

DIA Training Course on

Medical Devices: Regulations and lifecycle management

Course #15536

21-23 September 2015

Fleming's Hotel Wien-Westbahnhof, Vienna, Austria

OVERVIEW

This course will give clear and practical guidelines on how to navigate the development of a medical device in the regulatory landscape, and how to identify the correct development path. It focuses on Europe, but also addresses global standards.

Overview of the EU device legislative system and the principles and philosophy behind it will be discussed. Instructors will also explain the essential features of EU medical device regulation, such as essential requirements, risk classification, the relationship between risk classification and conformity assessment procedures and the role of notified bodies.

For medical devices that need to be tested clinically, the process of planning, conducting and reporting a clinical investigation with medical devices will be described in detail.

Furthermore, the process of drafting a design dossier will be highlighted, both for medical devices and for combination products.

KEY TOPICS

- EU Medical device regulation: philosophy, content and structure
- Directive 93/42/EC, as amended by 2007/47/EC
- CE mark
- ISO 14155, ISO 13485 and ISO 14791
- Risk-classification of medical devices
- Drug-device combination products
- Clinical evaluation and clinical investigation
- Medical devices vigilance system
- Recent and upcoming legal changes in Europe

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Apply the principles of EU medical device regulation
- Classify medical devices according to rules for risk classification
- Identify the applicable conformity assessment procedure
- Understand the issues surrounding combination products (including ATMPs)
- Conduct a medical device trial according to ISO14155
- Understand ethical and regulatory considerations of medical device trials
- Understand the practical differences between medical device and drug development
- Identify responsibilities in post-marketing surveillance
- Evaluate risks and handle incident reports

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

WHO WILL ATTEND

This course is designed for professionals starting work in industry and regulatory bodies, who would like to get acquainted quickly with all aspects of medical device regulation.

This course is also aimed at professionals in pharmaceuticals (e.g. regulatory affairs, clinical development), who would like to obtain an overview of device regulation, or who are involved in either drug-device combinations or medical devices.



FACULTY

Sabina Hoekstra-van den Bosch

(Course Director)
Senior Manager Standards & Regulations
Philips Healthcare - Global Regulations & Standards
The Netherlands

Joris Bannenberg

COO / Medical Director
Factory - CRO for Medical Devices
The Netherlands

Reinhard Berger

Senior Expert Medical Devices
Austrian Agency for Health and Food Safety (AGES)
Austria

Gert Bos

Head of Regulatory and Clinical Affairs, Medical Devices
BSI Assurance Ltd.
United Kingdom

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

DAY 1

08:00	REGISTRATION
08:45	WELCOME, INTRODUCTION AND OUTLINE OF THE COURSE PROGRAMME
09:15	SESSION 1
	WHAT IS A MEDICAL DEVICE? DEFINITIONS, DEMARCATION AND BORDERLINES (INCLUDING AN EXERCISE) <i>Sabina Hoekstra-van den Bosch</i>
10:00	COFFEE BREAK
10:30	SESSION 2
	HEADLINES OF THE EU REGULATORY SYSTEM FOR MEDICAL DEVICES <i>Sabina Hoekstra-van den Bosch</i>
11:15	SESSION 3
	RISK CLASSIFICATION (INCLUDING AN EXERCISE) <i>Gert Bos</i>
12:00	SESSION 4
	PRE-MARKETING: ESSENTIAL REQUIREMENTS <i>Gert Bos</i>
12:30	LUNCH
13:30	SESSION 5
	PRE-MARKETING: CONFORMITY ASSESSMENT PROCEDURES AND CE MARKING <i>Sabina Hoekstra-van den Bosch</i>
14:15	SESSION 6
	POSITION, ROLE AND RESPONSIBILITIES OF NOTIFIED BODIES <i>Gert Bos</i>
15:00	COFFEE BREAK
15:30	SESSION 7
	QUALITY MANAGEMENT <i>Gert Bos</i>
16:15	SESSION 8
	ECONOMIC OPERATOR OBLIGATIONS <i>Sabina Hoekstra-van den Bosch and Gert Bos</i>
16:45	QUESTIONS AND ANSWERS, WRAP-UP DAY 1
17:30	END OF DAY ONE

DAY 2

09:00	SESSION 9
	THE BASICS OF RISK MANAGEMENT IN THE DEVELOPMENT OF MEDICAL DEVICES AND DRUG-DEVICE COMBINATION PRODUCTS <i>Gert Bos</i>
09:45	SESSION 10
	DRUG-DEVICE COMBINATION PRODUCTS (INCLUDING COMBINATIONS WITH ATMPs) AND CONSULTATION PROCEDURES WITH NATIONAL COMPETENT AUTHORITIES AND/OR EMA <i>Sabina Hoekstra-van den Bosch</i>
10:30	COFFEE BREAK
11:00	SESSION 11
	POST-MARKETING SURVEILLANCE MEDICAL DEVICES VIGILANCE SYSTEM <i>Reinhard Berger</i>
11:45	SESSION 12
	INTRODUCTION TO CLINICAL EVALUATION AND CLINICAL INVESTIGATION <i>Joris Bannenber</i>
12:30	LUNCH
 <i>Following sessions on Day 2 are a part of The New Medical Device Regulation Information Day. Course participants will attend this event free of charge.</i>	
13:30	SESSION 13
	HIGHLIGHTS OF THE NEW MEDICAL DEVICE REGULATION <i>Sabina Hoekstra-van den Bosch</i>
14:00	SESSION 14
	CHANGED ROLE FOR NOTIFIED BODIES UNDER THE NEW MEDICAL DEVICE REGULATION AND IMPLICATIONS FOR MANUFACTURERS <i>Gert Bos</i>
14:45	COFFEE BREAK
15:15	SESSION 15
	CHANGES IN PRE- AND POST-MARKET CLINICAL REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION <i>Joris Bannenber</i>
16:00	SESSION 16
	CHANGES IN VIGILANCE AND POST-MARKET REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION <i>Reinhard Berger</i>
16:45	QUESTIONS AND ANSWERS
17:00	DRINKS RECEPTION
18:00	END OF DAY TWO

