DIA Training Course on

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices

Course #13547
10-12 June 2013
NH Caransa Hotel, Amsterdam, the Netherlands

Faculty

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Philips Healthcare - Global Regulations & Standards, the Netherlands

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

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Senior Consultant
Academic Medical Centre (AMC)
The Netherlands

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.
Participants are expected to have a relevant master's degree or to be working in pharmaceuticals or in medical devices.

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.

This course has limited capacity. Register early.

Overview

The course will give clear, practical guidelines on how to develop a medical device and how to identify the correct development path.

Part One: Philosophy and Legislation
Part One will deliver the knowledge base for the subsequent parts. It will give an overview of the EU device legislative system and the principles and philosophy behind it. It will explain the definition of a medical device and the demarcation between medical devices and pharmaceuticals. It will also explain risk classification of medical devices and the relationship between risk classification and conformity assessment procedures. This first part will highlight the role of the notified bodies and the legal basis for the requirements for clinical evaluation and clinical investigation. Also, the regulatory route for different types of combination products will be explained. A comparison of the EU and US regulatory systems will conclude this part.

Part Two: Operational Aspects I - Clinical and Vigilance
For medical devices that need to be tested clinically, the process of planning, conducting and reporting a clinical investigation with medical devices will be explained. The practical differences between the clinical development of pharmaceuticals and medical devices will be explored and the challenge of developing a drug device combination product will be touched upon. Responsibilities in post-marketing surveillance of medical devices (and drug device combination products) according to the Medical Device Vigilance System will be explained and illustrated with examples.

Part Three: Operational Aspects II - Quality Management, Risk Management, and Design Dossier
Part Three will start with the ins and outs of working with notified bodies. It will continue with the application of quality management and risk management to the development of medical devices, including the discussion of applicable ISO-standards. Differences between risk management of medical devices and pharmaceutical products will be pointed out. Furthermore, the process of 'constructing' a design dossier will be highlighted, both for medical devices and for combination products.

Part Four: In Vitro Diagnostics and Companion Diagnostics

Key Topics

- Medical device regulation: philosophy, content and structure
- Risk-classification of medical devices
- Drug-device combination products
- CE mark
- ISO 14155
- 93/42/EC, as amended by 2007/47/EC
- Clinical evaluation and clinical investigation
- Medical devices vigilance system
- In Vitro Diagnostics (IVD)
- Difference between IVD and personalised medicine

Learning Objectives

At the conclusion of this course, participants should be able to:
- Apply the principles of 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
- Apply the principles of the IVD directive
- Understand the difference in lifecycle of an IVD and personalised medicine

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MONDAY | 10 JUNE 2013

Philosophy and Legislation

08:00 REGISTRATION

08:45 **Welcome, Introduction and Outline of the Course Programme**

09:00 **Session 1**
What is a Medical Device? Definitions, demarcation and borderlines (including an exercise)
Sabina Hoekstra-van den Bosch

09:45 **Session 2**
Headlines of the EU Regulatory System for Medical Devices
Sabina Hoekstra-van den Bosch

10:30 COFFEE BREAK

11:00 **Session 2 continued**
Reading the Medical Devices Directive
Sabina Hoekstra-van den Bosch
Jos Kraus

11:45 **Session 3**
Risk Classification (including an exercise)
Jos Kraus

12:30 LUNCH

13:30 **Session 4**
Pre-Marketing: Essential requirements, conformity assessment procedures and CE marking
Jos Kraus

14:15 **Session 5**
Drug-Device Combination Products (including Combinations with ATMPs) and Consultation Procedures with National Competent Authorities and/or EMA
Role of Ethics Committees
Sabina Hoekstra-van den Bosch

15:00 COFFEE BREAK

15:30 **Session 6**
Global Regulation of Medical Devices (Differences and Similarities between US and EU Systems; Global Harmonisation Task Force)
Sabina Hoekstra-van den Bosch
Jos Kraus

16:00 **Session 7**
Exercise on How to Go to Market
Jos Kraus

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

TUESDAY | 11 JUNE 2013

Operational Aspects I - Clinical and Vigilance
Operational Aspects II – Quality Management

09:00 **Session 8**
Post-Marketing Surveillance Medical Devices Vigilance System
Jos Kraus

10:00 **Session 9**
Vigilance in Operation: Responsibilities, incident reporting and national requirements
Jos Kraus

11:00 COFFEE BREAK

11:30 **Session 10**
Legal Requirements of Clinical Investigation and Clinical Evaluation
Sabina Hoekstra-van den Bosch

11:50 **Session 11**
Clinical Trials with Medical Devices – Differences from trials with pharmaceutical products
Planning a Clinical Trial with a Medical Device
o Biometrical basics of clinical trials with medical devices
o Trial design
o Sample size calculation
Jos Kraus

12:45 LUNCH

13:45 **Session 11 continued**
Questions & Answers:
Clinical Trials with Medical Devices – Differences from trials with pharmaceutical products
Planning a Clinical Trial with a Medical Device
o Biometrical basics of clinical trials with medical devices
o Trial design
o Sample size calculation
Jos Kraus

