DIA European Regulatory Affairs Training Course

In-depth Review of Current Registration Procedures in the European Union

Course # 12569 15-16 November 2012 Paris, France



This training course will provide an excellent introduction to the European Regulatory procedures for personnel in regulatory affairs, clinical research, project management and other disciplines involved in the development of medicinal products

Course Instructor

Brenton E. James

Consultant in Strategic Regulatory Affairs in the European Union, UK

Key Topics

- European Union
- Centralised Procedure
- Decentralised Procedure
- Mutual Recognition Procedure
- National Procedure
- Key issues to consider for business opportunities
- Regulatory strategy
- Legal status of products and switching from Rx to OTC
- Medical devices legislation
- Clinical Trial Directive

Continuing Education

DIA meetings and trainings 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 and certificates are available.

This course has limited capacity. Register early.

Course Overview

The course will cover the evolution of the registration systems available for approval of products since January 1995 in the European Union, together with major changes in New Medicines Legislation. Title IV of Regulation EC726/2004 on the European Medicines Agency - Responsibilities and Administrative Structure, came into effect on May 20, 2004. The remainder of the Regulation and all of Directive 2004/27/EC became effective in November 20, 2005.

The very important changes in New Medicine Legislation concerning regulatory procedures, access to Centralised and Mutual Recognition Procedures, reduction in Regulatory Data protection will be described in detail.

Detailed review will be offered on the changed Centralised and Mutual Recognition Procedures and New Decentralised Procedure with discussion of practical examples of product types suitable for each procedure.

Other issues that impact on successful regulatory strategy in Europe, Harmonisation of Summary of Product Characteristics, Article 30 and Article 31 referrals and Supplementary Protection Certificate for Patents will be described.

Also reviewed and discussed is the legal status of medicinal products and the procedure for switching from prescription only sale to OTC sale, legislation controlling medical devices and the Clinical Trial Directive.

This course will provide strategic advice on how to file applications for the marketing authorisations in the European Union for staff involved in regulatory affairs.

Regulatory strategy which impacts on commercial, business and licensing arrangements will be of importance to those responsible for business development.

Who Will Attend

Professionals in regulatory affairs, clinical research, project management, toxicology, product development and data management.

Learning Objectives

At the conclusion of this course, participants should be able to:

- Explain the registration procedures for filing applications for medicinal products in the European Union and recognise which routes are available for each product type (NCE, biotechnology, OTC and generic)
- Describe the concepts of global marketing authorisation and regulatory data protection
- Discuss the key issues that impact the choice of the registration procedure including trademarks and patents
- Describe the legislation effecting medical devices and procedures for obtaining Clinical Trial and Ethics Committee approval in Europe



THURSDAY 15 NOVEMBER 2012

12:30 REGISTRATION

13:00 EUROPEAN UNION

- Development of European Union
- European Economic Area
- Role and responsibilities of European institutions
- European Monetary Union
- Importance of single market
- Medicines Control in the European Union

14:30 COFFEE BREAK

15:00 CENTRALISED PROCEDURE

- Centralised Procedure
- Types of Products: Optional and mandatory scope
- European Medicines Agency and its Work Programme
- Committee for Medicinal Products for Human Use
- New Scientific Committees of the European Medicines Agency (PDCO, CAT)
- Presubmission dialogue and scientific advice
- FDA/European Medicines Agency Parallel Scientific Advice
- Procedure for filing applications
- Rapporteurs Nomination Procedure
- Scientific Advisory Groups
- Importance of translations
- Role of European Commission
- Experience to date

17:00 DRINKS RECEPTION

FRIDAY | 16 NOVEMBER 2012

08:30 CENTRALISED PROCEDURE (continued)

09:30 DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES

- Procedure for filing applications
- Types of products
- Selection and role of reference Member State
- Coordinating Group for decentralised and mutual recognition procedure [CDMh]
- Access for line extensions
- Grant of National Authorisations
- Variations
- Inspections/samples
- Generic Medicinal Products
- Experience to date

10:45 COFFEE BREAK

11:00 NATIONAL PROCEDURE

 EU Commission Communication (July 1998) -Line extensions

11:15 KEY ISSUES TO CONSIDER FOR BUSINESS OPPORTUNITIES

- Arbitration Use of Article 30, 31
- Supplementary Protection Certificates (= Patent Term Restoration)
- · Market exclusivity
- Co-marketing and co-promotion
- Trademarks
- CADREAC
- ORPHAN medicinal products