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.

DAY 3**09:00** **SESSION 17****INTRODUCTION TO CLINICAL INVESTIGATION AND PLANNING
A CLINICAL INVESTIGATION***Joris Bannenberg***09:45** **SESSION 18****APPLICABLE REGULATIONS AND QUALITY STANDARDS**

- ISO 14155: Clinical investigation of medical devices for human subjects
- Good Clinical Practice
- Terms
- Responsibilities of investigators
- Responsibilities of sponsors

*Joris Bannenberg***10:30** **COFFEE BREAK****11:00** **SESSION 19****SUMMARY: DIFFERENCES BETWEEN GCP AND ISO 14155 AND
INTERNATIONAL DIFFERENCES***Joris Bannenberg***11:45** **SESSION 20****EXERCISE ON HOW TO GET TO MARKET***Reinhard Berger***12:30** **LUNCH****13:30** **SESSION 21****DESIGN DOSSIER: MEDICAL DEVICES AND DRUG-DEVICE
COMBINATION PRODUCTS (INCLUDING CLINICAL STUDIES
WITH COMBINATION PRODUCTS)***Joris Bannenberg***14:15** **SESSION 22****VIGILANCE IN OPERATION: RESPONSIBILITIES, INCIDENT
REPORTING AND NATIONAL REQUIREMENTS***Reinhard Berger***15:00** **COFFEE BREAK****15:30** **SESSION 23****CONCLUSION AND RECOMMENDATIONS OF KEY ASPECTS THAT
NEED TO BE CONSIDERED FOR REGIONAL STRATEGIES FOR
MEDICAL DEVICES***Joris Bannenberg and Reinhard Berger***16:30** **END OF TRAINING COURSE****VENUE INFORMATION**

DIA has blocked a limited number of rooms at the following hotel:

Fleming's Hotel Wien-Westbahnhof**Neubauguertel 26-28****1070 Vienna, AT****Tel: +43 1 22 73 70****E-mail: wien@flemings-hotels.com**

Limited number of hotel rooms have been booked for DIA course participants at the Fleming's Hotel Wien-Westbahnhof at rate of EUR 130.00 single room per night including breakfast, service charge, and VAT.

To make a booking please fill in the booking form and send it to reservation.vie@flemings-hotels.com. The room rate is available until 20 August 2015 or until the room block is sold-out, whichever comes first. Reservations can be cancelled free of charge until 20 August 2015. In case of a cancellation after this time, no show or early departure, the hotel does have the right to charge 100% of the confirmed booking.

Our mission hasn't changed. Our look has.

About DIA
DIA is an independent, nonprofit organization with our global center located in Washington, DC, US and regional offices covering the Americas, Europe, Middle East and Africa, and Asia (China, Japan and India).

DIA's Vision
DIA is your essential partner in catalyzing knowledge creation and sharing to accelerate health product development.

DIA's Mission
DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.

Core Values
Neutrality & Integrity
Accountability & Trust
Respect & Dignity
Responsibility & Diversity
Passion & Engagement

Learn about our new board at diahome.org

STAY CONNECTED

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<http://www.linkedin.com/company/dia-association>

f Stay Connected at DIA: <https://www.facebook.com/DIAEurope>

YouTube Stay Connected: <https://www.youtube.com/user/DIAAssociation>

Twitter Stay Connected at DIA: [@DIA_Europe](https://twitter.com/DIA_Europe)

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FORM

Medical Devices: Regulations and lifecycle management #15536
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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and training course material.

FEES	MEMBER*	NON-MEMBER*
INDUSTRY	€ 1'840.00 <input type="checkbox"/>	€ 2'000.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 920.00 <input type="checkbox"/>	€ 1'080.00 <input type="checkbox"/>
BECOME A DIA MEMBER NOW	€ 155.00 <input type="checkbox"/>	

*All fees will be subject to the Austrian VAT at 20%

Please enter your Company's Austrian VAT number: _____

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

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership.

Visit www.DIAHome.org and click on Membership for more details.

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

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52

Email: diaeurope@diaeurope.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.diahome.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East & Africa 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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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

Fax Number

email (Required for confirmation)

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 # 15536 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 Europe, Middle East & Africa.**

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.diahome.org/EUTerms>

Date

Signature