

Essentials of Medical Devices and Combination Products in the European Union

Virtual Live Training Course

2-4 November 2022

09:00-13:00 CET



OVERVIEW

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

This virtual live training course 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 conformity to 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. Additionally, some case studies will be shown how to implement the requirements. 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 current requirements of the MDR and learn from case studies how to implement these requirements
- Learn about the demarcation process and classification of medical devices according to risk classes
- Learn from case studies how risks for the product can be managed over lifetime
- Recognize the different stakeholders involved, besides the Notified Bodies
- Realize the challenges for Combination products in the EU, and learn from recent guidelines

WHO WILL ATTEND

This virtual live training course will be of importance to all those involved in the following departments:

- Regulatory Affairs
- Safety/Pharmacovigilance
- PMS and Vigilance
- Quality Assurance
- Product registration and distribution

and all those interested in new EU MDR requirements.

FACULTY

Maren von Fritschen

Head EU Regulatory Policy
Moderna
Netherlands

Reinhard Berger

Regulatory Affairs Medical Devices
Consulting-Advising
Austria

Anna Amich

Deputy EU QPPV / PRRC officer
Novartis
Spain

DAY 1

09:00 INTRODUCTION TO COURSE

Reinhard Berger 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: Commission Services, MDCG, NCA, EMA, CAMD, NB, Team NB, industry, SMEs, HTA, patients, etc.
- Purpose and structure of the law
- Timelines and transition provisions
- Definition and Demarcation
- Supervision and Harmonisation
 - Role of NBs
 - Latest status of NB designation
- Technical Documentation, Quality Management System
- Clinical evaluation and clinical investigations
- Vigilance and Market Surveillance
- General obligations of manufacturers: e.g. CE marking, Person responsible for regulatory compliance (PRRC)

10:15 BREAK

10:30 SESSION 2

MEDICAL DEVICE COORDINATION GROUP (MDCG)

Reinhard Berger

- Latest guidelines and publication by the MDCG
- Future developments
- Regulatory perspective
- Transparency
 - EUDAMED, Nomenclature
 - Traceability, UDI

11:00 SESSION 3

DEMARCATON AND CLASSIFICATION OF MEDICAL DEVICES: RULES AND PRACTICAL EXERCISE

Reinhard Berger

- 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

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 for the same course 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.

DAY 2

09:00 RECAP OF DAY 1, QUESTIONS AND ANSWERS

Anna Amich and Maren von Fritschen

09:15 SESSION 4

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)

Anna Amich

- Risk management and mitigation
- Annex II – technical documentation

09:45 SESSION 5

POST-MARKET SURVEILLANCE (PMS) AND VIGILANCE

Anna Amich

- 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
- Annex 3

10:45 BREAK

11:00 SESSION 6

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
- Borderline products

12:00 SESSION 7

PRACTICAL EXERCISE AND GROUP WORK

Anna Amich and Maren von Fritschen

13:00 END OF DAY 2

DAY 3

09:00 RECAP OF DAY 2, QUESTIONS AND ANSWERS

Anna Amich, Reinhard Berger and Maren von Fritschen

09:30 SESSION 8

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Anna Amich

- 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

10:30 BREAK

10:45 SESSION 9

PRACTICAL EXERCISE AND GROUP WORK

Anna Amich, Reinhard Berger and Maren von Fritschen

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 9 credits.



| Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore [eLearning](#) to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

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REGISTRATION FORM Virtual Live Training Course

Essentials of Medical Devices and Combination Products in the EU # 22530
2-4 November 2022 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 EARLY-BIRD valid until 7 Sep 2022	MEMBER valid from 8 Sep 2022	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'115.00 <input type="checkbox"/>	€ 1'240.00 <input type="checkbox"/>	€ 1'425.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 <input type="checkbox"/>	€ 805.00 <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](https://www.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](https://www.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 CE(S)T. **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 #22530 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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
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