EUROPEAN REGULATORY AFFAIRS
An In-Depth Review of Registration Procedures in the European Union

Course Description
This course is designed to present a comprehensive overview of the evolution of the registration systems available for approval of products in the European Union (EU) since 1995. It reviews Centralized, Mutual Recognition, and national registration procedures in detail, and includes practical examples of product types particularly suited to each procedure.

There will also be a discussion on the new medicines legislation, which is effective November 2005, and how it changes access to centralized procedure and alters regulatory data protection.

Target Audience
This course will particularly benefit professionals who work 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 disclosures will be included in the course materials.

KEY TOPICS
◆ CENTRALIZED, MUTUAL RECOGNITION, AND NATIONAL REGISTRATION PROCEDURES IN THE EU
◆ OFFICIAL REGULATORY POLICIES AND OTHER ISSUES PERTINENT TO SUCCESSFUL EU REGULATORY STRATEGY
◆ EU REGULATORY STRATEGY PERTINENT TO COMMERCIAL, BUSINESS, AND LICENSING ARRANGEMENTS
◆ TRADEMARKS AND PATENTS
◆ MEDICAL DEVICES
◆ CLINICAL TRIAL DIRECTIVE
◆ LEGAL STATUS AND SWITCHING

LEARNING OBJECTIVES
At the conclusion of this course, participants should be able to:
• Describe the medical and historical background of the development of the European Union and recognize the importance of the Single Market
• Explain the registration procedures for filing applications for medicinal products in the European Union and recognize what route is available for each product type
• Discuss the key issues regarding registration procedures including trademarks and patents
• Discuss future changes in new medicines legislation

SPECIAL FEATURES OF DIA TRAINING COURSES
◆ Experienced faculty in the pharmaceutical industry share the most up-to-date information
◆ Limited attendance allows active involvement and encourages meaningful interaction between faculty and students
◆ Informal dialogues continue at lunch
◆ Hands-on activities enhance understanding

FIRST DAY BEGINS 12:45 PM
FINAL DAY CONCLUDES 4:30 PM

For detailed program information, please contact Jenna Hannum at +1-215-442-6183 or Jenna.Hannum@diahome.org

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1 continuing education units (CEUs) to participants who successfully complete this program.

To receive a statement of credit, participants must attend the program, sign in at the registration desk each day, complete the CE Request and Evaluation Forms, and return them to DIA. Statements of credit will be mailed to participants within one month of program completion.

Hyatt Regency McCormick Place
CHICAGO, IL, USA
AUGUST 28-29, 2006

This course is limited to 30 participants. Register early!
**TRAINING COURSE REGISTRATION FORM**

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

Walk-in registration will NOT be accepted. Registration must be confirmed in writing by the DIA office. If you have not received confirmation within 5 business days, please contact Tim Hershey at Tel. +1-215-442-6157, Fax +1-215-442-6105, or email Tim.Hershey@diahome.org

**EUROPEAN REGULATORY AFFAIRS: AN IN-DEPTH REVIEW OF REGISTRATION PROCEDURES IN THE EUROPEAN UNION**

Meeting I.D. #06413: August 28-29, 2006
Hyatt Regency McCormick Place
Chicago, IL, USA

**TUITION/REGISTRATION FEES:** Registration fee includes continental breakfast, luncheon, reception and all course materials. If DIA cannot verify your membership upon receipt of this registration form, you will be charged the nonmember fee.

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<th>Membership Type</th>
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<td>Member</td>
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*A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ☐  I do NOT want to be a DIA member ☐

Please check the applicable category below.

☐ Academia  ☐ Government  ☐ Industry  ☐ CSO  ☐ Student (Full-time, verification required)

**PAYMENT METHODS** – Register online at [www.diahome.org](http://www.diahome.org) or check payment method.

☐ CHECK drawn on a US bank payable to: Drug Information Association, mailed along with this form to: DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595. Please include a copy of this registration form to facilitate identification of attendee.

☐ BANK TRANSFER 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 made in US dollars. Your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your account.

☐ CREDIT CARD number may be faxed to: +1-215-442-6105. You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX  Exp Date ___________________ #_________________________________

Name of Cardholder ____________________________________________________________

Signature_____________________________________________________________________

Last Name                First Name                Middle Initial

☐ Dr. ☐ Mr. ☐ Ms.

Degrees ____________________________________________________________

Job Title ____________________________________________________________

Affiliation (Company) ______________________________________________________

Address ____________________________________________________________

City State Zip Code Country

(Please write your address in the format required for delivery to your country.)

email ____________________________________________________________

Telephone Number  Fax Number *(A telephone and fax number are required for faxed confirmation.)*

☐ I am unable to attend this course but would like information on future dates of this course.

**PARTICIPANTS WITH DISABILITIES:** DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

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**TRAVEL AND HOTEL INFORMATION**

Meeting ID # 06413

Begins 12:45 PM; concludes 4:30 PM

**TRAVEL**

The Hyatt Regency McCormick Place is located in the South Loop, in the heart of Chicago. Local attractions include Soldier Field, the Magnificent Mile, and Navy Pier. The hotel is approximately ten miles from Midway Airport, and 23 miles from O’Hare International Airport. The hotel is within walking distance to restaurants, theaters, and world class shopping. Contact the hotel for airport shuttle information.

**Hotel**

A limited block of rooms has been reserved at the Hyatt Regency McCormick Place at a low rate per night until the release date of August 7, 2006. We urge you to make your hotel reservations early and plan on staying at the hotel in order to facilitate interactive discussion with faculty and fellow participants.

Single $149  Double $174

Attendees must make their own hotel reservations. To reserve your room, contact the Hyatt Regency McCormick Place by telephone at +1-312-567-1234 or +1-800-233-1234 or by fax at +1-312-528-4000 and mention the DIA Training Course.

**United Airlines & US Airways**

Save through Area Pricing and Discount Fees

To obtain schedule information and the best fares, call United Airlines’ Specialized Meeting Reservations Center at 1-800-521-4041. Make sure you refer to Meeting ID Number 571AK. Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

**CANCELLATION POLICY**

On or before AUGUST 14, 2006

Administrative fee that will be deducted = $200

Cancellations must be made two weeks prior to the course with a $200 administrative charge deducted from fee. Cancellations must be in writing and received in the DIA office by the date above. After this date, there will be no refunds. Registrants are responsible for cancelling their own hotel and travel reservations. Registrants who do not cancel prior to the course and do not attend will be responsible for the full registration fee. 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.

**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. Transfers must be in writing and received in the DIA office by the date of the course.