DIA Training Course on

Medical Devices: Regulations and Lifecycle Management

10-12 May 2016
Renaissance Duesseldorf Hotel, Dusseldorf, Germany

OVERVIEW

This course will give clear and practical guidelines on how to develop a medical device 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 DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

Faculty

Sabina Hoekstra-van den Bosch
Lead for European Regulatory
Philips Healthcare – Global Regulations & Standards
The Netherlands

Niels van Tienen
Project Manager
Factory – CRO for Medical Devices
The Netherlands

Reinhard Berger
Head of Medical Device Market Surveillance Department
Austrian Agency for Health and Food Safety (AGES)
Austria

Gert Bos
Executive Director & Partner
Qserve Group B.V
The Netherlands

DEVELOP.
INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

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 DRINKS RECEPTION

18:30 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

HIGHLIGHTS OF THE NEW MEDICAL DEVICE REGULATION

Sabina Hoekstra-van den Bosch

11:45 SESSION 12

CHANGED ROLE FOR NOTIFIED BODIES UNDER THE NEW MEDICAL DEVICE REGULATION AND IMPLICATIONS FOR MANUFACTURERS

Gert Bos

12:30 LUNCH

13:30 SESSION 13

INTRODUCTION TO CLINICAL EVALUATION AND CLINICAL INVESTIGATION

Niels van Tienen

14:00 SESSION 14

POST-MARKETING SURVEILLANCE MEDICAL DEVICES VIGILANCE SYSTEM

Reinhard Berger

15:15 COFFEE BREAK

15:45 SESSION 15

CHANGES IN PRE- AND POST-MARKET CLINICAL REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION

Niels van Tienen

16:30 SESSION 16

CHANGES IN VIGILANCE AND POST-MARKET REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION

Reinhard Berger

17:00 QUESTIONS AND ANSWERS

17:15 END OF DAY TWO

Day 3

09:00 SESSION 17

INTRODUCTION TO CLINICAL INVESTIGATION AND PLANNING A CLINICAL INVESTIGATION

Niels van Tienen

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

Niels van Tienen

10:30 COFFEE BREAK

11:00 SESSION 19

SUMMARY: DIFFERENCES BETWEEN GCP AND ISO 14155 AND INTERNATIONAL DIFFERENCES

Niels van Tienen

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)

Niels van Tienen

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

Niels van Tienen and Reinhard Berger

16:30 END OF TRAINING COURSE

Follow **@DrugInfoAssn**

Training Course Venue

Renaissance Duesseldorf Hotel
Noerdlicher Zubringer 6
40470 Duesseldorf, Germany

Tel: +49 211 621 60
Fax: +49 211 62 16 666

Web: www.marriott.com/hotels/travel/dusrn-renaissance-duesseldorf-hotel

Information about how to book a hotel room will be available shortly.

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom and the has accredited this training course with credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with credits.

SwAPP
Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

REGISTRATION FORM

Medical Devices: Regulation and Lifecycle Management # 16536
10-12 May 2016 | Renaissance Duesseldorf Hotel | Dusseldorf, Germany

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 ❑	€ 1,090.00 ❑

All fees will be subject to the German VAT at 19%

Please enter your company's German 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 non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

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: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and 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) 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 # 16536 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 and 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.diaglobal.org/EUTerms

Date	Signature