11:45 REGULATORY STRATEGY

- Information sources
- How to be successful with registration Procedures in the European Union

12:00 NEW MEDICINES LEGISLATION IMPACT

- Regulation for Advanced Therapy Products
- Support for small and medium sized enterprises
- Regulation for financial penalties
- Paediatric regulation

12:30 LUNCH

13:30 LEGAL STATUS OF PRODUCTS AND SWITCHING FROM PRESCRIPTION TO OTC

- EU Commission Guideline
- Criteria for classifying a medicinal product without a medical prescription

14:30 COFFEE BREAK

14:45 MEDICAL DEVICES

- Three directives on medical devices
- CE marking
- MHRA Guidance on Medical Devices
- Future legislation

15:15 CLINICAL TRIAL DIRECTIVE

- Overview of the Directive
- Commission Guidances
- Submission to competent authority

16:00 END OF THE TRAINING COURSE

REGISTRATION FORM

European Regulatory Affairs - In-depth Review of Current Registration Procedures in the European Union | 15-16 November 2012 | Paris, France



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. *All fees are subject to local French VAT of 19.6%.

CATEGORY	Member Fee*			Non-Member Fee*
Industry	€ 1'155.00 □	Industry		€ 1'270.00 □
Government /Charitable/Non-profit/Academia (Full-Time)	€ 578.00 □	Charitable/Non-profit/Academia/G	overnment (Full-Time)	€ 693.00 □
Join DIA now to qualify for the member rate			Fee	€ 115.00 🗆
TOTAL AMOUNT DUE: €	NOTE: PAYMENT DUE 3	O DAYS AFTER REGISTRATION AND	MUST BE PAID IN FULL BY COMMENC	CEMENT OF THE EVENT
				12569DIAWEB
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.				
CMC	Medical Writing		Public Policy/Law	
Clinical Data Management/	Non-clinical		Quality Assurance/Quality Con	ntrol
eClinical	Outsourcing		Regulatory Affairs	
Clinical Research & Development	Comparative Effectivenes	s/Health Technology	Statistics	
Clinical Safety/Pharmacovigilance		Assessment/Evidence-based MedicineIT/Validation		
Document Management/	Pricing/Reimbursement		_ '	
eSubmissions	Project Management			
Medical Communications	Professional Education &	Fraining		
ATTENDEE DETAILS		PAYMENT METHODS - Cred	lit cards are the preferred pay	ment method.
PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE	REGISTRATION EVEN			
SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARE	HERE	☐ Please charge my credit card - C	redit card payments by VISA, Mastero	card or AMEX can be made
Don't Don DM- DM-		by completing the relevant detail	ils below. Please note that other type	es of credit card cannot be
□ Prof □ Dr □ Ms □ Mr		accepted.		
Last Name		□ VISA □MC □ AMEX		
First Name				
		Card Number		
Company				
Company		Expiry Date		
Job Title				
Sun doc		Cardholder's Name		
		Cardifolder's Name		
Street Address / P.O. Box				
		Date	Cardholder's Signature	
Postal Code City				
		☐ Cheques should be made payable	e to DIA and mailed together with a co	opy of the registration form
Country Telephone		for identification to: DIA Europe, E	Elisabethenanlage 25, Postfach, 4002	Basel, Switzerland
Fax (Required for confirmation)		☐ Bank transfers: When DIA comple	etes your registration, an email will be	sent to the address on the
Tax (Required for committation)		•	,	
		=	s on how to complete the bank transfer	-
Email (Required to receive presentation download instructions)			": DIA." including your name, company	y, Meeting ID# 12569 as well
		as the invoice number to ensure o	correct allocation of your payment.	
Please enter your company's French VAT number here:				
		Payments must be net of all char	rges and bank charges must be borne	by the payer.
Please indicate your professional category: Academia	☐ Government			
☐ Industry	☐ Contract Service Organisation			

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 Regretfully, if you do not cancel five working days prior to the course 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 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.

IMPORTANT:

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

HOW TO REGISTER

The DIA Europe 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.

www.diahome.org

Fax +41 61 225 51 52

Email diaeurope@diaeurope.org

Mail

DIA Europe Postfach, 4002 Basel, Switzerland