

Introduction to European Regulatory Affairs

Brand New Training Course!

COURSE OVERVIEW

Introduction to European Regulatory Affairs is the first of a number of key modules developed by DIA Europe's Regulatory Affairs Training Sub-Committee. This course will be part of a postgraduate training course for obtaining a Master's degree in Regulatory Affairs. The course can also be attended and certified as a stand-alone training course. The course focuses on Europe but also looks at regulations in other regions including the USA and Japan.

The course is designed to:

- Provide a profound understanding of the historical evolution and the current legislation for drug regulation with a focus on the European regulatory environment
- Describe the function of regulatory affairs in the pharmaceutical industry and at the regulatory agencies during the phases of drug development, drug approval and post marketing
- Explain the different regulatory procedures for obtaining marketing authorisation
- Give examples and guidance for the most efficient interaction between regulatory agencies and pharmaceutical industry during the different phases of a drug life cycle
- Identify key points to consider for setting up and conducting a successful regulatory strategy
- Discuss the main international differences of key drug regulations
- Learn directly from the extensive experience of regulators and professionals in regulatory affairs in the industry

COURSE FACULTY

Each Faculty member has decades of expertise and knowledge in Regulatory Affairs with a number of them coming directly from Regulatory Agencies in Europe.

Mohamed Baccouche, PhD

IPMB GmbH, Institute for Regulatory Affairs & Pharmaceutical Services, Germany

Peter Bachmann, MD

BfArM, Germany

Rolf Bass, MD

Professor for Pharmacology and Toxicology, retired from BfArM, Germany

Christa Wirthumer-Hoche, PhD

AGES PharmMed, Austria



The Drug Information Association (DIA) has been approved as an 'Authorized Provider' by the International

Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer **1.8 CEUs** for this programme.

If you would like to receive a statement of credit, you must attend the programme, return your evaluation form and complete the online credit request process through My Transcript at

www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the programme audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

WHO WILL ATTEND

As this module provides a comprehensive description and discussion of the regulatory environment, it provides an excellent education and training tool, not only to participants in the postgraduate course, but also to experts and managers from the regulatory agencies and pharmaceutical industry working in the areas of:

- Regulatory Affairs
- Clinical drug development
- Preclinical drug development
- Pharmaceutical development
- Manufacturing
- Drug quality control
- Quality assurance and compliance
- Regulatory writing
- Drug import / export

KEY TOPICS

- Drug regulations
- Role of Regulatory Affairs in drug - development / approval / marketing
- Efficient interactions between regulatory agencies and the pharmaceutical industry
- Regulatory strategy
- Key differences of international regulatory environments
- ICH Guidelines - EFPIA

LEARNING OBJECTIVES

- Define the drug legislation and regulation with a focus on the EU
- Identify the key functions of Regulatory Affairs during the different phases of a drug life cycle
- Assess information from the extensive experience of experts of regulatory agencies and industry
- Set up successful regulatory strategies

Course ID# 08550

First Day Begins: 09:00
End Day Concludes: 17:00

Radisson SAS Hotel, Media City

DUBAI, UNITED ARAB EMIRATES

October 26-28, 2008

This course has limited capacity. Register early!



08:00	Registration
09:00	Welcome and Introduction
09:30	Session 1
	Drug Legislation and Drug Regulation
	<ul style="list-style-type: none"> • Development of drug legislation • Drug regulations in the EU and USA • Regulatory bodies, structure, responsibilities
10:30	Coffee Break
11:00	Session 1 (cont.)
	Drug Legislation and Drug Regulation
	<ul style="list-style-type: none"> • Communication with and between regulatory agencies • Regulatory guidelines: national and international
12:00	Lunch
13:30	Session 2
	Regulatory Definition and Basic Classification of Medicines
	<ul style="list-style-type: none"> • Allopathics • Homeopathics • Herbals • Biologicals • Borderlines products • Foods • Cosmetics • Medical devices
15:00	Coffee Break
15:30	Session 3
	The Role of Regulatory Affairs during Drug Development
	<ul style="list-style-type: none"> • Phases of Drug development / life cycle of medicines • Scientific advice • IMPD / IND; Clinical trials • Paediatric regulation • Good regulatory practices - GMP, GLP, GCP
17:30	End of Day 1
17:30	Reception

09:00	Session 4
	Registration Dossier
	<ul style="list-style-type: none"> • Content: Benefit-Risk ratio, key points to consider • Format: CTD; Electronic submission; eCTD
10:30	Coffee Break
11:00	Session 5
	Regulatory Procedures of Drug Marketing Authorisations in the EU
	<ul style="list-style-type: none"> • Centralised Procedure (CP) • Decentralised Procedure (DCP) • Mutual Recognition Procedure (MRP) • National procedure • Potential serious risk to public health
12:00	Lunch
13:30	Session 6
	Referrals
	Product Information: Summary Product Characterisation (SPC), Package Leaflet (PL) and label
15:00	Coffee Break
15:30	Session 7
	Legal Types of Marketing Authorisations in the EU
	<ul style="list-style-type: none"> • Full dossier • Generics, abbreviated drug application • Biosimilars • Bibliographic application, well established use • Combination products
	Regulatory Data Protection and Exclusivity
	<ul style="list-style-type: none"> • Data protection • Market exclusivity • Extension of supplementary protection certificate
17:30	End of Day 2

