Good Management of Medical Devices

Course #10543
26-28 April 2010
Marriott Rive Gauche, Paris, France

Course Faculty

Gert Bos, Dr. Ir.
Head of Regulatory and Clinical Affairs
Healthcare, UK

Roger Grase, PhD, Dir. and Prof. a.D.
former Head of Regulatory Affairs Division and Medical Devices Division, BfArM, Germany

Andreas Grund, PhD
Managing Director / CEO,
GCP-Service International Ltd. & Co.KG, Germany

Sabina Hoekstra-van den Bosch, Pharm.D.
Senior Advisor, Ministry of Health, Welfare and Sport
Department of Pharmaceutical Affairs and Medical Technology, The Netherlands

Jos Kraus, Pharm.D.
Senior Inspector, Health Care Inspectorate,
The Netherlands

Target Audience

This course is designed for persons with the challenging task of developing medical devices

This course is designed for experienced and starting professionals in industry and regulatory bodies, who would like to get acquainted with all aspects of medical device regulation in a quick and broad way.

This course aims 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 drug-device combinations and for professionals involved in medical devices.

Participants are expected to have a relevant master's degree and be working in pharmaceutical or medical device area.

Course Overview

Day I

Day I will deliver the knowledge base for the subsequent days. 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 relation between risk classification and conformity assessment procedures. The first day 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 with pharmaceuticals will be explained. An overview of the regulation of in vitro diagnostics and a comparison of the EU and US regulatory systems will conclude day I.

Day II

The course will give a clear guide how to develop practically a medical device. It will show how to identify the correct development path. For medical devices which need to be tested clinically, the process of planning, conducting and reporting a clinical investigation with medical devices will be explained to the course attendees. The practical differences between the development of pharmaceuticals and medical devices will be trained and the challenge of developing a drug device combination product should be sketched.

Day III

Responsibility in post marketing surveillance of medical devices (and drug devices combination products) according to the Medical Device Vigilance System will be explained and illustrated by examples. Differences between risk management of medical devices and pharmaceutical products will be pointed out.

Emphasis that 2007 47 comes into force in 2010.

Key Topics

- Medical device regulation: philosophy, content and structure
- Risk-classification of medical devices
- Drug-device combination products
- In Vitro Diagnostics
- CE mark
- ISO 14155
- 93/42/EC, as amended by 2007/47/EC
- Clinical Evaluation and Clinical Investigation
- Medical devices vigilance system

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 of devices and pharmaceuticals (including ATMPs)
- Develop a medical device
- 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
- Realise responsibilities in Post-marketing Surveillance
- Evaluate risks and handle incident reports

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MONDAY | 26 APRIL 2010

Day 1: Philosophy and Legislation

08.00 **Registration**

08.45 **Welcome and Introduction**

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 EU Regulatory System for Medical Devices
Sabina Hoekstra-van den Bosch

10.30 **Coffee Break**

11.00 **Session 3**
Risk Classification (including exercise)
Jos Kraus

11.45 **Session 4**
Pre-marketing: Essential Requirements, Conformity Assessment Procedures and CE Marking
Jos Kraus

12.30 **Lunch Break**

13.30 **Session 5**
Pre-marketing: Clinical Evaluation and Clinical Investigations
Sabina Hoekstra-van den Bosch

14:00 **Session 6**
Drug-Device Combination Products (including Combinations with ATMPs) and Consultation Procedures with National Competent Authorities and/or European Medicines Agency
Sabina Hoekstra-van den Bosch

15:00 **Coffee Break**

15.30 **Session 7**
In Vitro Diagnostics: The In Vitro Diagnostics Directive explained (Scope, Borderlines, Differences and Similarities with the MDD)
Jos Kraus

16.15 **Session 8**
Global Regulation of Medical Devices (Differences and Similarities between US and EU System; GHTF)
Jos Kraus

17.30 **Drinks Reception**

18.30 **End of Day I**

TUESDAY | 27 APRIL 2010

Day 2: Operational Aspects

09.00 **Session 9**
Introduction of Clinical Trials with Medical Devices - Differences to Trials with Pharmaceutical Products
Andreas Grund

09.45 **Session 10**
Biometrical Basics of Clinical Trials with MDs, Trial Designs, Sample Size Calculation
Andreas Grund

10.30 **Coffee Break**

11.00 **Session 11**
Applicable Regulations and Quality Standards
Andreas Grund

12.00 **Session 12**
Ethics Submission, Role of Competent Authorities
Andreas Grund

12.30 **Session 13**
Differences between GCP and ISO 14155 and International Differences
Andreas Grund

13.00 **Lunch**

14.00 **Session 14**
Working with Notified Bodies
Roger Grase

15.00 **Session 15**
Post-marketing Surveillance Medical Devices Vigilance System
Roger Grase

16.00 **Coffee Break**

16.30 **Session 16**
Vigilance in Operation: Responsibilities, Incident Reporting and National Requirements
Roger Grase

17.30 **End of Day II**

WEDNESDAY | 28 APRIL 2010

Day 3: Case Studies and Exercises, summary and wrap-up

09.00 **Session 17**
Different Vigilance Examples in Different Medical Device Classes
Roger Grase

9.45 **Session 18**
Quality Management
Gert Bos

10.30 **Coffee Break**

11.00 **Session 19**
The Basics of Risk Management in the Development of Medical Device and Drug-Device Combination Products
Gert Bos

12.30 **Lunch**

13.30 **Session 20**
Design Dossier: Medical Device and Device-Drug Combination Products
Gert Bos

15.00 **Coffee Break**

15.30 **Session 21**
Conclusion by giving Recommendations of Key Aspects that need to be considered for Regional Strategies for Medical Devices
Gert Bos

17.00 **End of Day III**

Upcoming DIA Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK and selected European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

REGISTRATION FORM

Good Management of Medical Devices

26-28 April 2010 - Marriott Rive Gauche, Paris, France

ID# 10543

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 19.6%	TOTAL	FEE	VAT 19.6%	Membership	TOTAL	FEE	VAT 19.6%	TOTAL
Industry	€ 1'785.00	€ 349.86	**€ 2'134.86** ❑	€ 1'785.00	€ 349.86	€ 115.00	**€ 2'249.86** ❑	€ 1'900.00	€ 372.40	**€ 2'272.40** ❑
Government/Academia (Full-Time)	€ 893.00	€ 175.03	**€ 1'068.03** ❑	€ 893.00	€ 175.03	€ 115.00	**€ 1'183.03** ❑	€ 1'008.00	€ 197.57	**€ 1'205.57** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line. **10543DIA**

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
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__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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PAYMENT METHODS

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **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." including your name, company, Meeting ID# 10543 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.

Persons under 18 are not allowed to attend DIA meetings.

Hotel Information

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

Marriott Rive Gauche
17, Blvd. Saint-Jacques
75014 Paris, France

at the special rate of EUR 159.00 (single occupancy) including breakfast and VAT.

To reserve a room, please liaise directly with the Hotel Marriott Rive Gauche with the following telephone number: +33 1 40 78 79 80, using the Group Code SEOSEOA.

Alternatively, you can also book your room through the Internet: www.marriott.com. Please use the group section to access online reservations (https://www.marriott.com/reservation/availability.mi?propertyCode=parst)

IMPORTANT: To be assured of accommodation at Marriott Rive Gauche, registrants are recommended to complete their reservation as soon as possible but no later than 26 March 2010.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA European Office Postfach, 4002 Basel, Switzerland