

DEVELOPING STANDARD OPERATING PROCEDURES (SOPs)

Course Description

One-day Course

One of the best ways to ensure that organizations meet their business and regulatory obligations is to follow standard operating procedures (SOPs). Standard operating procedures are the "procedures" and processes that you use and "operate" under that have been "standardized" to ensure that you do them the same way each time. SOPs are clearly written descriptions of how particular tasks are to be performed. This course will explore what SOPs are, their uses, and how to write them. Participants will have the opportunity to write an SOP in a group setting during the course.

Target Audience

Anyone involved in determining processes and procedures, or writing the associated SOPs, whether at a pharma company (sponsor, CRO), an investigative site, or an IRB. Although the examples and exercises may be focused primarily on clinical trials, the information related directly to the formulation of SOPs is applicable to many different settings within these organizations.

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



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 .7 continuing education units (CEUs) to participants who successfully complete this program.

To receive a credit certificate, participants must attend the program, sign in at the registration desk, 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 8:30 AM
FINAL DAY CONCLUDES 4:30 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

- ◆ SOPs AND THE BENEFITS OF HAVING SOPs
- ◆ OUTLINING PROCEDURES FOR SOPs
- ◆ WRITING SOPs, INCLUDING FORMATS, ADMINISTRATIVE ISSUES AND CONTENT
- ◆ ORGANIZATIONAL ISSUES FOR SOPs
- ◆ SOP TRAINING AND IMPLEMENTATION

LEARNING OBJECTIVES

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

- Describe what SOPs are and their importance to an organization
- Explain how SOPs will standardize organizational processes, with the goal of functioning consistently and well
- Define various formats for SOPs, as well as the content for each section of the SOP
- Write and/or revise an SOP
- Recognize the importance of training with respect to SOPs
- Implement SOPs in your organization

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



**DIA Headquarters
HORSHAM, PA, USA
MAY 22, 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, fax or online.

DEVELOPING STANDARD OPERATING PROCEDURES (SOPs)

Meeting I.D. #06452: MAY 22, 2006

DIA Headquarters
Horsham, PA, USA

TUITION/REGISTRATION FEES: Registration fee includes continental breakfast, luncheon, 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 \$825 Government/Academia Member US \$415
Nonmember* US \$955 Government/Academia Nonmember* US \$545

*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 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 _____

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 #06452
Begins 8:30 AM; concludes 4:30 PM

TRAVEL AND HOTEL INFORMATION

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

TRAINING COURSE LOCATION

DIA Headquarters

800 Enterprise Road
Horsham, PA 19044, USA

HOTEL LOCATION

Spring Hill Suites Philadelphia Willow Grove

2480 Maryland Road
Willow Grove, PA 19090, USA

Travel Information

The Spring Hill Suites Philadelphia Willow Grove is located just ten minutes from the DIA Worldwide Headquarters. DIA will provide transportation each day for attendees. Specific details will be included in the confirmation letter.

Hotel Information

A limited block of rooms has been reserved at the Spring Hill Suites Philadelphia Willow Grove at a low rate per night until the **release date of April 30, 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 \$129 Double \$129

Attendees must make their own hotel reservations. To reserve your room, contact the Spring Hill Suites Philadelphia Willow Grove Hotel by telephone at **+1 888 287 9400 or 215 657 7800** and mention the DIA Training Course.

United Airlines & US Airways

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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 MAY 8, 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.