14:15 **Session 12**
Applicable Regulations and Quality Standards
o ISO14155: Clinical investigation of medical devices for human subjects
o Good Clinical Practice
o Terms
o Responsibilities of investigators
o Responsibilities of sponsors
Gert Bos

15:00 **Session 13**
Summary: Differences between GCP and ISO 14155 and International Differences
Gert Bos

15:15 COFFEE BREAK

15:45 **Session 14**
Highlights of the Upcoming Revision of the Medical Devices Directive
Sabina Hoekstra-van den Bosch

16:15 **Session 15**
Working with Notified Bodies
Gert Bos

17:00 **Session 16**
Quality Management
Gert Bos

17:45 END OF DAY TWO

WEDNESDAY | 12 JUNE 2013

Operational Aspects II - Risk Management and Design Dossier

In Vitro Diagnostics and Companion Diagnostics

09:00 **Session 17**
The Basics of Risk Management in the Development of Medical Device and Drug-Device Combination Products
Gert Bos

10:30 COFFEE BREAK

11:00 **Session 18**
Design Dossier: Medical device and drug-device combination products
Gert Bos

12:30 LUNCH

13:30 **Session 19**
Conclusion and Recommendations of Key Aspects That Need To Be Considered for Regional Strategies for Medical Devices
Gert Bos
Jos Kraus

14:15 **Session 20**
IVD Directive (including upcoming legal changes)
Jos Kraus

15:00 COFFEE BREAK

15:30 **Session 21**
Personalised Medicine
Jos Kraus

16:15 **Session 22**
The IVD Directive in Practice - How to get your IVD to market Case Study Exercise, followed by Q&A
Gert Bos

17:00 END OF TRAINING COURSE

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HOTEL INFORMATION

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

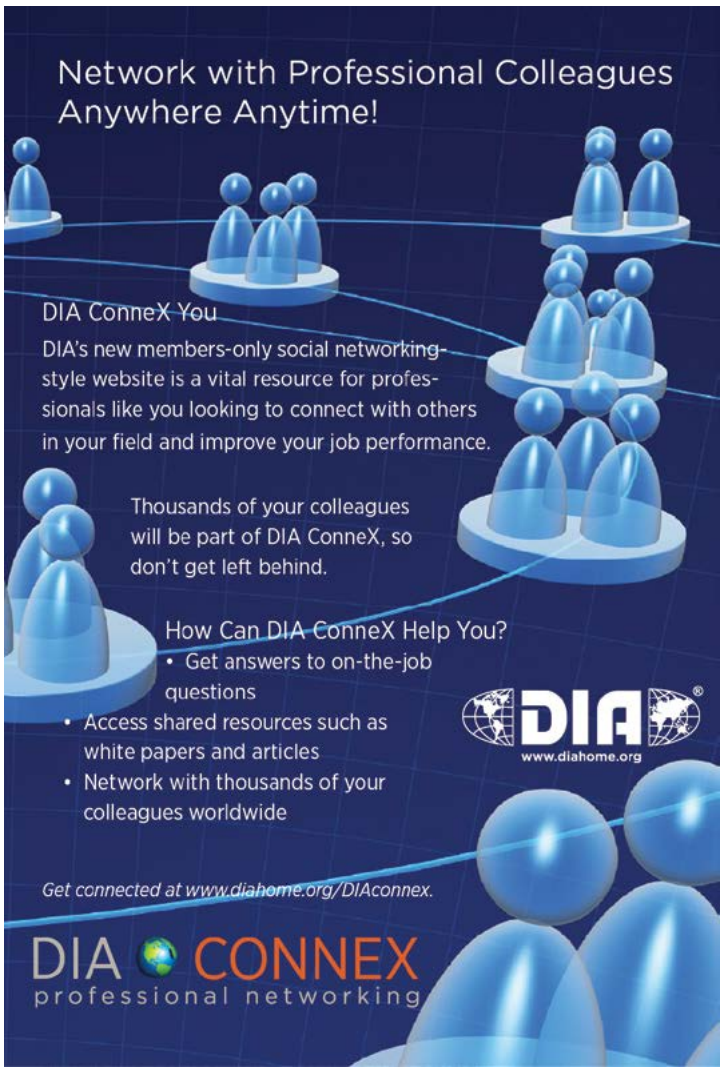
NH Caransa Hotel
Rembrandtplein 19
1017 CT Amsterdam
The Netherlands

Tel.: +31 20 554 0800
Fax: +31 20 622 2773
Email: nhcaransa@nh-hotels.com

At the rate of EUR 131.00 per room/night inclusive of breakfast, exclusive of city tax and VAT.

To make your reservation, please use the link available on the DIA website.

IMPORTANT: The room rate is available until 26 April 2013 or until the group block is sold-out, whichever comes first.



REGISTRATION FORM

DIA Training Course: Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics | 10-12 June 2013 | NH Caransa Hotel, Amsterdam, the Netherlands

DIA www.diahome.org

ID #13547

FEES

	Member*	Non-Member*
Industry	€ 1'785.00 ❑	€ 1'900.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 893.00 ❑	€ 1'008.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*All fees will be subject to the Dutch VAT at 21 %

Please advise your European VAT number: _____

TOTAL AMOUNT DUE: _____

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

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

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

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*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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

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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 # 13547 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.**

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

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days 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
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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