DIA European Regulatory Affairs Training Course

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

Course # 12553
16-17 February 2012
Hotel MGallery am Konzerthaus, Vienna, Austria

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

DIA®
www.diahome.org

THURSDAY| 16 FEBRUARY 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 | 17 FEBRUARY 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

HOTEL INFORMATION

TThe DIA has blocked a limited number of rooms at the following hotel:

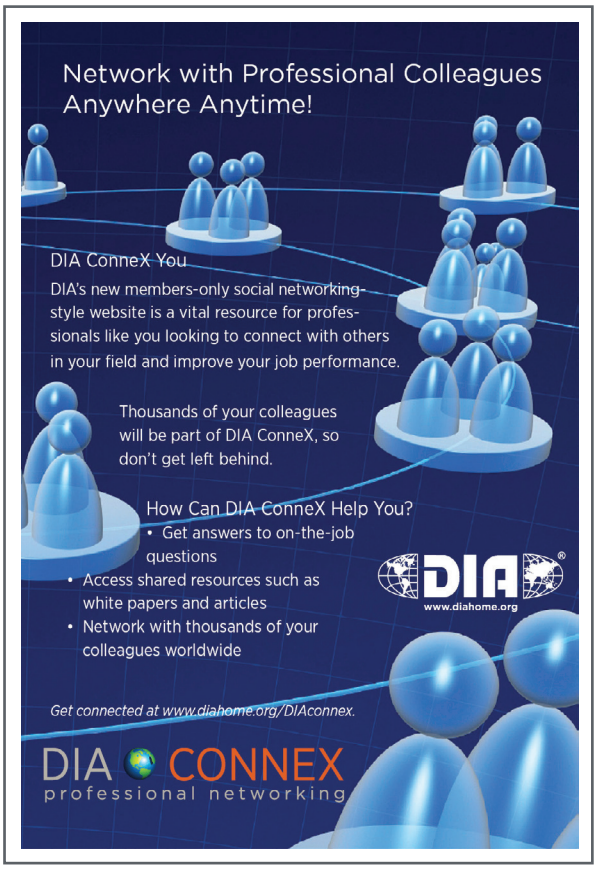
Hotel MGallery am Konzerhaus
Am Heumarkt 35-37
1030 - VIENNA
AUSTRIA
Email: H1276@accor.com
Tel: (+43)1/716160
Fax: (+43)1/71616844

at the special rate of:
EUR 136.00 per room inclusive of breakfast, service and VAT.

To make your reservation please:
Email: H1276@accor.com
Tel: (+43)1/716160
Fax: (+43)1/71616844

Please quote the booking reference: DIA Training Course on "ERA".

Important: Please complete your reservation by 14 January 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.



DIA Upcoming Training Courses in Regulatory Affairs

Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
May 2012 | Basel, Switzerland | ID 12559

Building the eCTD - Practical solutions to compile electronic submissions
March 2012 | Barcelona, Spain | ID 12564
October 2012 | Berlin, Germany | ID 12577

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
25-27 April 2012 | Prague, Czech Republic | ID 12557

Comprehensive Training on European Regulatory Affairs: Keeping your finger on the pulse of Marketing Authorisation
May 2012 | Vienna, Austria | ID 12563

European Regulatory Affairs: In-depth review of current registration procedures in the European Union
16-17 February 2012 | Vienna, Austria | ID 12553
14-15 June 2012 | Location to be confirmed
15-16 November 2012 | Paris, France | ID 12569

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects as used in personalised medicine
13-17 February 2012 | Basel, Switzerland | ID 12552
November 2012 | Location to be confirmed | ID 12576

Health Technology Assessment (HTA)
November 2012 | Location to be confirmed

REGISTRATION FORM

European Regulatory Affairs - In-depth Review of Current Registration Procedures in the European Union | 16-17 February 2012 | Hotel MGallery am Konzerthaus, Vienna, Austria

ID # 12553

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. * All Fees are subject to the local Austrian VAT of 20%

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/Government (Full-Time)	€ 693.00 ❑

Join DIA now to qualify for the member rate — Fee € 115.00 ❑

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

12553DIAWEB

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
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

*Please enter your company's European VAT number here:*_____

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

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ 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

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, 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# 12553 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.

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.

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