INTRODUCTION TO GOOD CLINICAL PRACTICES AND AUDITING

Course Description

This introductory GCP auditing course is designed to provide a working understanding of Good Clinical Practices (GCP) regulations and the GCP quality assurance audit process. The course presents a unique perspective on GCP and the audit process allowing the attendee to understand and integrate the role of monitoring and oversight of clinical trials with the audit process.

Target Audience

This course will benefit clinical research associates, quality assurance auditors, and allied clinical research professionals with entry level to three years experience. This course may also benefit professionals in data processing, regulatory affairs, and other aspects of clinical research who wish to better understand GCP and the audit process.

Faculty comprises professionals in the pharmaceutical and related industries who are experts actively practicing in their particular disciplines.

Corexcel *is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. This program is designated for 21.0 nursing contact hours.*

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 1.8 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 morning, 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.

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.*

FIRST DAY BEGINS 9:00 AM

FINAL DAY CONCLUDES 3:30 PM

For detailed program information including faculty and topics, please contact Dori Eberhardt at +1-215-442-6192 or Dori.Eberhardt@diahome.org

KEY TOPICS

- **GOOD CLINICAL PRACTICES (GCP)**
- **ROLE OF GCP IN CLINICAL RESEARCH**
- **REGULATORY REQUIREMENTS SPECIFIC TO GCP**
- **DATA REQUIREMENTS SPECIFIC TO GCP**
- **GCP AUDITS/INSPECTIONS**
- **THE QUALITY ASSURANCE AUDIT PROCESS AS A METHOD OF ENSURING DATA QUALITY**

LEARNING OBJECTIVES

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

- Discuss current issues and problems in the implementation of GCP regulations
- Apply principles of GCP to the conduct of clinical trials in the US and other countries
- Manage GCP documentation to ensure regulatory compliance
- Strategically plan, prepare for, and organize an FDA GCP inspection
- Recognize the various types of clinical trial fraud and misconduct and the ramifications
- Describe the quality assurance audit process

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 each day at lunch**
- **Hands-on activities enhance understanding**

DIA®
CENTER FOR CAREER & PROFESSIONAL DEVELOPMENT

Hilton Inn at Penn

PHILADELPHIA, PA, USA
SEPTEMBER 25-27, 2006

This course is limited to 50 participants. Register early!

TRAINING COURSE REGISTRATION FORM

Registration is limited to 50 and is reserved for the first 50 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***

PLEASE CONSIDER THIS FORM AN INVOICE. Registration will be accepted by mail or fax.

INTRODUCTION TO GOOD CLINICAL PRACTICES AND AUDITING

Meeting I.D. #06418: September 25-27, 2006
Hilton Inn at Penn
Philadelphia, PA, USA

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

Member	**US $1595** ☐	**Government/Academia Member**	**US $800** ☐
Nonmember*	**US $1725** ☐	**Government/Academia Nonmember***	**US $930** ☐

**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 – Please 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

Degrees ☐ Dr. ☐ Mr. ☐ Ms.

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.*

Meeting ID # 06418

Begins 9:00 AM; concludes 3:30 PM

TRAVEL AND HOTEL INFORMATION

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

TRAINING COURSE LOCATION

Hilton Inn at Penn
3600 Sansom Street
Philadelphia, PA 19104 USA

Travel Information

The Hilton Inn at Penn is in the heart of University City and the beautiful Penn Campus, and just a few blocks from downtown. The Philadelphia Zoo and Museum of Art are a short distance from the hotel, as well as other points of historical interest, such as the Liberty Bell and Independence Hall. Contact the hotel for information about shuttles from Philadelphia International Airport, a 25-minute drive downtown.

Hotel Information

A limited block of rooms has been reserved at the Hilton Inn at Penn at a low rate per night until the **release date of September 1, 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 $189 Double $189

Attendees must make their own hotel reservations. To reserve your room, contact the Hilton Inn at Penn by telephone at **+1-215-222-0200 or +1-800-231-4587** and mention the DIA Training Course.

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To obtain schedule information and the best fares, call United Airlines's 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 **SEPTEMBER 11, 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.