GMP Webinar *Recording*

**The new Medical Device Regulation and its influence on Combination Products**

Date of the recording: Thursday, 21 March 2019

Speaker:
Dr Peer Schmidt, AbbVie Deutschland GmbH & Co. KG, Ludwigshafen
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 (AIm-DD) 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:** € 199,- for ECA Members
- **Single participation:** € 249,- 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

If 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 each individually on your own PC. Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de for details.

### 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.

### Technical Requirements

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### Registration for the GMP-Webinar

**Recordings The new Medical Device Regulation and its influence on Combination Products of 21 March 2019**

**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.

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