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 develop a medical device and how to identify the correct development path.

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 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

- Medical device regulation: philosophy, content and structure
- 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

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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

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 DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

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)
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 — **SESSION 4**

PRE-MARKETING: ESSENTIAL REQUIREMENTS
Gert Bos

12:30 — **LUNCH**

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**

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:

InterCityHotel
Hamburg Hauptbahnhof
Glockengiesserwall 14/15
20095 Hamburg, DE

Tel: +49 40 248 70 0
E-mail: hamburg-hauptbahnhof@intercityhotel.de
www.hamburg-hauptbahnhof.intercityhotel.de

Limited number of hotel rooms have been booked for DIA course participants at the InterCityHotel Hamburg Hauptbahnhof at rate of EUR 110.00 standard / EUR 120.00 business single room per night including breakfast, service charge, VAT and free use of public transport in Hamburg. The ticket for the public transportation system will be provided on arrival.

To make a booking please contact Ms. Juliane Rath on +49 40 248 70 110 or juliane.rath@hamburg-hauptbahnhof.intercityhotel.de. The room rate is available until 9 February 2015 or until the room block is sold-out, whichever comes first.

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 ❑	€ 2'000.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 920.00 ❑	€ 1'080.00 ❑
BECOME A DIA MEMBER NOW	€ 130.00 ❑	

*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
- Tutorial cancellation € 50.00

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