pfizer, IDEA AG and PQD. She is working on a self-employed basis in the area CMC (Chemistry-Manufacturing-Controls) - technical project management since 2005. She is also technical expert at LGA Intercert GmbH (TÜV Rheinland Group) for conformity assessment procedures for medical devices especially of class III as well as for combination products.

Participation of a Group

The registration fee only authorises an individual to take part in the Webinar. Therefore, we do not issue more than one certificate per registration. With the registration fee being paid only once, it would infringe the copyright of CONCEPT HEIDELBERG as well as that of the speaker if the transmission was followed by several persons.

If you wish to register a group, please send an e-mail to info@concept-heidelberg.de or contact us by phone (+49 (0)62 21 / 84 44 51 Mr Strohwald). Prior to the Webinar date, we will help you to establish and test your Internet and phone connection correspondingly.

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.

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 download. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?

Mr Sven Pommeranz, phone +49 62 21 - 84 44 47,
E-Mail: pommeranz@concept-heidelberg.de, will answer your questions.

Registration for the GMP-Webinar: The new EU Requirements for the Regulation of Medicinal Products – what may come?
Wednesday, 20 February 2013, 14.00 – 16.00 h, Speaker: Dr Andrea Weiland-Waibel
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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