

# Medical Devices and Drug-Device Combination Products in the EU

## Virtual Live Training Course

28-30 June 2021

09:00-13:00 CEST



### 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 experts who 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

#### **Maren von Fritschen**

AddOn Pharma GmbH  
Former Chair DIA Regional Advisory Council EMEA  
Germany

#### **Reinhard Berger**

Regulatory Affairs Medical Devices  
Consulting-Advising  
Austria

#### **Martin Renhardt**

Head of Department  
Pharmaceuticals and Medical Devices,  
Blood, Tissue and Transplantation  
Federal Ministry of Social Affairs, Health,  
Care and Consumer Protection  
Austria

## 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, OBJECTIVES AND KEY ELEMENTS 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
- 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 BREAK

### 10:30 SESSION 2

#### MEDICAL DEVICE COORDINATION GROUP (MDCG)

*Martin Renhardt*

- Latest guidelines
- Future developments
- Regulatory perspective

### 11:00 SESSION 3

#### DEMARCATON AND CLASSIFICATION OF MEDICAL DEVICES: RULES AND PRACTICAL EXERCISE

*Reinhard Berger, Martin Renhardt and Maren von Fritschen*

- Demarcation between Medical Device resp. IVD and/or other kind of product
- Risk classes I to III, classification rules
- Application of classification rules
- Impact on conformity assessment route
- Practical exercise

### 11:45 BREAK

### 12:00 SESSION 3 CONTINUED

#### DEMARCATON AND CLASSIFICATION OF MEDICAL DEVICES: RULES AND PRACTICAL EXERCISE

*Reinhard Berger, Martin Renhardt and Maren von Fritschen*

### 12:45 QUESTIONS AND ANSWERS

### 13:00 END OF DAY 1

## 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
- 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).

## Group Discounts

**Register 3 individuals from the same company and receive complimentary registration for a 4th!**

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to [basel@diaglobal.org](mailto:basel@diaglobal.org).

## DAY 2

09:00 RECAP OF DAY 1, QUESTIONS AND ANSWERS

*Reinhard Berger, Martin Renhardt and Maren von Fritschen*

09:15 SESSION 4

### SOFTWARE AS MEDICAL DEVICE

*Martin Renhardt*

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

10:00 SESSION 5

### GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)

*Reinhard Berger*

- Risk management and mitigation
- Annex II – technical documentation

10:45 BREAK

11:00 SESSION 6

### PRACTICAL EXERCISE AND GROUP WORK

*Reinhard Berger, Martin Renhardt and Maren von Fritschen*

12:00 SESSION 7

### POST-MARKET SURVEILLANCE (PMS) AND VIGILANCE

*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
- Annex 3

13:00 END OF DAY 2

## DAY 3

09:00 RECAP OF DAY 2, QUESTIONS AND ANSWERS

*Reinhard Berger, Martin Renhardt and Maren von Fritschen*

09:30 SESSION 8

### 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

10:30 BREAK

10:45 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

11:45 BREAK

12:00 RECAP OF THE COURSE, QUESTIONS AND ANSWERS

13:00 END OF TRAINING COURSE

## Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8 credits.



Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

## 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](mailto:Basel@DIAGlobal.org)

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# REGISTRATION FORM Virtual Live Training Course

Medical Devices and Drug-Device Combination Products in the EU # 21530  
28-30 June 2021 09:00-13:00 CEST



## 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 EARLY-BIRD valid until 3 May 2021	MEMBER valid from 4 May 2021	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'305.00 <input type="checkbox"/>	€ 1'450.00 <input type="checkbox"/>	€ 1'635.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 725.00 <input type="checkbox"/>	€ 910.00 <input type="checkbox"/>

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](http://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](http://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](mailto:Basel@DIAglobal.org) Mail: DIA, KÜchengasse 16, 4051 Basel, Switzerland

Web: [www.DIAglobal.org](http://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 #21530 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