DIA Learning

Medical Devices and Drug-Device Combination Products in the EU

Virtual Live Training Course

12-13 November 2020
09:00-13:00 CET

OVERVIEW

The regulatory environment for medical devices in Europe is changing. With an increased focus on patient safety, the European Medical Device Regulation (MDR) has introduced new requirements and processes.

This training provides insights into the MDR and the practical implications for manufacturers and decision makers. The course is designed to guide through the main challenges associated with MDR, including classification and the requirements for the vigilance system, post-market surveillance (PMS) and post-market clinical follow-up (PMCF) studies.

In interactive practical exercises participants will gain understanding of product demarcation, classification and the need of an integrated pathway for Drug-Device Combination (DDC) products. Delegates will have the opportunity to discuss the complexities involved with two experts, both of whom have significant knowledge and experience in this field.

LEARNING OBJECTIVES

- Gain a comprehensive understanding of the new requirements of the MDR and realize the major changes incl. Vigilance and Post Market Surveillance
- Learn about the demarcation process and classification of medical devices according to risk classes
- Understand how risk should be managed
- Recognize the different stakeholders involved, besides the Notified Bodies
- Consider the challenges and opportunities of Drug-Device Combination products

WHO WILL ATTEND

This course was designed for delegates working with Medical Device and Medicinal products in regulatory affairs, safety and pharmacovigilance, quality assurance, clinical development and technical support.

This event will be of particular interest to all personnel who are either new to the medical device or combination product issues or have been working under the “old” system from industry as well as from decision making perspective.

FACULTY

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Regulatory Affairs Medical Devices
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Federal Ministry of Social Affairs, Health,
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PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

09:00 INTRODUCTION TO COURSE

Reinhard Berger, Martin Renhardt and Maren von Fritschen

- Introduction to course content and course structure
- Brief presentation of course participants and course leaders

09:30 SESSION 1

BACKGROUND AND OBJECTIVES OF THE MEDICAL DEVICE REGULATION (MDR)

Maren von Fritschen

- Reason for revision
- Relevant actors: EMA, NCA, CAMD, MDCG, NB, Team NB, industry, SMEs, HTA, patients, etc.
- Purpose and structure of the law
- Timelines and transition provisions

09:45 SESSION 2

KEY ELEMENTS OF THE MDR - OVERVIEW

Maren von Fritschen

- Definition and Demarcation
- Supervision and Harmonisation
  - Latest status of NB designation
  - Latest publication by the MDCG
- Transparency
  - EUDAMED, Nomenclature
  - Traceability, UDI
- Technical Documentation, Quality Management System
- Clinical evaluation and clinical investigations
- Vigilance and Market Surveillance
- General obligations of a manufacturers: e.g. CE marking, Person responsible for regulatory compliance (PRRC)

10:15 SESSION 3

CLASSIFICATION RULES

Reinhard Berger

- Class III
- Class IIb
- Class IIa
- Class I
- Conformity Assessment

10:45 BREAK

11:00 SESSION 4

PRACTICAL EXERCISE: DEMARCATION AND CLASSIFICATION OF MEDICAL DEVICES

Reinhard Berger, Martin Renhardt and Maren von Fritschen

11:30 SESSION 5

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)

Reinhard Berger

12:00 SESSION 6

MEDICAL DEVICE COORDINATION GROUP (MDCG)

Martin Renhardt

- Latest guidelines
- Future developments
- Regulatory perspective

12:30 QUESTIONS AND ANSWERS

13:00 END OF DAY 1

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@DIAglobal.org

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 12.00 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12.00 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

DAY 2

09:00 RECAP OF DAY 1

Reinhard Berger, Martin Renhardt and Maren von Fritschen

09:15 SESSION 7

DRUG DEVICE COMBINATION PRODUCTS

Maren von Fritschen

- What is new with MDR being applicable?
- Roles, responsibilities and remits of decision makers
- Medicinal products with an integral device
- Medicinal products with a non-integral device (co-packed)
- Separate Medicinal product and medical device cross references in labelling
- Relevant guidance
- Combined ATMPs
- EMA Regulatory Science Strategy 2025

09:45 SESSION 8

VIGILANCE AND POST-MARKET SURVEILLANCE (PMS)

Reinhard Berger

- Case reporting
- Post Market Surveillance Plan
- Post Market Clinical Follow-up (PMCF)
- Periodic Safety Update Report (PSUR)
- Summary of Safety and Clinical Performance (SSCP)
- Trending and Risk Management
- Registries

10:30 SESSION 9

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Reinhard Berger

- Understanding the expectations for clinical evaluations and investigations
- Understanding the relationship between clinical data, clinical evaluation and clinical investigation
- Assessing the Clinical Evaluation Reports (CERs) requirements under EU MDR
- Information required to be included in CER
- Clinical performance
- Clinical Assessment
- Clinical follow-up during life-cycle

11:00 BREAK

11:15 SESSION 10

SOFTWARE AS MEDICAL DEVICE

Martin Renhardt

- Software and Medical Apps
- Classification of standalone software
- Platform Technology

12:00 SESSION 11

PRACTICAL EXERCISE AND GROUP WORK

Reinhard Berger, Martin Renhardt and Maren von Fritschen

12:30 QUESTIONS AND ANSWERS

13:00 END OF TRAINING COURSE

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

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REGISTRATION FORM Virtual Live Training Course

Medical Devices and Drug-Device Combination Products in the EU # 20530
12-13 November 2020 09:00-13:00 CET

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.		

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CET. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #20530 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature