European Regulatory Affairs

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

Course #10538
June 3-4, 2010
Radisson SAS, Prague, Czech Republic

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

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.

The workshop 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 what route is 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

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THURSDAY | JUNE 3, 2010

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 **RECEPTION**

FRIDAY | JUNE 4, 2010

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
- Trade Marks
- 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**

HOTEL INFORMATION

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

Radisson SAS Alcron Hotel
Štepánská 40
110 00 Prague 1, Czech Republic

Telephone: +420 2 22 820 000
telefax: +420 2 22 820 100
www.radissonblu.com/hotel-prague

at the special rate of:

Single Room EUR 130.00
Double Room EUR 130.00

This rate is per room, per night, service, taxes and buffet breakfast included. 9% VAT is excluded.

To reserve a room, please use the hotel booking form on the DIA website or call the hotel.

IMPORTANT: To be assured of accommodation at the Radisson SAS Alcron Hotel, registrants are recommended to complete their reservation by May 1, 2010 latest. Reservations received after that date are subject to availability.

DIA Upcoming 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
For course details on EV, please visit www.diahome.org > Educational Offerings > 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

REGISTRATION FORM

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

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ID# 10538

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 20%	TOTAL	FEE	VAT 20%	Membership	TOTAL	FEE	VAT 20%	TOTAL
Industry	€ 1'155.00	€ 231.00	€ **1'386.00** ❑	€ 1'155.00	€ 231.00	€ 115.00	€ **1'501.00** ❑	€ 1'270.00	€ 254.00	€ **1'524.00** ❑
Government/Academia (Full-Time)	€ 578.00	€ 115.60	€ **693.60** ❑	€ 578.00	€ 115.60	€ 115.00	€ **808.60** ❑	€ 693.00	€ 138.60	€ **831.60** ❑

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

Please indicate your areas of professional interest:

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- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - Validation

REGISTRANT

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

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

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Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

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.

❑ **VISA** ❑ **MC** ❑ **AMEX**

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
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# 10538 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.

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