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.

DIA Training Course on Medical Devices: Regulations and lifecycle management

Course #15536
21-23 September 2015
Fleming’s Hotel Wien-Westbahnhof, Vienna, Austria

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DIA Training Course on Medical Devices: Regulations and lifecycle management

Course #15536
21-23 September 2015
Fleming’s Hotel Wien-Westbahnhof, Vienna, Austria
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)
Sabina Hoekstra-van den Bosch
10:00  COFFEE BREAK
10:30  SESSION 2
HEADLINES OF THE EU REGULATORY SYSTEM FOR MEDICAL DEVICES
Sabina Hoekstra-van den Bosch
11:15  SESSION 3
RISK CLASSIFICATION (INCLUDING AN EXERCISE)
Gert Bos
12:00  LUNCH
12:30  SESSION 4
PRE-MARKETING: ESSENTIAL REQUIREMENTS
Gert Bos
13:30  SESSION 5
PRE-MARKETING: CONFORMITY ASSESSMENT PROCEDURES AND CE MARKING
Sabina Hoekstra-van den Bosch
14:15  SESSION 6
POSITION, ROLE AND RESPONSIBILITIES OF NOTIFIED BODIES
Gert Bos
15:00  COFFEE BREAK
15:30  SESSION 7
QUALITY MANAGEMENT
Gert Bos
16:15  SESSION 8
ECONOMIC OPERATOR OBLIGATIONS
Sabina Hoekstra-van den Bosch and Gert Bos
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
Gert Bos
09:45  SESSION 10
DRUG-DEVICE COMBINATION PRODUCTS (INCLUDING COMBINATIONS WITH ATMPS) AND CONSULTATION PROCEDURES WITH NATIONAL COMPETENT AUTHORITIES AND/OR EMA
Sabina Hoekstra-van den Bosch
10:30  COFFEE BREAK
11:00  SESSION 11
POST-MARKETING SURVEILLANCE MEDICAL DEVICES VIGILANCE SYSTEM
Reinhard Berger
11:45  SESSION 12
INTRODUCTION TO CLINICAL EVALUATION AND CLINICAL INVESTIGATION
Joris Bannenberg
12:30  LUNCH
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.
13:30  SESSION 13
HIGHLIGHTS OF THE NEW MEDICAL DEVICE REGULATION
Sabina Hoekstra-van den Bosch
14:00  SESSION 14
CHANGED ROLE FOR NOTIFIED BODIES UNDER THE NEW MEDICAL DEVICE REGULATION AND IMPLICATIONS FOR MANUFACTURERS
Gert Bos
14:45  COFFEE BREAK
15:15  SESSION 15
CHANGES IN PRE- AND POST-MARKET CLINICAL REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION
Joris Bannenberg
16:00  SESSION 16
CHANGES IN VIGILANCE AND POST-MARKET REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION
Reinhard Berger
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.
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.
**REGISTRATION FORM**
Medical Devices: Regulations and lifecycle management #15536
21-23 September 2015 | Fleming’s Hotel Wien-Westbahnhof, Vienna, Austria

**REGISTRATION FEES**
Registration fee includes refreshment breaks and lunches and training course material.

<table>
<thead>
<tr>
<th>FEES</th>
<th>MEMBER*</th>
<th>NON-MEMBER*</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUSTRY</td>
<td>€ 1'840.00</td>
<td>€ 2'000.00</td>
</tr>
<tr>
<td>ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)</td>
<td>€ 920.00</td>
<td>€ 1'080.00</td>
</tr>
</tbody>
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€ 155.00

*All fees will be subject to the Austrian VAT at 20%
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If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

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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

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**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)

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**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.

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**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 __________________________

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