Course Overview

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 which became effective May 1st, 2004.

The workshop will provide strategic advice on how to file applications for the marketing authorisations in the European Union for staff involved in International Regulatory Affairs.

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

Target Audience
Professionals in regulatory affairs, clinical research, project management and related fields.

Course Instructor
Brenton E. James
Consultant in Strategic Regulatory Affairs in the European Union, Ascot, UK

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.
12:00  Registration
12:50  Meeting Introduction

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 Procedures
- Types of Products... List A and B
- European Medicines Agency
- Committee for Medicinal Products for Human Use
- for Human Use
- Presubmission Dialogue and Scientific Advice
- Procedure for Filing Applications
- Selection of Rapporteurs
- Importance of Translations
- Role of European Commission
- Experience to Date

17:00  RECEPTION IMMEDIATELY FOLLOWING END OF DAY ONE

11:00  NATIONAL PROCEDURE
- EU Commission Communication (July 1998) - Line Extensions
- Generic

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 and PERF
- Medicines Information Network Europe
- ORPHAN Medicinal Products

11:45  REGULATORY STRATEGY
- Information Sources
- How to be Successful with Registration Procedures in the European Union

QUESTIONS & ANSWERS

12:30  LUNCHEON

13:30  LEGAL STATUS OF PRODUCTS AND SWITCHING TO OTC
- EU Commission Guideline
- Criteria for classifying a medicinal product subject to medical prescription
- UK Reclassification Process

14:30  COFFEE BREAK

14:45  MEDICAL DEVICES
- Three Directives on Medical Devices
- CE Marking
- MHRA Guidance on Medical Devices

15:30  CLINICAL TRIAL DIRECTIVE
- Overview of the Directive
- Commission Guidelines
- Submission to Competent Authority

16:30  END OF THE TRAINING COURSE
The DIA has blocked a limited number of rooms at the:

**Renaissance Amsterdam Hotel**  
Kattengat 1  
NL-1012 SZ  
Amsterdam  
The Netherlands

Tel: +31 20 621 2223  
Fax: +31 20 627 5245

at the special rate of:

- **Rate**  
  - Single room: EUR 189.00  
  - Double room: EUR 189.00

(Includes taxes, services and excludes city tax of 5%. Buffet breakfast is available at EUR 22.00)

All reservations must be made through the Renaissance Amsterdam Hotel reservation department by telephone: +31 20 621 2223 or by Fax: +31 20 627 5245, referring to the DIA Training Course on European Regulatory Affairs.

**IMPORTANT:** To be assured of accommodation at Renaissance Amsterdam Hotel, registrants are recommended to complete their reservation, if possible, by July 24, 2006.

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**COURSE CANCELLATION POLICY**

**On or before August 29, 2006**

An administrative fee will be deducted from the registration fee:

- **Member and Nonmember** = EUR 200.00
- **Government & Academia (Member/Nonmember)** = EUR 100.00

Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellations must be in writing. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

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**COURSE TRANSFER POLICY**

You may transfer your registration and payment, only once, 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.

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**ACCOMMODATION BOOKING FORM**

1 FORM PER RESERVATION

Please fax completed form to the

**Renaissance Amsterdam Hotel**

by July 24, 2006

Kattengat 1, NL-1012 SZ  
Amsterdam, The Netherlands

Tel: +31 20 621 2223  
Fax: +31 20 627 5245

1. **Prof.**  
2. **Dr.**  
3. **Ms.**  
4. **Mr.**

**Last Name**

**First Name & Middle Initial**

**Company**

**Job Title**

**Street Address / P.O. Box**

**Postal Code**

**City**

**Country**

**Telephone**

**Telefax**

**E-Mail**

**Room Rate:**  
- Single room: EUR 189.00 per room per night  
- Double room: EUR 189.00 per room per night

(Includes taxes, services and buffet breakfast)

**Arrival date:**

**Expected Time of Arrival:**

**Departure Date:**

**Number of Nights:**

In case of cancellation: Cancellation must be in writing. One night deposit will be kept as cancellation fee.

**Payment**

1. I hereby authorise the Renaissance Amsterdam Hotel to charge my credit card according to the conditions mentioned above.

2. **Visa**  
3. **MC**  
4. **AMEX**  
5. **Diners**  
6. Other: ________________

**Card N°**

**Exp.date**

**Cardholder's Name**

**Date**

**Cardholder's signature**
**EUROPEAN REGULATORY AFFAIRS**

Meeting I.D. 06503: September 4-5, 2006
Renaissance Amsterdam Hotel, Amsterdam, The Netherlands

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

**TRAINING COURSE REGISTRATION FORM**

Registration is limited to 30 and is reserved for the first 30 registrants.

**REGISTRATION FEES**

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<th>MEMBER</th>
<th>NONMEMBER (with optional membership)</th>
<th>NONMEMBER (without optional membership)</th>
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**PAYMENT METHODS** (Please check payment method):
- [ ] Cheques should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethenanlage 11, 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. Payment should be in EURO and your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your DIA account. Your name and company must be included on the transfer document to ensure payment to your account.
- [ ] 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

**PLEASE INDICATE THE TOTAL AMOUNT TO BE PAID:** €

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

**EUROPEAN BRANCH OFFICE**

ELISABETHENANLAGE 11, POSTFACH
4002 BASEL, SWITZERLAND
PHONE: +41 61 225 51 51 / FAX: +41 61 225 51 52
E-MAIL: diaeurope@diaeurope.org

**WORLDWIDE HEADQUARTERS**

800 ENTERPRISE ROAD, SUITE 200
HORSHAM, PA 19044-3595
PHONE: +1 215 442 6100 / FAX: +1 215 442 6199
E-MAIL: dia@diahome.org

**DRUG INFORMATION ASSOCIATION LLC (JAPAN)**

LEVEL 2, TORAOKUMON 10 MORI BUILDING
1-18-1, TORAOKUMON, MINATO-KU, TOKYO 105-0001 JAPAN
PHONE: +81 3 5511 1131 / FAX: +81 3 5511 0100
E-MAIL: diajapan@diajapan.org