MEMBER EARLY-BIRD RATE – Register by October 19, 2012 and ***SAVE $100***

Global Considerations for Regulatory Strategy Development

November 8-9, 2012, Horsham, PA

Most regulatory professionals focus their careers on the regulations of a single country or region such as the US or EU. In order for a global regulatory leader to be truly effective, it is critical to understand the key regulatory issues in all major markets and to apply this knowledge to a global regulatory strategy. Communication between health authorities is increasing, making it vitally important that regulatory leaders develop their strategies with a global view. In addition, current trends in the pharmaceutical industry indicate that more and more companies are expanding their global presence to benefit from the explosive growth being projected in the emerging markets. It is essential, therefore, that a global regulatory leader possess the knowledge and skills necessary to enable successful product registrations in multiple markets around the world.

This course will allow participants to understand key requirements for the development and execution of a global regulatory strategy by identifying the strategic and tactical aspects of pharmaceutical development in the US, EU and emerging markets. Course participants will have the opportunity to apply learning objectives in a hands-on workshop.

WHAT YOU WILL LEARN

- Survey of the Global Regulatory Landscape
- Unique Challenges in Emerging Markets
- Assembling and Working with Global Development Teams
- Constructing and Implementing Global Regulatory Strategies

CONTINUING EDUCATION

Drug Information Association has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer 1.5 CEUs for this program. Participants **must attend the entire** course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program, sign in at the registration desk each day of the program, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests two weeks after the last day of the activity. Please note: If you do not sign-in, you will not receive CE credit as partial credit will not be awarded.

This course is part of DIA's Certificate Program and is awarded the following:

- Regulatory Affairs Certificate Program: 8 Elective Units

Disclosure Policy: It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

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

- Explain the importance of the regulatory strategy in pharmaceutical development and commercialization
- Apply key requirements for development in a global market to product strategy
- Plan for the implementation of the Global Regulatory Strategy across multiple regions
- Identify development areas requiring special considerations across various regions

Registration is limited. Register Early!

WHO SHOULD ATTEND

Pharmaceutical professionals with an interest in global regulatory requirements in the areas of:

- Regulatory affairs with basic knowledge of investigational and marketing applications
- Business development
- Commercial or marketing
- Clinical development
- Quality and manufacturing
- Nonclinical development
- Technical writing
- Biostatistics
- Academic research professionals
- Medical writers
- Basic researchers
- Business and marketing professionals
- Clinical research Academicians

FACULTY

DR. MARK A. AMMANN
President
Catalyst Regulatory Services, LLC

LISA D. RYSSO-DEMAGGIO, RAC
President
Raquelian Consulting

For registration questions,please contact Elizabeth Espich at +1-215-293-5802 or Elizabeth.Espich@diahome.org
For detailed program information, please contact Susan Berkelbach at +1.215.442.6183 or Susan.Berkelbach@diahome.org

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers, agenda and CE information are subject to change without notice. Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at www.diahome.org.

Global Considerations for Regulatory Strategy Development

REGISTRATION FORM • **Meeting ID# 12439** • *Registration is limited. Register Early!*

You may register online at **www.diahome.org**, or you may return this completed form by mail to DIA at the address below under check payment method, or by fax to **+1.215.442.6199**. Walk-in registration will **NOT** be accepted. **Registration must be confirmed in writing by the DIA office.** If you have not received confirmation within five business days, please telephone DIA at **+1.215.442.6100** or email **confirmationservices@diahome.org**.

▶ **GLOBAL CONSIDERATIONS FOR REGULATORY STRATEGY DEVELOPMENT**
November 8-9 • Meeting ID# 12439 • DIA Headquarters, Horsham, PA, USA
For additional offerings, visit www.diahome.org

TUITION/REGISTRATION FEES: Registration fee includes continental breakfast(s), luncheon(s), reception (if applicable), and all course materials. If DIA cannot verify your membership, you will be charged the nonmember fee.

MEMBER EARLY-BIRD OPPORTUNITY
Available on **nondiscount** member fee only.

	On or before Oct. 19, 2012	After Oct. 19, 2012
MEMBER FEE	US $1375 ❑	US $1475 ❑

To qualify for the early-bird discount, registration and accompanying payment must be received by the date above. Early-bird does not apply to government/academia/nonprofit members.

Join DIA now to qualify for the early-bird member fee (if applicable) and to enjoy all the benefits of membership for a full year! **www.diahome.org/Membership**

MEMBERSHIP *US $175 ❑

NONMEMBER FEE US $1700 ❑

DISCOUNT FEES
Member Government/Academia (Full-time) US $810 ❑
Nonmember Government/Academia (Full-time) US $1035 ❑

*NONMEMBERS: JOIN DIA & SAVE. Check MEMBERSHIP above.

GROUP DISCOUNTS

Register 3 individuals from the same company for this course and receive complimentary registration for a 4th to attend this course! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.**

1. _____
2. _____
3. _____

PAYMENT METHODS: Register online at **www.diahome.org** or check the preferred 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: **+1.215.442.6199** 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 _____

Card # _____

REGISTRANT'S CONTACT INFORMATION

Please check the applicable category: ❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student (Full-time, verification required)

Registrant's Name _____
Last Name First Name M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Address _____

_____

Meeting ID # 12439
First day begins 8:00 AM
Final day concludes 4:45 PM

COURSE CANCELLATION AND TRANSFER POLICIES

On or before OCTOBER 25, 2012
$200 administrative fee will be deducted.

Cancellations: *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. Cancellation voids all discounts.*

Transfers: *You may transfer your registration to a colleague at any time but membership is not transferable. Please notify the DIA North American office of such transfers in writing as soon as possible. Substitute registrants will be responsible for the nonmember fee, if applicable.*

TRAINING COURSE LOCATION

DIA Worldwide Headquarters
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

HOTEL LOCATION/INFORMATION

Hotel reservations should only be made after receipt of registration confirmation from DIA.

Courtyard Philadelphia Montgomeryville
544 Dekalb Pike
North Wales, Pennsylvania 19454

A limited block of rooms has been reserved at the Courtyard Philadelphia Montgomeryville at a low rate per night **until the release date of October 18, 2012.** 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 $165.00 / Double $165.00

Attendees must make their own hotel reservations. To reserve your room, contact the Courtyard Philadelphia Montgomeryville by telephone at 1-215-699-7247 and mention the DIA Training Course.

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