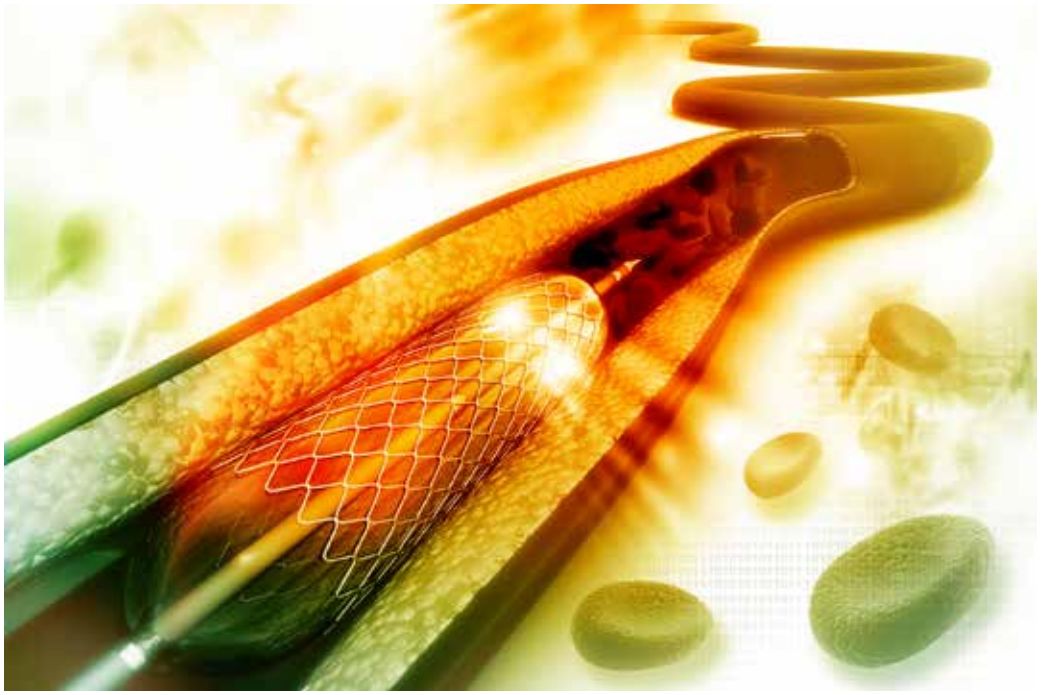
ECA Academy
Your GMP/GDP Information Source

GMP Webinar

The new Medical Device Regulation and its influence on Combination Products

Date:
Thursday, 21 March 2019, 14.00 - 15.30 (CET)

Speaker:
Dr Peer Schmidt, AbbVie Deutschland GmbH & Co. KG, Ludwigshafen



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

Background
In the EU, Medical Devices are regulated by two EU Directives (90/385/EEC, 93/42/ EEC) whereas in-vitro diagnostics are regulated by an independent directive. This will change in the near future. With the publication of the new Medical Devices Regulation (MDR) in the Official Journal of the European Union, a transition period has started which will end in May 2020. The MDR will supersede the two directives regarding the active implantable Medical Devices (AiMDD) and all other Medical Devices (MDD). The changes concern all classes of Medical Devices and will lead to distinct, detailed and extensive requirements. They will also apply to the Medical Device elements of Combination Products.

- What do manufacturers of Medical Devices/Combination Products have to expect in the near future?
- What are the crucial changes?
- What has to be considered for implementation?
- What should be done already now?

These questions will be clarified during the webinar.

Educational Objectives
The following issues around the new Medical Device Regulation will be addressed:

- Background of the changes in medical device regulation
- Transition periods
- Changes in product classification
- Conformity assessment of Combination Products according to MDR
- New requirements regarding technical documentation
- Identification of products by means of UDI
  - What is UDI
  - Differences/Similarities to US requirements
- The person responsible for regulatory compliance („QP for Medical Devices")
- Requirement profile
- Interim solutions
- Medical Devices Coordination Group (MDCG)
- Scrutiny procedure for specific Medical Devices
- Clinical evaluation / studies
- Supervision by competent authorities
- EUDAMED data base
- What to consider when getting ready for the new regulations?
- Compatibility of the MDR, Quality System for Medical Devices (21 CFR 820) and GMP for Combination Products (21 CFR 4)

Target Audience
This training is intended for employees of enterprises who want to be informed about the requirements of the Medical Devices Regulation, especially manufacturers of Medical Devices. It also applies to drug manufacturers utilizing medical devices to administer their products (Combination Products) .

Speaker

Dr Peer Schmidt, AbbVie Deutschland GmbH & Co. KG
Peer Schmidt brings more than 15 years of experience in the development, manufacturing, registration and supervision of Medicinal Products, Medical Devices and Combination Products. As Senior Manager Global Quality Systems, he leads the AbbVie Center of Excellence for Quality Risk Management. He also acts as EU Authorized Representative and Management Representative for AbbVie´s Medical Devices. He holds a PhD in Molecular Biology and was previously the Head of Quality Assurance at Abbott Biotechnology Germany.

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
http://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
For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At **http://www.webex.com/test-meeting.html** you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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 please contact
Mr Gerhard Becker, phone +49 62 21 - 84 44 65,
E-Mail: becker@concept-heidelberg.de

For questions regarding technical aspects please contact
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13
email: schopka@concept-heidelberg.de

Registration for the GMP-Webinar: The new Medical Device Regulation and its influence on Combination Products, 21 March 2019, 14.00 - 15.30 h
Speaker: Dr Peer Schmidt, AbbVie Deutschland
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important:
Deadline is 12 noon on 20 March 2019

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

General Terms and Conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.
CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!