08:30	<p>Session 8</p> <hr/> <p>The Role of Regulatory Affairs after Marketing Authorisation</p> <ul style="list-style-type: none"> • Change control / product variations
10:00	<p>Coffee Break</p>
10:30	<p>Session 8 (cont.)</p> <hr/> <p>The Role of Regulatory Affairs after Marketing Authorisation</p> <ul style="list-style-type: none"> • Line extension • Renewals • Pharmacovigilance • Post marketing commitments
11:30	<p>Lunch</p>
13:00	<p>Session 9</p> <hr/> <p>Transparency in Drug Regulatory Affairs</p> <ul style="list-style-type: none"> • Freedom of information • Public assessment report • RMI-product index <p>Co-operation between Regulatory Agencies</p> <ul style="list-style-type: none"> • Information exchange • Confidentiality agreement • Mutual recognition agreement • Parallel- / co-assessment during drug development, marketing authorisation, post marketing
14:30	<p>Coffee Break</p>
15:00	<p>Session 10</p> <hr/> <p>Regulatory Strategy</p> <ul style="list-style-type: none"> • International development plan • International regulatory procedures • Market access • Most benefit for all stakeholders: patient, health care professionals, industry, regulatory agencies, buyers, academia, society
16:30	<p>Closing Remarks</p>
17:00	<p>End of Training Course</p>

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

Radisson SAS Hotel, Media City
Dubai Media City
PO Box 211
723, Dubai
United Arab Emirates

Telephone: + 971 4 366 9111
Fax: + 971 4 361 1011
Website: www.dubai.radissonsas.com

at the special rate of:

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To reserve a room, please call the Reservations Department on +971 4 366 9111 mentioning the keyword "DIA".

IMPORTANT: To be assured of accommodation at the Radisson SAS Hotel, Media City, registrants are recommended to complete their reservation by September 25, 2008.

COURSE CANCELLATION POLICY

Cancellations must be in writing and be received at the DIA Europe office by October 17, 2008.

Cancellations received by the date above are subject to an administrative fee:

Member/Non-member = EUR 200.00

Government/Academia (Member/Non-member) = EUR 100.00.

Registrants who do not cancel by the date above, and do not attend, will be responsible for the full registration fee. Course cancellations must be made in writing. Registrants are responsible for cancelling their own hotel reservations. DIA Europe reserves the right to alter the venue if necessary. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants.

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You may transfer your registration and payment, once only, from one course to a future date of that same course. If you are unable to attend the new date selected, there will be no refund of the registration fee. You may transfer your registration to a colleague prior to the course start 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.

HOTEL AND TRAVEL RESERVATIONS

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation letter via fax within five working days, please contact us: diaeurope@diaeurope.org.

TRAINING COURSE REGISTRATION FORM

FAX to: +41 61 225 51 52
Course ID# 08550

Registration must be confirmed in writing by the DIA office.

If you have not received confirmation within five business days, please contact the
DIA Europe: Tel. **+41 61 225 51 51**, Fax **+41 61 225 51 52**, or email
diaeuropa@diaeuropa.org

PLEASE CONSIDER THIS FORM AN INVOICE. Registration will be accepted by mail, fax or online at www.diahome.org

For detailed programme information including faculty and topics, please contact the DIA Customer Services Department on +41 61 225 51 42 or email: diaeuropa@diaeuropa.org

INTRODUCTION TO EUROPEAN REGULATORY AFFAIRS

ID# 08550: October 26-28, 2008

Radisson SAS Hotel, Media City, Dubai, United Arab Emirates

TUITION/REGISTRATION FEES: Registration fee includes coffee breaks, luncheons, reception and all course materials.
If DIA cannot verify your membership upon receipt of this registration form, you will be charged the non-member fee.

Please check the applicable category: Academia Government Industry CSO

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REGISTRATION FEES	MEMBER		NON-MEMBER (with optional membership)			NON-MEMBER (without optional membership)	
	FEE	TOTAL	FEE	MEMBERSHIP	TOTAL	FEE	TOTAL
Industry	€ 1'700.00	€1'700.00 <input type="checkbox"/>	€ 1'700.00	€ 130.00	€1'830.00 <input type="checkbox"/>	€ 1'830.00	€1'830.00 <input type="checkbox"/>
Discount Registration Fees Government/Academia (Full-Time)	€ 850.00	€ 850.00 <input type="checkbox"/>	€ 850.00	€ 130.00	€ 980.00 <input type="checkbox"/>	€ 980.00	€ 980.00 <input type="checkbox"/>

PLEASE INDICATE THE TOTAL AMOUNT TO BE PAID: € _____

Note: Payment of registration fees must be received before commencement of the meeting.

08550DIAWEB

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Please note that other types of credit card cannot be accepted.

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Signature _____

- Cheques should be made payable to:** Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA Europe, Elisabethen Anlage 25, Postfach, 4002 Basel, Switzerland.
- Bank transfers:** When DIA Europe completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payment should be in EURO and your name and company, as well as the Course ID# 08550 and invoice number, must be included on the transfer document to ensure correct allocation of your payment. **Payments must be net of all charges.**

Dr. Mr. Ms. _____
Last Name First Name Middle Initial

Job Title _____

Affiliation (Company) _____

Address _____

Postal Code _____ City _____ Country _____
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If you are unable to attend this course, but would like information on future course dates, please call us on +41 61 225 5151

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